



Aneesh Mallick &lt;aneesh.mallick@rkassociates.org&gt;

**Re: Quotation for TEV Study of M/s Skylimit Research Pvt. Ltd.**

46 messages

Shahid . &lt;shahid@rkassociates.org&gt;

Wed, Apr 17, 2024 at 11:26 PM

To: "skylimitresearch@gmail.com" &lt;skylimitresearch@gmail.com&gt;, roshni@skylimitresearch.com

Cc: mcbhatt13@gmail.com, Gaurav Kumar &lt;gaurav.kumar@rkassociates.org&gt;, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" &lt;mohit.agarwal@rkassociates.org&gt;, "R.K Associates, The Valuers | LIE | TEV | ASM" &lt;valuers@rkassociates.org&gt;, clpc6277@pnb.co.in, Aneesh Mallick &lt;aneesh.mallick@rkassociates.org&gt;

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
  - A. **Land:**
    - a) Total Area of the land used for the project.
    - b) Layout Plan.
    - c) Sale/Lease Deed.
    - d) Current status/utilization of the land.
    - e) Address of the Unit
    - f) Google coordinates of the location.
    - g) Attach sale deed.
  - B. **Building and Civil works:**
    - a) Total Area proposed for the Building.
    - b) Layout/ Site plan.
    - c) Site Map Approval/Sanctioned.
    - d) Details of the contractor's engaged.
    - e) Attach agreement with contractor.
  - C. **Proposed Equipment:**
    - a) List of proposed equipment as per below heads:
      - Serial Number, if any
      - Equipment name
      - Manufacturer name
      - Specification/capacity
      - Expected Landed Price
      - Current status of the order
    - b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
    - c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.

17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

--

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Mohd Shahid,  
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Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

m c bhatt pnb <mcbhatt13@gmail.com>

Thu, Apr 18, 2024 at 12:19 PM

To: "Shahid ." <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>

Cc: "skylimitresearch@gmail.com" <[skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)>, roshni@skylimitresearch.com, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, "R.K Associates, The Valuers | LIE | TEV | ASM" <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, clpc6277@pnb.co.in, Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.


Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

[Quoted text hidden]

#### 6 attachments

 **SRPL- Letter dated 18.04.2024 to valuer.docx**  
61K

 **SRPL-TAN.pdf**  
796K

 **SRPL-PAN.pdf**  
481K

 **SRPL-Electricity Bill.pdf**  
107K

 **Detaled Project Report -SRPL.docx**  
1074K

 **CMA Data SRPL-27.02.2024.xls**  
290K

m c bhatt pnb <mcbhatt13@gmail.com>

Thu, Apr 18, 2024 at 12:22 PM

To: "Shahid ." <shahid@rkassociates.org>

Cc: "skylimitresearch@gmail.com" <skylimitresearch@gmail.com>, roshni@skylimitresearch.com, Gaurav Kumar <gaurav.kumar@rkassociates.org>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <mohit.agarwal@rkassociates.org>, "R.K Associates, The Valuers | LIE | TEV | ASM" <valuers@rkassociates.org>, clpc6277@pnb.co.in, Aneesh Mallick <aneesh.mallick@rkassociates.org>

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards


For Skylimit research Private Limited


Authorized Signatory


[Quoted text hidden]


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#### 8 attachments


 **SKYLIMIT INVOICE-1-Quotation Freezer.pdf**  
799K


 **SKYLIMIT INVOICE-2-Quotation freezer.pdf**  
138K


 **SKYLIMIT INVOICE-3-Agilent HPLC.pdf**  
167K

 **SKYLIMIT INVOICE-4-Agilent-HPLC.pdf**  
2414K

 **SKYLIMIT INVOICE-5- Agilent- Terms.pdf**  
92K

 **SKYLIMIT INVOICE-6-Sciex-LCMS.pdf**  
501K

 **SKYLIMIT INVOICE-7-Sciex-LCMS.pdf**  
496K

 **SKYLIMIT INVOICE-8-Sciex-LCMS.pdf**  
679K

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m c bhatt pnb <mcbhatt13@gmail.com>

Thu, Apr 18, 2024 at 12:24 PM

To: "Shahid ." <shahid@rkassociates.org>

Cc: "skylimitresearch@gmail.com" <skylimitresearch@gmail.com>, roshni@skylimitresearch.com, Gaurav Kumar <gaurav.kumar@rkassociates.org>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <mohit.agarwal@rkassociates.org>, "R.K Associates, The Valuers | LIE | TEV | ASM" <valuers@rkassociates.org>, clpc6277@pnb.co.in, Aneesh Mallick <aneesh.mallick@rkassociates.org>

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

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For Skylimit research Private Limited


Authorized Signatory


[Quoted text hidden]


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#### 5 attachments

 **SKYLIMIT INVOICE-9-Sciex-LCMS.pdf**  
3123K

 **SKYLIMIT INVOICE-10-Sbi 24 Cell System.pdf**  
347K

 **SKYLIMIT INVOICE-11-Cell system.pdf**  
1156K

 **SKYLIMIT INVOICE-12-Bluestar room freezer.pdf**  
185K

 **SKYLIMIT INVOICE-13-Takahe nitrogen evaporator.pdf**  
401K

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m c bhatt pnb <mcbhatt13@gmail.com>

Thu, Apr 18, 2024 at 12:25 PM

To: "Shahid ." <shahid@rkassociates.org>

6/10/24, 1:19 PM

Rkassociates.org Mail - Re: Quotation for TEV Study of M/s Skylimit Research Pvt. Ltd.

Cc: "skylimitresearch@gmail.com" <skylimitresearch@gmail.com>, roshni@skylimitresearch.com, Gaurav Kumar <gaurav.kumar@rkassociates.org>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <mohit.agarwal@rkassociates.org>, "R.K Associates, The Valuers | LIE | TEV | ASM" <valuers@rkassociates.org>, clpc6277@pnb.co.in, Aneesh Mallick <aneesh.mallick@rkassociates.org>

Dear Sir/Madam,

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Thanks & Regards

For Skylimit research Private Limited


Authorized Signatory

[Quoted text hidden]

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4 attachments

 **SKYLIMIT-14-TAKAHE NTROGEN EVAPORATOR.pdf**  
1116K

 **SKYLIMIT INVOICE-15-Takahe.pdf**  
364K

 **SKYLIMIT INVOICE-16-Takahe.pdf**  
443K

 **SRPL-LEASE DEED.pdf**  
5375K

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m c bhatt pnb <mcbhatt13@gmail.com>

Thu, Apr 18, 2024 at 12:26 PM

To: "Shahid ." <shahid@rkassociates.org>

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Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards


For Skylimit research Private Limited

Authorized Signatory

[Quoted text hidden]

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2 attachments

 **SRPL-UDYAM.pdf**  
265K

 **SRPL-MOA.pdf**  
4512K

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m c bhatt pnb <mcbhatt13@gmail.com>

Thu, Apr 18, 2024 at 12:26 PM

To: "Shahid ." <shahid@rkassociates.org>

Cc: "skylimitresearch@gmail.com" <skylimitresearch@gmail.com>, roshni@skylimitresearch.com, Gaurav Kumar <gaurav.kumar@rkassociates.org>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <mohit.agarwal@rkassociates.org>, "R.K Associates, The Valuers | LIE | TEV | ASM" <valuers@rkassociates.org>, clpc6277@pnb.co.in, Aneesh Mallick <aneesh.mallick@rkassociates.org>

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

[Quoted text hidden]

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 **SRPL-AOA.pdf**  
11706K

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m c bhatt pnb <mcbhatt13@gmail.com>

Thu, Apr 18, 2024 at 12:27 PM


To: "Shahid ." <shahid@rkassociates.org>




Cc: "skylimitresearch@gmail.com" <skylimitresearch@gmail.com>, roshni@skylimitresearch.com, Gaurav Kumar <gaurav.kumar@rkassociates.org>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <mohit.agarwal@rkassociates.org>, "R.K Associates, The Valuers | LIE | TEV | ASM" <valuers@rkassociates.org>, clpc6277@pnb.co.in, Aneesh Mallick <aneesh.mallick@rkassociates.org>

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## 2 attachments

 **SKYLIMIT INVOICE-17- Mahendra Bolero.pdf**  
240K

 **SKYLIMIT INVOICE-19-Mahindra Scorpio.pdf**  
241K

**Aneesh Mallick** <aneesh.mallick@rkassociates.org>

Fri, Apr 19, 2024 at 3:07 PM

To: m c bhatt pnb <mcbhatt13@gmail.com>

Cc: "Shahid ." <shahid@rkassociates.org>, "skylimitresearch@gmail.com" <skylimitresearch@gmail.com>, roshni@skylimitresearch.com, Gaurav Kumar <gaurav.kumar@rkassociates.org>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <mohit.agarwal@rkassociates.org>, "R.K Associates, The Valuers | LIE | TEV | ASM" <valuers@rkassociates.org>, clpc6277@pnb.co.in

Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions & Projections** (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



World's first fully digital Automated Platform for

Integrating Valuation Life Cycle -

A product of R.K. Associates

[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

=====

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m c bhatt pnb &lt;mcbhatt13@gmail.com&gt;

Mon, Apr 22, 2024 at 1:07 PM

To: Aneesh Mallick &lt;aneesh.mallick@rkassociates.org&gt;

Cc: "Shahid ." &lt;shahid@rkassociates.org&gt;, "skylimitresearch@gmail.com" &lt;skylimitresearch@gmail.com&gt;, roshni@skylimitresearch.com, Gaurav Kumar &lt;gaurav.kumar@rkassociates.org&gt;, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" &lt;mohit.agarwal@rkassociates.org&gt;, "R.K Associates, The Valuers | LIE | TEV | ASM" &lt;valuers@rkassociates.org&gt;, clpc6277@pnb.co.in

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**

(A Clinical Research Organization)

VILLA-2/9, LAND 2, JAYPEE GREENS,

GREATER NOIDA, UP-201306

Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)

Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers &amp; Techno Engineering Consultants (P) Ltd.,

Corporate Office : D-39, Second Floor, Sector-2,

Noida, Uttar Pradesh-201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
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	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

#### Justification for the above projections and assumptions is as under:

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service, the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000

7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	<b>Head Clinical</b>	1	25,00,000.00
2	<b>Principal Investigators</b>	2	30,00,000.00
3	<b>Research Associates for clinical department</b>	4	16,00,000.00

4	Phlebotomists	5	12,50,000.00
5	Pharmacists	2	5,00,000.00
6	Trainee	4	8,00,000.00
7	Custodian and Recruiter	2	15,00,000.00
8	Head Bioanalytical	1	15,00,000.00
9	Team Leader	3	36,00,000.00
10	Research Associate	4	20,00,000.00
11	Trainee	4	10,00,000.00
12	Custodian	1	7,50,000.00
13	Clinical QA Associate	2	10,00,000.00
14	Bioanalytical QA	1	10,00,000.00
15	Bioanalytical QA Associate	2	10,00,000.00
16	Statistician	1	6,00,000.00
17	Report Writing team leader	1	7,50,000.00
18	Report Writing Research Associate	2	12,00,000.00
19	HR Manager	1	7,50,000.00
20	Head Quality Assurance	1	15,00,000.00
21	Clinical QA	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

**h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

### **i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

### **3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R  714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):**

NA

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

**7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.** The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

**8. Site layout Plan is attached.**

**9. Google coordinates of the location are attached.**

**10. Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida

and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

**11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

**12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) -** The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<b>Sr. No.</b>	<b>Content</b>	<b>Actual Study Subject Cost (INR)</b>	<b>Vendor Industry Cost (INR)</b>
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical Study cost for 30 subjects</b>	<b>5,40,000</b>	<b>7,65,000</b>
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000



7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

#### 14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) –

The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

15. Loan disbursement schedule month wise. The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith

the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

16. GST certificate of the company is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

### Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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Voice: +91-120 411 0117; 4324647

**Corporate Office:**  
D-39, 2nd Floor, Sector- 2, Noida  
Uttar Pradesh- 201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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We assure our best services and response to you all the time.

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <shahid@rkassociates.org> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:

**A. Land:**

- a) Total Area of the land used for the project.
- b) Layout Plan.
- c) Sale/Lease Deed.
- d) Current status/utilization of the land.
- e) Address of the Unit
- f) Google coordinates of the location.
- g) Attach sale deed.

**B. Building and Civil works:**

- a) Total Area proposed for the Building.
- b) Layout/ Site plan.
- c) Site Map Approval/Sanctioned.
- d) Details of the contractor's engaged.
- e) Attach agreement with contractor.

**C. Proposed Equipment:**

- a) List of proposed equipment as per below heads:
- Serial Number, if any
  - Equipment name
  - Manufacturer name
  - Specification/capacity
  - Expected Landed Price
  - Current status of the order
- b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
- c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.

12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).

13. Pricing Strategy of the company along with selling & marketing plan.

14. Updated agreements for the proposed unit, if any.

15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).

16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.

17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

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**Thanks & Regards,**  
**Mohd Shahid,**  
**Senior Coordinator Business Operation**  
**+91-9350027216**

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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**Thanks & Regards,**  
**Mohd Shahid,**  
**Senior Coordinator Business Operation**  
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Website: [www.rkassociates.org](http://www.rkassociates.org)

### 3 attachments



**SRPL- REPLY TO TEV QUERY (1).docx**  
47K



**SRPL-GST REGISTRATION.pdf**  
191K



m c bhatt pnb <mcbhatt13@gmail.com>

Tue, Apr 23, 2024 at 11:51 AM

To: Aneesh Mallick <aneesh.mallick@rkassociates.org>

Cc: "Shahid ." <shahid@rkassociates.org>, "skylimitresearch@gmail.com" <skylimitresearch@gmail.com>, roshni@skylimitresearch.com, Gaurav Kumar <gaurav.kumar@rkassociates.org>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <mohit.agarwal@rkassociates.org>, "R.K Associates, The Valuers | LIE | TEV | ASM" <valuers@rkassociates.org>, clpc6277@pnb.co.in

Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00

Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service, the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical Study cost for 30 subjects</b>	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 18,75,00,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>

9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	<b>Head Clinical</b>	1	25,00,000.00
2	<b>Principal Investigators</b>	2	30,00,000.00
3	<b>Research Associates for clinical department</b>	4	16,00,000.00
4	<b>Phlebotomists</b>	5	12,50,000.00
5	<b>Pharmacists</b>	2	5,00,000.00
6	<b>Trainee</b>	4	8,00,000.00
7	<b>Custodian and Recruiter</b>	2	15,00,000.00
8	<b>Head Bioanalytical</b>	1	15,00,000.00
9	<b>Team Leader</b>	3	36,00,000.00
10	<b>Research Associate</b>	4	20,00,000.00
11	<b>Trainee</b>	4	10,00,000.00



12	<b>Custodian</b>	1	7,50,000.00
13	<b>Clinical QA Associate</b>	2	10,00,000.00
14	<b>Bioanalytical QA</b>	1	10,00,000.00
15	<b>Bioanalytical QA Associate</b>	2	10,00,000.00
16	<b>Statistician</b>	1	6,00,000.00
17	<b>Report Writing team leader</b>	1	7,50,000.00
18	<b>Report Writing Research Associate</b>	2	12,00,000.00
19	<b>HR Manager</b>	1	7,50,000.00
20	<b>Head Quality Assurance</b>	1	15,00,000.00
21	<b>Clinical QA</b>	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

**h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

**i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period

which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R  714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

5. **List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):**  
NA

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

**10. Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

**11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

**12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) -** The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<b>- Sr. No.</b>	<b>- Content</b>	<b><u>Actual Study Subject Cost (INR).</u></b>	<b><u>Vendor Industry Cost (INR).</u></b>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>		5,40,000	7,65,000
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000

8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000  <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000  <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000  <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000  <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000  <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000  <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000  <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000  <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

#### 14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)

– The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

15. Loan disbursement schedule month wise. The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

16. GST certificate of the company is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

### Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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Voice: +91-120 411 0117; 4324647

**Corporate Office:**  
D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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We assure our best services and response to you all the time.

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <shahid@rkassociates.org> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
  - A. Land:**
    - a) Total Area of the land used for the project.
    - b) Layout Plan.
    - c) Sale/Lease Deed.
    - d) Current status/utilization of the land.
    - e) Address of the Unit
    - f) Google coordinates of the location.
    - g) Attach sale deed.
  - B. Building and Civil works:**
    - a) Total Area proposed for the Building.
    - b) Layout/ Site plan.
    - c) Site Map Approval/Sanctioned.
    - d) Details of the contractor's engaged.
    - e) Attach agreement with contractor.
  - C. Proposed Equipment:**
    - a) List of proposed equipment as per below heads:
      - Serial Number, if any
      - Equipment name



- Manufacturer name
  - Specification/capacity
  - Expected Landed Price
  - Current status of the order
- b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
- c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.

12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).

13. Pricing Strategy of the company along with selling & marketing plan.

14. Updated agreements for the proposed unit, if any.

15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).

16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.

17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
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R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

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Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

Tue, Apr 23, 2024 at 12:16 PM

To: m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)>

Cc: "Shahid ." <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>, "skylimitresearch@gmail.com" <[skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)>, roshni@skylimitresearch.com, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, "R.K Associates, The Valuers | LIE | TEV | ASM" <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, [clpc6277@pnb.co.in](mailto:clpc6277@pnb.co.in)

Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

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Thanks &amp; Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Analyst



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Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks &amp; Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
**(A Clinical Research Organization)**  
**VILLA-2/9, LAND 2, JAYPEE GREENS,**  
**GREATER NOIDA, UP-201306**  
**Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)**  
**Mobile: 9719193909**

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
 Corporate Office : D-39, Second Floor, Sector-2,  
 Noida, Uttar Pradesh-201301  
 Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service , the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies

in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>

<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>
------------------------	--	---------------------	---------------------

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected to conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	Head Clinical	1	25,00,000.00
2	Principal Investigators	2	30,00,000.00
3	Research Associates for clinical department	4	16,00,000.00
4	Phlebotomists	5	12,50,000.00
5	Pharmacists	2	5,00,000.00
6	Trainee	4	8,00,000.00
7	Custodian and Recruiter	2	15,00,000.00
8	Head Bioanalytical	1	15,00,000.00
9	Team Leader	3	36,00,000.00
10	Research Associate	4	20,00,000.00
11	Trainee	4	10,00,000.00
12	Custodian	1	7,50,000.00
13	Clinical QA Associate	2	10,00,000.00
14	Bioanalytical QA	1	10,00,000.00
15	Bioanalytical QA Associate	2	10,00,000.00
16	Statistician	1	6,00,000.00
17	Report Writing team leader	1	7,50,000.00
18	Report Writing Research Associate	2	12,00,000.00
19	HR Manager	1	7,50,000.00
20	Head Quality Assurance	1	15,00,000.00
21	Clinical QA	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year

onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

**h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

**i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the

average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R  714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

**6. List of the expected customer-line -** The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research



area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's—Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

12. **Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory



authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<b>Sr. No.</b>	<b>Content</b>	<b>Actual Study Subject Cost (INR)</b>	<b>Vendor Industry Cost (INR)</b>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>	<b>Total Clinical Study cost for 30 subjects</b>	<b>5,40,000</b>	<b>7,65,000</b>
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000 X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000 X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>

9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	$5,40,000 \times 2 \times 25 = \text{Rs. } 2,70,00,000$  <b>Plus</b> $7,50,000 \times 2 \times 25 = \text{Rs. } 3,75,00,000$  <b>Sub-total = Rs. 6,45,00,000</b>	$7,65,000 \times 2 \times 25 = \text{Rs. } 3,82,50,000$  <b>Plus</b> $12,00,000 \times 2 \times 25 = \text{Rs. } 6,00,00,000$  <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

**15.** Loan disbursement schedule month wise. The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

**16.** GST certificate of the company is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
  - A. **Land:**
    - a) Total Area of the land used for the project.
    - b) Layout Plan.
    - c) Sale/Lease Deed.
    - d) Current status/utilization of the land.
    - e) Address of the Unit
    - f) Google coordinates of the location.
    - g) Attach sale deed.
  - B. **Building and Civil works:**
    - a) Total Area proposed for the Building.
    - b) Layout/ Site plan.
    - c) Site Map Approval/Sanctioned.
    - d) Details of the contractor's engaged.
    - e) Attach agreement with contractor.
  - C. **Proposed Equipment:**
    - a) List of proposed equipment as per below heads:
      - Serial Number, if any
      - Equipment name
      - Manufacturer name
      - Specification/capacity
      - Expected Landed Price
      - Current status of the order
    - b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
    - c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.

12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

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Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

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Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)>

Tue, Apr 23, 2024 at 12:55 PM

To: Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

Cc: "Shahid ." <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>, "skylimitresearch@gmail.com" <[skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)>, roshni@skylimitresearch.com, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, "R.K Associates, The Valuers | LIE | TEV | ASM" <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, [clpc6277@pnb.co.in](mailto:clpc6277@pnb.co.in)

Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Analyst



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A product of R.K. Associates  
[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9958632707

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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**Note:** The e-mail content is intended for the sole use of the intended recipient/s and may contain material that is **CONFIDENTIAL AND PRIVATE COMPANY INFORMATION**. Any review or reliance by others or copying or distribution or forwarding of any or all of the contents in this message is **STRICTLY PROHIBITED**. If you have erroneously received this message, please delete it immediately and notify the sender. Before opening any attachments please check them for viruses and defects.

On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)

Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: www.rkassociates.org

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service , the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each



Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for

conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected to conduct around 104 studies (52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	Head Clinical	1	25,00,000.00
2	Principal Investigators	2	30,00,000.00
3	Research Associates for clinical department	4	16,00,000.00
4	Phlebotomists	5	12,50,000.00
5	Pharmacists	2	5,00,000.00
6	Trainee	4	8,00,000.00
7	Custodian and Recruiter	2	15,00,000.00
8	Head Bioanalytical	1	15,00,000.00
9	Team Leader	3	36,00,000.00
10	Research Associate	4	20,00,000.00
11	Trainee	4	10,00,000.00
12	Custodian	1	7,50,000.00
13	Clinical QA Associate	2	10,00,000.00
14	Bioanalytical QA	1	10,00,000.00
15	Bioanalytical QA Associate	2	10,00,000.00
16	Statistician	1	6,00,000.00
17	Report Writing team leader	1	7,50,000.00
18	Report Writing Research Associate	2	12,00,000.00
19	HR Manager	1	7,50,000.00
20	Head Quality Assurance	1	15,00,000.00
21	Clinical QA	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from December,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory

bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

#### **g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

#### **h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

#### **i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year.

With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong perspectives of the sector.

**3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R  714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report

published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's—Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

12. **Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to

improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<b>- Sr. No.</b>	<b>- Content</b>	<b>Actual Study Subject Cost (INR)</b>	<b>Vendor Industry Cost (INR)</b>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>	<b>Total Clinical Study cost for 30 subjects</b>	<b>5,40,000</b>	<b>7,65,000</b>
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	$5,40,000 \times 25 = \text{Rs. } 1,35,00,000$ <b>Plus</b> $7,50,000 \times 25 = \text{Rs. } 1,87,50,000$ <b>Sub-total = Rs. 3,22,50,000</b>	$7,65,000 \times 25 = \text{Rs. } 1,91,25,000$ <b>Plus</b> $12,00,000 \times 25 = \text{Rs. } 3,00,00,000$ <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	$5,40,000 \times 2 \times 25 = \text{Rs. } 2,70,00,000$ <b>Plus</b> $7,50,000 \times 2 \times 25 = \text{Rs. } 3,75,00,000$ <b>Sub-total = Rs. 6,45,00,000</b>	$7,65,000 \times 2 \times 25 = \text{Rs. } 3,82,50,000$ <b>Plus</b> $12,00,000 \times 2 \times 25 = \text{Rs. } 6,00,00,000$ <b>Sub-total = Rs. 9,82,50,000</b>

10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

**15. Loan disbursement schedule month wise.** The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

**16. GST certificate of the company** is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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Integrating Valuation Life Cycle -  
A product of R.K. Associates  
[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
  - A. Land:**
    - a) Total Area of the land used for the project.
    - b) Layout Plan.
    - c) Sale/Lease Deed.
    - d) Current status/utilization of the land.
    - e) Address of the Unit
    - f) Google coordinates of the location.
    - g) Attach sale deed.
  - B. Building and Civil works:**
    - a) Total Area proposed for the Building.
    - b) Layout/ Site plan.
    - c) Site Map Approval/Sanctioned.
    - d) Details of the contractor's engaged.
    - e) Attach agreement with contractor.
  - C. Proposed Equipment:**
    - a) List of proposed equipment as per below heads:
      - Serial Number, if any
      - Equipment name
      - Manufacturer name
      - Specification/capacity
      - Expected Landed Price
      - Current status of the order
    - b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
    - c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)


--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
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Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

## 2 attachments

 **SRPL-QUOTATION-21-ADHARSHILA INTERIOR.pdf**  
1164K

 **SRPL-QUOTATION-21-ARCHITECTS ARTILLER.pdf**  
493K

Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

To: Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>

Cc: Shahid <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>

Wed, Apr 24, 2024 at 11:17 AM

Hi Gaurav

Please find below list of queries/requirements and financial model.

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.
- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
- Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well

S. No.	Equipment	Qty.	Use	Specification
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- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

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Thanks &amp; Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)

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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9958632707

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

--

Thanks &amp; Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Analyst



*World's first fully digital Automated Platform for  
Integrating Valuation Life Cycle -  
A product of R.K. Associates  
[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P.)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks &amp; Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
**(A Clinical Research Organization)**  
**VILLA-2/9, LAND 2, JAYPEE GREENS,**  
**GREATER NOIDA, UP-201306**  
**Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)**  
**Mobile: 9719193909**

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
 Corporate Office : D-39, Second Floor, Sector-2,  
 Noida, Uttar Pradesh-201301  
 Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service , the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal

studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>

<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>
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The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	Head Clinical	1	25,00,000.00
2	Principal Investigators	2	30,00,000.00
3	Research Associates for clinical department	4	16,00,000.00
4	Phlebotomists	5	12,50,000.00
5	Pharmacists	2	5,00,000.00
6	Trainee	4	8,00,000.00
7	Custodian and Recruiter	2	15,00,000.00
8	Head Bioanalytical	1	15,00,000.00
9	Team Leader	3	36,00,000.00
10	Research Associate	4	20,00,000.00
11	Trainee	4	10,00,000.00
12	Custodian	1	7,50,000.00
13	Clinical QA Associate	2	10,00,000.00
14	Bioanalytical QA	1	10,00,000.00
15	Bioanalytical QA Associate	2	10,00,000.00
16	Statistician	1	6,00,000.00
17	Report Writing team leader	1	7,50,000.00
18	Report Writing Research Associate	2	12,00,000.00
19	HR Manager	1	7,50,000.00
20	Head Quality Assurance	1	15,00,000.00
21	Clinical QA	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>



The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

**h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

**i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027

respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

2. **Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat, Director	02/01/2000	08163436	GXWPS7371P 806698463827	Graduate	04 years
Yash Pratap Singh, Director	11/08/2001	10075889	MSCPS9247R 226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R 714667948713	Post Graduate	03 ears

4. **List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

5. **List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

6. **List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

12. **Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a

multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<u>Sr. No.</u>	<u>Content</u>	<u>Actual Study Subject Cost (INR)</u>	<u>Vendor Industry Cost (INR)</u>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>	<b>Total Clinical Study cost for 30 subjects</b>	<b>5,40,000</b>	<b>7,65,000</b>
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	$5,40,000 \times 25 = \text{Rs. } 1,35,00,000$ <b>Plus</b> $7,50,000 \times 25 = \text{Rs. } 1,87,50,000$ <b>Sub-total = Rs. 3,22,50,000</b>	$7,65,000 \times 25 = \text{Rs. } 1,91,25,000$ <b>Plus</b> $12,00,000 \times 25 = \text{Rs. } 3,00,00,000$ <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average	$5,40,000 \times 2 \times 25 = \text{Rs. } 2,70,00,000$ <b>Plus</b>	$7,65,000 \times 2 \times 25 = \text{Rs. } 3,82,50,000$ <b>Plus</b>

	number of 60 subjects in each Pivotal study) in a year	7,50,000X 2 X 25 = Rs. 3,75,00,000  <b>Sub-total = Rs. 6,45,00,000</b>	12,00,000X 2 X 25 = Rs. 6,00,00,000  <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

15. Loan disbursement schedule month wise. The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

16. GST certificate of the company is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <shahid@rkassociates.org> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
  - A. Land:**
    - a) Total Area of the land used for the project.
    - b) Layout Plan.
    - c) Sale/Lease Deed.
    - d) Current status/utilization of the land.
    - e) Address of the Unit
    - f) Google coordinates of the location.
    - g) Attach sale deed.
  - B. Building and Civil works:**
    - a) Total Area proposed for the Building.
    - b) Layout/ Site plan.
    - c) Site Map Approval/Sanctioned.
    - d) Details of the contractor's engaged.
    - e) Attach agreement with contractor.
  - C. Proposed Equipment:**
    - a) List of proposed equipment as per below heads:
      - Serial Number, if any
      - Equipment name
      - Manufacturer name
      - Specification/capacity
      - Expected Landed Price
      - Current status of the order
    - b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
    - c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).



16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.

17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,


Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
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Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

 **Financial Model - SRPL.xlsx**  
142K

**Aneesh Mallick** <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

Wed, Apr 24, 2024 at 2:37 PM

To: m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)>

Cc: "Shahid ." <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>, "skylimitresearch@gmail.com" <[skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)>, roshni@skylimitresearch.com, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, "R.K Associates, The Valuers | LIE | TEV | ASM" <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, [clpc6277@pnb.co.in](mailto:clpc6277@pnb.co.in), "Business Operations R.K Associates" <[bo@rkassociates.org](mailto:bo@rkassociates.org)>, FA Team <[fateam@rkassociates.org](mailto:fateam@rkassociates.org)>

Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.

- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
- **Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well)

S. No.	Equipment	Qty.	Use	Specification
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- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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Integrating Valuation Life Cycle -  
A product of R.K. Associates  
[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



*World's first fully digital Automated Platform for  
Integrating Valuation Life Cycle -  
A product of R.K. Associates  
[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service, the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>

	in each Pivotal study) in a year @ 65000/- per study		
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	<b>Head Clinical</b>	1	25,00,000.00
2	<b>Principal Investigators</b>	2	30,00,000.00
3	<b>Research Associates for clinical department</b>	4	16,00,000.00
4	<b>Phlebotomists</b>	5	12,50,000.00
5	<b>Pharmacists</b>	2	5,00,000.00
6	<b>Trainee</b>	4	8,00,000.00
7	<b>Custodian and Recruiter</b>	2	15,00,000.00
8	<b>Head Bioanalytical</b>	1	15,00,000.00
9	<b>Team Leader</b>	3	36,00,000.00
10	<b>Research Associate</b>	4	20,00,000.00
11	<b>Trainee</b>	4	10,00,000.00
12	<b>Custodian</b>	1	7,50,000.00
13	<b>Clinical QA Associate</b>	2	10,00,000.00
14	<b>Bioanalytical QA</b>	1	10,00,000.00
15	<b>Bioanalytical QA Associate</b>	2	10,00,000.00
16	<b>Statistician</b>	1	6,00,000.00
17	<b>Report Writing team leader</b>	1	7,50,000.00
18	<b>Report Writing Research Associate</b>	2	12,00,000.00
19	<b>HR Manager</b>	1	7,50,000.00
20	<b>Head Quality Assurance</b>	1	15,00,000.00
21	<b>Clinical QA</b>	1	10,00,000.00

	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>
--	--------------	-----------	-----------------------

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

**h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

**i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R  714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to



countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

**12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) -** The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<b>Sr. No.</b>	<b>Content</b>	<b>Actual Study Subject Cost (INR)</b>	<b>Vendor Industry Cost (INR)</b>
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	Total Clinical Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000 X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000 X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>

9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	$5,40,000 \times 2 \times 25 = \text{Rs. } 2,70,00,000$ <b>Plus</b> $7,50,000 \times 2 \times 25 = \text{Rs. } 3,75,00,000$ <b>Sub-total = Rs. 6,45,00,000</b>	$7,65,000 \times 2 \times 25 = \text{Rs. } 3,82,50,000$ <b>Plus</b> $12,00,000 \times 2 \times 25 = \text{Rs. } 6,00,00,000$ <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

15. Loan disbursement schedule month wise. The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

16. GST certificate of the company is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <shahid@rkassociates.org> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
  - A. Land:**
    - a) Total Area of the land used for the project.
    - b) Layout Plan.
    - c) Sale/Lease Deed.
    - d) Current status/utilization of the land.
    - e) Address of the Unit
    - f) Google coordinates of the location.
    - g) Attach sale deed.
  - B. Building and Civil works:**
    - a) Total Area proposed for the Building.
    - b) Layout/ Site plan.
    - c) Site Map Approval/Sanctioned.
    - d) Details of the contractor's engaged.
    - e) Attach agreement with contractor.
  - C. Proposed Equipment:**
    - a) List of proposed equipment as per below heads:
      - Serial Number, if any
      - Equipment name
      - Manufacturer name
      - Specification/capacity
      - Expected Landed Price
      - Current status of the order
    - b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
    - c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.

12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

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Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

---

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

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Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
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D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)>

Sat, Apr 27, 2024 at 4:15 PM

To: Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

Cc: "Shahid ." <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>, "skylimitresearch@gmail.com" <[skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)>, roshni@skylimitresearch.com, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, "R.K Associates, The Valuers | LIE | TEV | ASM" <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, [clpc6277@pnb.co.in](mailto:clpc6277@pnb.co.in), "Business Operations R.K Associates" <[bo@rkassociates.org](mailto:bo@rkassociates.org)>, FA Team <[fateam@rkassociates.org](mailto:fateam@rkassociates.org)>, [bratati@skylimitresearch.com](mailto:bratati@skylimitresearch.com)

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: www.rkassociates.org

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**  
**and**

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period, is over after 7 to 25 days (depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramide, Ophthalmic Emulsions, etc).**

**Response**

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

**Response**

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800



6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5: As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.**

**Response**

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 : We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.**

**Response**

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA ,FDA for USA, EMEA for EU market, MHRA for UK , TGI for Australia and NPRA for Malaysia, and other ROW s, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 : Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.**

**Response**

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8 External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.**

**Response**

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.**

**Response**

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.**

**Response**

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :Kindly list down expenses which are linked to revenue and which are not linked with revenue.**

**Response**

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

**Query 12 :Proposed Shareholding Pattern.**

**Response**

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.**

**Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).**

**Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
  - GST registration: Attached
  - Pollution certificate: Applied and will be obtained in due course.
  - Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
  - Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.
- Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.
- EPFO registration: Will be obtained in due course
  - ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**

**Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format**

**Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors

10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample dispensing, Bulk Spiking	1- channel, incl. Combitips advance rack, Combitips advance assortment pack Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:**

**Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- *EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.*
- *Bioanalytical Method Validation Guidance for Industry FDA- May 2018.*
- *Electronic Data – 21 CFR 11*
- *Good Laboratory Practice -21 CFR 58, ISO 17025-2017*
- *ISO 9001:2015, Quality Management Systems*

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

Process are described schematically as under for analysis:



**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).**

**Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August'2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.
- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
- **Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well

S. No.	Equipment	Qty.	Use	Specification
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- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9958632707

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**

(A Clinical Research Organization)

VILLA-2/9, LAND 2, JAYPEE GREENS,

GREATER NOIDA, UP-201306

Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)

Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service , the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue



generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected

for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	Head Clinical	1	25,00,000.00
2	Principal Investigators	2	30,00,000.00
3	Research Associates for clinical department	4	16,00,000.00
4	Phlebotomists	5	12,50,000.00
5	Pharmacists	2	5,00,000.00
6	Trainee	4	8,00,000.00
7	Custodian and Recruiter	2	15,00,000.00
8	Head Bioanalytical	1	15,00,000.00
9	Team Leader	3	36,00,000.00
10	Research Associate	4	20,00,000.00
11	Trainee	4	10,00,000.00
12	Custodian	1	7,50,000.00
13	Clinical QA Associate	2	10,00,000.00
14	Bioanalytical QA	1	10,00,000.00
15	Bioanalytical QA Associate	2	10,00,000.00
16	Statistician	1	6,00,000.00
17	Report Writing team leader	1	7,50,000.00
18	Report Writing Research Associate	2	12,00,000.00
19	HR Manager	1	7,50,000.00
20	Head Quality Assurance	1	15,00,000.00
21	Clinical QA	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

#### **g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

#### **h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

#### **i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

2. **Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat, Director	02/01/2000	08163436	GXWPS7371P 806698463827	Graduate	04 years
Yash Pratap Singh, Director	11/08/2001	10075889	MSCPS9247R 226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R 714667948713	Post Graduate	03 ears

4. **List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

5. **List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

6. **List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global

pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/building units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G-200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

12. **Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary

significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<u>Sr. No.</u>	<u>Content</u>	<u>Actual Study Subject Cost (INR)</u>	<u>Vendor Industry Cost (INR)</u>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>		5,40,000	7,65,000
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000 X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000 X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>

9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	$5,40,000 \times 2 \times 25 = \text{Rs. } 2,70,00,000$  <b>Plus</b> $7,50,000 \times 2 \times 25 = \text{Rs. } 3,75,00,000$  <b>Sub-total = Rs. 6,45,00,000</b>	$7,65,000 \times 2 \times 25 = \text{Rs. } 3,82,50,000$  <b>Plus</b> $12,00,000 \times 2 \times 25 = \text{Rs. } 6,00,00,000$  <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

15. Loan disbursement schedule month wise. The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

16. GST certificate of the company is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

## Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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We assure our best services and response to you all the time.

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

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Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <shahid@rkassociates.org> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
  - A. **Land:**
    - a) Total Area of the land used for the project.
    - b) Layout Plan.
    - c) Sale/Lease Deed.
    - d) Current status/utilization of the land.
    - e) Address of the Unit
    - f) Google coordinates of the location.
    - g) Attach sale deed.
  - B. **Building and Civil works:**
    - a) Total Area proposed for the Building.
    - b) Layout/ Site plan.
    - c) Site Map Approval/Sanctioned.
    - d) Details of the contractor's engaged.
    - e) Attach agreement with contractor.
  - C. **Proposed Equipment:**
    - a) List of proposed equipment as per below heads:
      - Serial Number, if any
      - Equipment name
      - Manufacturer name
      - Specification/capacity
      - Expected Landed Price
      - Current status of the order
    - b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.

c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.

12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

--

Thanks & Regards,  
Mohd Shahid,  
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Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
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D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

 **SRPL- Reply to TEV queries-Bratati.docx**  
207K

**Aneesh Mallick** <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>  
To: Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>

Tue, Apr 30, 2024 at 1:12 PM

Hi Gaurav

PFA financial model of SRPL.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**

and

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period, is over after 7 to 25 days (depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

**Response**

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

**Response**

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b>

	number of 15 subjects in each Pilot study) in a year	7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5: As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.**

#### **Response**

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 : We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.**

#### **Response**

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA, FDA for USA, EMEA for EU market, MHRA for UK, TGI for Australia and NPRA for Malaysia, and other ROWs, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 : Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises is 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.**

#### **Response**

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8 External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.**

#### **Response**

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.**

#### **Response**

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.**

#### **Response**

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :Kindly list down expenses which are linked to revenue and which are not linked with revenue.**

#### **Response**

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

#### Query 12 :Proposed Shareholding Pattern.

##### Response

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

#### Query 13: Experience in the subject Industry of promoters/ directors.

##### Response

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

#### Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).

##### Response

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
  - GST registration: Attached
  - Pollution certificate: Applied and will be obtained in due course.
  - Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
  - Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.
- Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.
- EPFO registration: Will be obtained in due course
  - ESIC registration: Will be obtained in due course

#### Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).

##### Response

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

#### Query 16: Technical specifications of the proposed equipment in the below format

##### Response

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer Capacity : 828 Litres



2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated-Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated-Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors
10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample dispensing, Bulk Spiking	1- channel, incl. Combitips advance rack, Combitips advance assortment pack Variable range for Volume range for 500-5000 ul



12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:**

**Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- *EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.*
- *Bioanalytical Method Validation Guidance for Industry FDA- May 2018.*
- *Electronic Data – 21 CFR 11*
- *Good Laboratory Practice -21 CFR 58, ISO 17025-2017*
- *ISO 9001:2015, Quality Management Systems*

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

**Process are described schematically as under for analysis:**

**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).****Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August'2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.
- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
- **Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well

S. No.	Equipment	Qty.	Use	Specification
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- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: www.rkassociates.org

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies.

Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service , the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected to conduct around 104 studies (52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	Head Clinical	1	25,00,000.00
2	Principal Investigators	2	30,00,000.00
3	Research Associates for clinical department	4	16,00,000.00
4	Phlebotomists	5	12,50,000.00
5	Pharmacists	2	5,00,000.00
6	Trainee	4	8,00,000.00
7	Custodian and Recruiter	2	15,00,000.00
8	Head Bioanalytical	1	15,00,000.00
9	Team Leader	3	36,00,000.00
10	Research Associate	4	20,00,000.00
11	Trainee	4	10,00,000.00
12	Custodian	1	7,50,000.00
13	Clinical QA Associate	2	10,00,000.00
14	Bioanalytical QA	1	10,00,000.00
15	Bioanalytical QA Associate	2	10,00,000.00
16	Statistician	1	6,00,000.00
17	Report Writing team leader	1	7,50,000.00
18	Report Writing Research Associate	2	12,00,000.00
19	HR Manager	1	7,50,000.00
20	Head Quality Assurance	1	15,00,000.00
21	Clinical QA	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from December,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European

medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

#### **g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

#### **h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

#### **i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98



crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R  714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and

development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

12. **Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval

timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<b>- Sr. No.</b>	<b>- Content</b>	<b>Actual Study Subject Cost (INR)</b>	<b>Vendor Industry Cost (INR)</b>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>	<b>Total Clinical Study cost for 30 subjects</b>	<b>5,40,000</b>	<b>7,65,000</b>
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000  <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000  <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000  <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000  <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000  <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000  <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000  <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000  <b>Sub-total = Rs. 9,82,50,000</b>

10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

**15. Loan disbursement schedule month wise.** The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

**16. GST certificate of the company** is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.

3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K. Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

=====

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

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Thanks & Regards

For Skylimit research Private Limited

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Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
  - A. **Land:**
    - a) Total Area of the land used for the project.
    - b) Layout Plan.
    - c) Sale/Lease Deed.
    - d) Current status/utilization of the land.
    - e) Address of the Unit
    - f) Google coordinates of the location.
    - g) Attach sale deed.
  - B. **Building and Civil works:**
    - a) Total Area proposed for the Building.
    - b) Layout/ Site plan.
    - c) Site Map Approval/Sanctioned.
    - d) Details of the contractor's engaged.
    - e) Attach agreement with contractor.
  - C. **Proposed Equipment:**
    - a) List of proposed equipment as per below heads:
      - Serial Number, if any
      - Equipment name
      - Manufacturer name
      - Specification/capacity
      - Expected Landed Price
      - Current status of the order
    - b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
    - c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.

17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

--

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D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)



Financial Model - SRPL\_v2.xlsx

169K

Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>  
To: [nischay.gautam@rkassociate.org](mailto:nischay.gautam@rkassociate.org)

Tue, Apr 30, 2024 at 6:13 PM

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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Uttar Pradesh- 201301

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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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**6 attachments**

**SRPL- Letter dated 18.04.2024 to valuer.docx**  
61K

**SRPL-TAN.pdf**  
796K

**SRPL-PAN.pdf**  
481K

**SRPL-Electricity Bill.pdf**  
107K

**Detaled Project Report -SRPL.docx**  
1074K

**CMA Data SRPL-27.02.2024.xls**  
290K

**Aneesh Mallick** <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>  
To: [nischay.gautam@rkassociate.org](mailto:nischay.gautam@rkassociate.org)

Tue, Apr 30, 2024 at 6:13 PM

--

Thanks & Warm Regards,

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----- Forwarded message -----

From: **m c bhatt pnb** <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)>

Date: Thu, 18 Apr 2024 at 12:23 PM

Subject: Re: Quotation for TEV Study of M/s Skylimit Research Pvt. Ltd.

To: Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>

Cc: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com) <[skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)>, <[roshni@skylimitresearch.com](mailto:roshni@skylimitresearch.com)>, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, Mohit Agarwal (Executive Sr. Vice President), R.K Associates <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, R.K Associates, The Valuers | LIE | TEV | ASM <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, <[clpc6277@pnb.co.in](mailto:clpc6277@pnb.co.in)>, Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

[Quoted text hidden]





**8 attachments**

**SKYLIMIT INVOICE-1-Quotation Freezer.pdf**  
799K

**SKYLIMIT INVOICE-2-Quotation freezer.pdf**  
138K

**SKYLIMIT INVOICE-3-Agilent HPLC.pdf**  
167K

**SKYLIMIT INVOICE-4-Agilent-HPLC.pdf**  
2414K

-  **SKYLIMIT INVOICE-5- Agilent- Terms.pdf**  
92K
-  **SKYLIMIT INVOICE-6-Sciex-LCMS.pdf**  
501K
-  **SKYLIMIT INVOICE-7-Sciex-LCMS.pdf**  
496K
-  **SKYLIMIT INVOICE-8-Sciex-LCMS.pdf**  
679K

Aneesh Mallick <aneesh.mallick@rkassociates.org>  
To: nischay.gautam@rkassociate.org

Tue, Apr 30, 2024 at 6:13 PM

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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----- Forwarded message -----

From: **m c bhatt pnb** <mcbhatt13@gmail.com>

Date: Thu, 18 Apr 2024 at 12:24 PM

Subject: Re: Quotation for TEV Study of M/s Skylimit Research Pvt. Ltd.

To: Shahid . <shahid@rkassociates.org>


Cc: skylimitresearch@gmail.com <skylimitresearch@gmail.com>, <roshni@skylimitresearch.com>, Gaurav Kumar <gaurav.kumar@rkassociates.org>, Mohit Agarwal (Executive Sr. Vice President), R.K Associates <mohit.agarwal@rkassociates.org>, R.K Associates, The Valuers | LIE | TEV | ASM <valuers@rkassociates.org>, <clpc6277@pnb.co.in>, Aneesh Mallick <aneesh.mallick@rkassociates.org>


[Quoted text hidden]


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**5 attachments**

 **SKYLIMIT INVOICE-9-Sciex-LCMS.pdf**  
3123K

 **SKYLIMIT INVOICE-10-Sbi 24 Cell System.pdf**  
347K

 **SKYLIMIT INVOICE-11-Cell system.pdf**  
1156K

 **SKYLIMIT INVOICE-12-Bluestar room freezer.pdf**  
185K

 **SKYLIMIT INVOICE-13-Takahe nitrogen evaporator.pdf**  
401K

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**Aneesh Mallick** <aneesh.mallick@rkassociates.org>  
To: nischay.gautam@rkassociate.org

Tue, Apr 30, 2024 at 6:13 PM

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9958632707

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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----- Forwarded message -----

From: **m c bhatt pnb** <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)>

Date: Thu, 18 Apr 2024 at 12:25 PM

Subject: Re: Quotation for TEV Study of M/s Skylimit Research Pvt. Ltd.

To: Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>


Cc: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com) <[skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)>, <[roshni@skylimitresearch.com](mailto:roshni@skylimitresearch.com)>, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, Mohit Agarwal (Executive Sr. Vice President), R.K Associates <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, R.K Associates, The Valuers | LIE | TEV | ASM <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, <[clpc6277@pnb.co.in](mailto:clpc6277@pnb.co.in)>, Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

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**4 attachments**

 **SKYLIMIT-14-TAKAHE NTROGEN EVAPORATOR.pdf**  
1116K

 **SKYLIMIT INVOICE-15-Takahe.pdf**  
364K

 **SKYLIMIT INVOICE-16-Takahe.pdf**  
443K

 **SRPL-LEASE DEED.pdf**  
5375K

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**Aneesh Mallick** <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>  
To: [nischay.gautam@rkassociate.org](mailto:nischay.gautam@rkassociate.org)

Tue, Apr 30, 2024 at 6:13 PM

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From: **m c bhatt pnb** <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)>

Date: Thu, 18 Apr 2024 at 12:26 PM

Subject: Re: Quotation for TEV Study of M/s Skylimit Research Pvt. Ltd.

To: Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>Cc: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com) <[skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)>, <[roshni@skylimitresearch.com](mailto:roshni@skylimitresearch.com)>, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, Mohit Agarwal (Executive Sr. Vice President), R.K Associates <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, R.K Associates, The Valuers | LIE | TEV | ASM <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, <[clpc6277@pnb.co.in](mailto:clpc6277@pnb.co.in)>, Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

[Quoted text hidden]

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**2 attachments** **SRPL-UDYAM.pdf**  
265K **SRPL-MOA.pdf**  
4512K

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**Aneesh Mallick** <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>  
To: [nischay.gautam@rkassociate.org](mailto:nischay.gautam@rkassociate.org)

Tue, Apr 30, 2024 at 6:13 PM

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Thanks &amp; Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Assets



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[Quoted text hidden]

 **SRPL-AOA.pdf**  
11706K

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To: [nischay.gautam@rkassociate.org](mailto:nischay.gautam@rkassociate.org)

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To: Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>

Cc: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com) <[skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)>, <[roshni@skylimitresearch.com](mailto:roshni@skylimitresearch.com)>, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, Mohit Agarwal (Executive Sr. Vice President), R.K Associates <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, R.K Associates, The Valuers | LIE | TEV | ASM <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, <[clpc6277@pnb.co.in](mailto:clpc6277@pnb.co.in)>, Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

[Quoted text hidden]

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**2 attachments**

**SKYLIMIT INVOICE-17- Mahendra Bolero.pdf**  
240K

**SKYLIMIT INVOICE-19-Mahindra Scorpio.pdf**  
241K

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**Aneesh Mallick** <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>  
To: [nischay.gautam@rkassociate.org](mailto:nischay.gautam@rkassociate.org)

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From: **m c bhatt pnb** <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)>

Date: Mon, 22 Apr 2024 at 1:07 PM

Subject: Re: Quotation for TEV Study of M/s Skylimit Research Pvt. Ltd.

To: Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

Cc: Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>, [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com) <[skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)>, <[roshni@skylimitresearch.com](mailto:roshni@skylimitresearch.com)>, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, Mohit Agarwal (Executive Sr. Vice President), R.K Associates <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, R.K Associates, The Valuers | LIE | TEV | ASM <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, <[clpc6277@pnbc.co.in](mailto:clpc6277@pnbc.co.in)>

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: www.rkassociates.org

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service , the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December’2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
---------	---------	---------------------------------	---

<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs.

22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.


**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	Head Clinical	1	25,00,000.00
2	Principal Investigators	2	

### 3 attachments

 **SRPL- REPLY TO TEV QUERY (1).docx**  
47K

 **SRPL-GST REGISTRATION.pdf**  
191K

 **SRPL-SITE PLAN.pdf**  
664K

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To: nischay.gautam@rkassociate.org

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

=====

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----- Forwarded message -----

From: **m c bhatt pnb** <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)>

Date: Tue, 23 Apr 2024 at 12:55 PM

Subject: Re: Quotation for TEV Study of M/s Skylimit Research Pvt. Ltd.

To: Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

Cc: Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>, [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com) <[skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)>, <[roshni@skylimitresearch.com](mailto:roshni@skylimitresearch.com)>, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, Mohit Agarwal (Executive Sr. Vice President), R.K Associates <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, R.K Associates, The Valuers | LIE | TEV | ASM <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, <[clpc6277@pnb.co.in](mailto:clpc6277@pnb.co.in)>

Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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Mobile No.- +91 9958632707

Voice: +91-120 411 0117; 4324647

**Corporate Office:**  
D-39, 2nd Floor, Sector- 2, Noida  
Uttar Pradesh- 201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service, the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800



6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected to conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

b.

## 2 attachments



SRPL-QUOTATION-21-ADHARSHILA INTERIOR.pdf  
1164K



SRPL-QUOTATION-21-ARCHITECTS ARTILLER.pdf  
493K

Aneesh Mallick <aneesh.mallick@rkassociates.org>  
To: nischay.gautam@rkassociate.org

Tue, Apr 30, 2024 at 6:15 PM

Thanks & Warm Regards,

Aneesh Mallick



Consultant-Securities &amp; Financial Assets



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Mobile No.- +91 9958632707

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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----- Forwarded message -----

From: **m c bhatt pnb** <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)>

Date: Sat, 27 Apr 2024 at 4:15 PM

Subject: Re: Quotation for TEV Study of M/s Skylimit Research Pvt. Ltd.

To: Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

Cc: Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>, [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com) <[skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)>, <[roshni@skylimitresearch.com](mailto:roshni@skylimitresearch.com)>, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, Mohit Agarwal (Executive Sr. Vice President), R.K Associates <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, R.K Associates, The Valuers | LIE | TEV | ASM <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, <[clpc6277@pnb.co.in](mailto:clpc6277@pnb.co.in)>, Business Operations R.K Associates <[bo@rkassociates.org](mailto:bo@rkassociates.org)>, FA Team <[fateam@rkassociates.org](mailto:fateam@rkassociates.org)>, <[bratati@skylimitresearch.com](mailto:bratati@skylimitresearch.com)>

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: www.rkassociates.org

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**

**and**

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period, is over after 7 to 25 days (depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

**Response**

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

**Response**

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical	500	800

	sample		
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5: As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.**

#### Response

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 : We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.**

#### Response

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA ,FDA for USA, EMEA for EU market, MHRA for UK , TGI for Australia and NPRA for Malaysia, and other ROW s, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 : Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.**

#### Response

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8 External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.**

#### Response

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.**

#### Response

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.****Response**

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :Kindly list down expenses which are linked to revenue and which are not linked with revenue.****Response**

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

**Query 12 :Proposed Shareholding Pattern.****Response**

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.****Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).****Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
  - GST registration: Attached
  - Pollution certificate: Applied and will be obtained in due course.
  - Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
  - Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.
- Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.
- EPFO registration: Will be obtained in due course
  - ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).****Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format****Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System			

 **SRPL- Reply to TEV queries-Bratati.docx**  
207K

**Aneesh Mallick** <aneesh.mallick@rkassociates.org>

Fri, May 3, 2024 at 3:40 PM

To: m c bhatt pnb <mcbhatt13@gmail.com>

Cc: "Shahid ." <shahid@rkassociates.org>, "skylimitresearch@gmail.com" <skylimitresearch@gmail.com>, roshni@skylimitresearch.com, Gaurav Kumar <gaurav.kumar@rkassociates.org>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <mohit.agarwal@rkassociates.org>, "R.K Associates, The Valuers | LIE | TEV | ASM" <valuers@rkassociates.org>, clpc6277@pnb.co.in, "Business Operations R.K Associates" <bo@rkassociates.org>, FA Team <fateam@rkassociates.org>, bratati@skylimitresearch.com

Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000
- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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We assure our best services and response to you all the time.

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

=====

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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**

**and**

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period, is over after 7 to 25 days (depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.



**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

#### Response

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

#### Response

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
	Approximate cost for 50 studies (25 Pilot	<b>10,00,00,000</b>	<b>15,06,25,000</b>

<b>11.Overall Cost</b>	and 25 Pivotal) in a year		
------------------------	---------------------------	--	--

**Query 5: As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.**

#### Response

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 : We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.**

#### Response

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA, FDA for USA, EMEA for EU market, MHRA for UK, TGI for Australia and NPRA for Malaysia, and other ROWs, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 : Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises is 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.**

#### Response

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8 External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.**

#### Response

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.**

#### Response

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.**

#### Response

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :Kindly list down expenses which are linked to revenue and which are not linked with revenue.**

#### Response

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

**Query 12 :Proposed Shareholding Pattern.**

#### Response

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.**

#### Response



Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).**

**Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
  - GST registration: Attached
  - Pollution certificate: Applied and will be obtained in due course.
  - Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
  - Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.
- Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.
- EPFO registration: Will be obtained in due course
  - ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**

**Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format**

**Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection

5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated-Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated-Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors
10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample dispensing, Bulk Spiking	1- channel, incl. Combitips advance rack, Combitips advance assortment pack  Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range  Analytical Balance : For 20 mg to 220 gm weighing range

14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:**

**Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- *EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.*
- *Bioanalytical Method Validation Guidance for Industry FDA- May 2018.*
- *Electronic Data – 21 CFR 11*
- *Good Laboratory Practice -21 CFR 58, ISO 17025-2017*
- *ISO 9001:2015, Quality Management Systems*

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

**Process are described schematically as under for analysis:**

**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).****Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August'2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
  - With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
  - Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
  - As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
  - As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
  - We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
  - Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
  - External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
  - In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
  - Financial Model of the Project in excel with proper assumptions & Projections and rationale.
  - Kindly list down expenses which are linked to revenue and which are not linked with revenue.
  - Proposed Shareholding Pattern.
  - Experience in the subject Industry of promoters/ directors.
  - Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
  - **Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**
  - Technical specifications of the proposed equipment in the below format (kindly mention the use as well)
- | S. No. | Equipment | Qty. | Use | Specification |
|--------|-----------|------|-----|---------------|
| •      |           |      |     |               |

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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**Corporate Office:**

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Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: www.rkassociates.org

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies.

Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service , the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.



The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected to conduct around 104 studies (52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospects of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	Head Clinical	1	25,00,000.00
2	Principal Investigators	2	30,00,000.00
3	Research Associates for clinical department	4	16,00,000.00
4	Phlebotomists	5	12,50,000.00
5	Pharmacists	2	5,00,000.00
6	Trainee	4	8,00,000.00
7	Custodian and Recruiter	2	15,00,000.00
8	Head Bioanalytical	1	15,00,000.00
9	Team Leader	3	36,00,000.00
10	Research Associate	4	20,00,000.00
11	Trainee	4	10,00,000.00
12	Custodian	1	7,50,000.00
13	Clinical QA Associate	2	10,00,000.00
14	Bioanalytical QA	1	10,00,000.00
15	Bioanalytical QA Associate	2	10,00,000.00
16	Statistician	1	6,00,000.00
17	Report Writing team leader	1	7,50,000.00
18	Report Writing Research Associate	2	12,00,000.00
19	HR Manager	1	7,50,000.00
20	Head Quality Assurance	1	15,00,000.00
21	Clinical QA	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from December,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European

medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

#### **g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

#### **h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

#### **i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98

crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R  714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and

development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

12. **Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval

timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<b>- Sr. No.</b>	<b>- Content</b>	<b>Actual Study Subject Cost (INR)</b>	<b>Vendor Industry Cost (INR)</b>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>	<b>Total Clinical Study cost for 30 subjects</b>	<b>5,40,000</b>	<b>7,65,000</b>
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000  <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000  <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000  <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000  <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000  <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000  <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000  <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000  <b>Sub-total = Rs. 9,82,50,000</b>

10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

**15. Loan disbursement schedule month wise.** The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

**16. GST certificate of the company** is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.

3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards  
  
For Skylimit research Private Limited  
  
Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards  
  
For Skylimit research Private Limited  
  
Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards  
  
For Skylimit research Private Limited  
  
Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards  
  
For Skylimit research Private Limited  
  
Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards  
  
For Skylimit research Private Limited  
  
Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards  
  
For Skylimit research Private Limited  
  
Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,



Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
  - A. **Land:**
    - a) Total Area of the land used for the project.
    - b) Layout Plan.
    - c) Sale/Lease Deed.
    - d) Current status/utilization of the land.
    - e) Address of the Unit
    - f) Google coordinates of the location.
    - g) Attach sale deed.
  - B. **Building and Civil works:**
    - a) Total Area proposed for the Building.
    - b) Layout/ Site plan.
    - c) Site Map Approval/Sanctioned.
    - d) Details of the contractor's engaged.
    - e) Attach agreement with contractor.
  - C. **Proposed Equipment:**
    - a) List of proposed equipment as per below heads:
      - Serial Number, if any
      - Equipment name
      - Manufacturer name
      - Specification/capacity
      - Expected Landed Price
      - Current status of the order
    - b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
    - c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.

17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

m c bhatt pnb <mcbhatt13@gmail.com>

Fri, May 3, 2024 at 3:54 PM

To: Aneesh Mallick <aneesh.mallick@rkassociates.org>

Cc: "Shahid ." <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>, "skylimitresearch@gmail.com" <[skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)>, roshni@skylimitresearch.com, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, "R.K Associates, The Valuers | LIE | TEV | ASM" <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, [clpc6277@pnb.co.in](mailto:clpc6277@pnb.co.in), "Business Operations R.K Associates" <[bo@rkassociates.org](mailto:bo@rkassociates.org)>, FA Team <[fateam@rkassociates.org](mailto:fateam@rkassociates.org)>, [bratati@skylimitresearch.com](mailto:bratati@skylimitresearch.com)

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity will be minimum per month - 12,000 which will be enhanced to 25000 samples per month or more as per the requirement.
- Total average Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:40 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000

- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

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Thanks &amp; Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Assets



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Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: www.rkassociates.org

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**

**and**

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period, is over after 7 to 25 days (depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

**Response**

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

**Response**

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000

<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5:** As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.

#### Response

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 :** We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.

#### Response

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA ,FDA for USA, EMEA for EU market, MHRA for UK , TGI for Australia and NPRA for Malaysia, and other ROW s, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 :** Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.

#### Response

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8** External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.

#### Response

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :**In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.

**Response**

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.****Response**

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :Kindly list down expenses which are linked to revenue and which are not linked with revenue.****Response**

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

**Query 12 :Proposed Shareholding Pattern.****Response**

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.****Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).****Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
- GST registration: Attached
- Pollution certificate: Applied and will be obtained in due course.
- Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
- Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.

Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.

- EPFO registration: Will be obtained in due course
- ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).****Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies

such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format**

**Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets

9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors
10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample dispensing, Bulk Spiking	1- channel, incl. Combitips advance rack, Combitips advance assortment pack  Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range  Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:**

**Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- **EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.**
- **Bioanalytical Method Validation Guidance for Industry FDA- May 2018.**
- **Electronic Data – 21 CFR 11**
- **Good Laboratory Practice -21 CFR 58, ISO 17025-2017**
- **ISO 9001:2015, Quality Management Systems**

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.



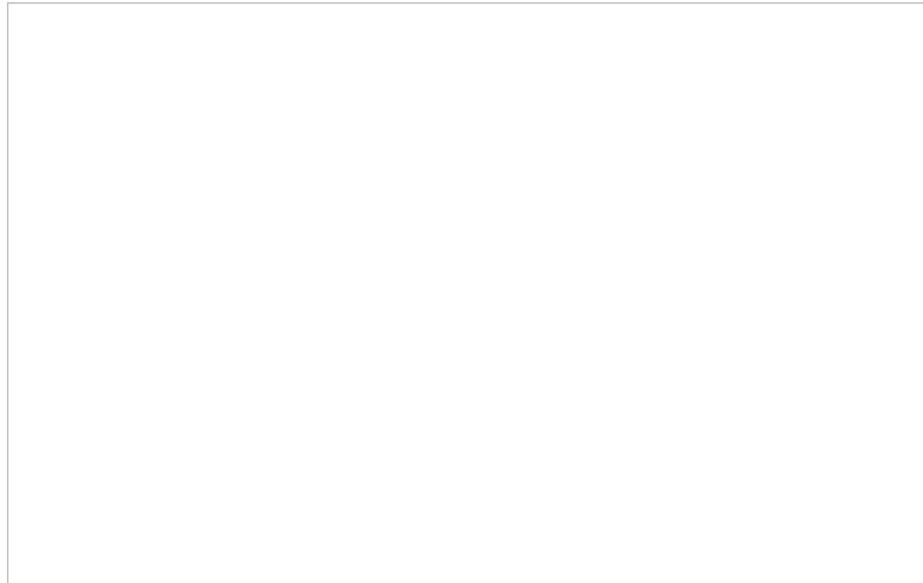
**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

**Process are described schematically as under for analysis:**



**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).**

**Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August'2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.
- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).

- Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well)

S. No.	Equipment	Qty.	Use	Specification
--------	-----------	------	-----	---------------

- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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Mobile No.- +91 9958632707

Voice: +91-120 411 0117; 4324647

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D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards

For Skylimit Research Pvt Ltd

## Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
 (A Clinical Research Organization)  
 VILLA-2/9, LAND 2, JAYPEE GREENS,  
 GREATER NOIDA, UP-201306  
 Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
 Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
 Corporate Office : D-39, Second Floor, Sector-2,  
 Noida, Uttar Pradesh-201301  
 Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies.

Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service, the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 18,75,00,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>

10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	Rs. 32,50,000	Rs. 32,50,000
11.Overall Cost	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	10,00,00,000	15,06,25,000

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	Head Clinical	1	25,00,000.00
2	Principal Investigators	2	30,00,000.00
3	Research Associates for clinical department	4	16,00,000.00
4	Phlebotomists	5	12,50,000.00
5	Pharmacists	2	5,00,000.00
6	Trainee	4	8,00,000.00
7	Custodian and Recruiter	2	15,00,000.00
8	Head Bioanalytical	1	15,00,000.00
9	Team Leader	3	36,00,000.00
10	Research Associate	4	20,00,000.00
11	Trainee	4	10,00,000.00
12	Custodian	1	7,50,000.00
13	Clinical QA Associate	2	10,00,000.00
14	Bioanalytical QA	1	10,00,000.00
15	Bioanalytical QA Associate	2	10,00,000.00
16	Statistician	1	6,00,000.00
17	Report Writing team leader	1	7,50,000.00
18	Report Writing Research Associate	2	12,00,000.00

19	<b>HR Manager</b>	1	7,50,000.00
20	<b>Head Quality Assurance</b>	1	15,00,000.00
21	<b>Clinical QA</b>	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

**h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

**i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R  714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are



mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study. India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall

partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

**12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<b>Sr. No.</b>	<b>Content</b>	<b>Actual Study Subject Cost (INR)</b>	<b>Vendor Industry Cost (INR)</b>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>		5,40,000	7,65,000
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000

8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	$5,40,000 \times 25 = \text{Rs. } 1,35,00,000$ <b>Plus</b> $7,50,000 \times 25 = \text{Rs. } 1,87,50,000$ <b>Sub-total = Rs. 3,22,50,000</b>	$7,65,000 \times 25 = \text{Rs. } 1,91,25,000$ <b>Plus</b> $12,00,000 \times 25 = \text{Rs. } 3,00,00,000$ <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	$5,40,000 \times 2 \times 25 = \text{Rs. } 2,70,00,000$ <b>Plus</b> $7,50,000 \times 2 \times 25 = \text{Rs. } 3,75,00,000$ <b>Sub-total = Rs. 6,45,00,000</b>	$7,65,000 \times 2 \times 25 = \text{Rs. } 3,82,50,000$ <b>Plus</b> $12,00,000 \times 2 \times 25 = \text{Rs. } 6,00,00,000$ <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

15. Loan disbursement schedule month wise. The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

16. GST certificate of the company is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

### Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**  
D-39, 2nd Floor, Sector- 2, Noida  
Uttar Pradesh- 201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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We assure our best services and response to you all the time.

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <shahid@rkassociates.org> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
  - A. Land:**
    - a) Total Area of the land used for the project.
    - b) Layout Plan.
    - c) Sale/Lease Deed.
    - d) Current status/utilization of the land.
    - e) Address of the Unit
    - f) Google coordinates of the location.
    - g) Attach sale deed.
  - B. Building and Civil works:**
    - a) Total Area proposed for the Building.
    - b) Layout/ Site plan.
    - c) Site Map Approval/Sanctioned.
    - d) Details of the contractor's engaged.
    - e) Attach agreement with contractor.
  - C. Proposed Equipment:**

- a) List of proposed equipment as per below heads:
- Serial Number, if any
  - Equipment name
  - Manufacturer name
  - Specification/capacity
  - Expected Landed Price
  - Current status of the order
- b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
- c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.

12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
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Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

m c bhatt pnb <mcbhatt13@gmail.com>

Fri, May 3, 2024 at 4:00 PM

To: Aneesh Mallick <aneesh.mallick@rkassociates.org>

Cc: "Shahid ." <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>, "skylimitresearch@gmail.com" <[skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)>, roshni@skylimitresearch.com, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, "R.K Associates, The Valuers | LIE | TEV | ASM" <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, [clpc6277@pnb.co.in](mailto:clpc6277@pnb.co.in), "Business Operations R.K Associates" <[bo@rkassociates.org](mailto:bo@rkassociates.org)>, FA Team <[fateam@rkassociates.org](mailto:fateam@rkassociates.org)>, [bratati@skylimitresearch.com](mailto:bratati@skylimitresearch.com)

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity is per month - 25,000.
- Total average Samples per subject - 60
- No of beds - 100 (170 from FY26)
- BA/BE studies capacity - 100 (170 from FY26)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:54 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity will be minimum per month - 12,000 which will be enhanced to 25000 samples per month or more as per the requirement.
- Total average Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:40 PM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:

Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000
- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



*World's first fully digital Automated Platform for  
Integrating Valuation Life Cycle -  
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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318



Voice: +91-120 411 0117; 4324647

**Corporate Office:**  
D-39, 2nd Floor, Sector- 2, Noida  
Uttar Pradesh- 201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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We assure our best services and response to you all the time.

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**  
**and**

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria , the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Phamakinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period ,is over after 7 to 25 days(depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

#### Response

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

#### Response

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
	Approximate cost for 50 studies (25 Pilot		

<b>11.Overall Cost</b>	and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>
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**Query 5: As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.**

**Response**

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 : We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.**

**Response**

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA, FDA for USA, EMEA for EU market, MHRA for UK, TGI for Australia and NPRA for Malaysia, and other ROWs, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 : Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises is 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.**

**Response**

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8 External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.**

**Response**

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.**

**Response**

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.**

**Response**

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :Kindly list down expenses which are linked to revenue and which are not linked with revenue.**

**Response**

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

**Query 12 :Proposed Shareholding Pattern.**

**Response**

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.**

**Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).**

**Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
- GST registration: Attached
- Pollution certificate: Applied and will be obtained in due course.
- Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
- Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.  
Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.
- EPFO registration: Will be obtained in due course
- ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**

**Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format**

**Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus

				CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated-Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated-Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors
10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample dispensing, Bulk Spiking	1- channel, incl. Combipips advance rack, Combipips advance assortment pack Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included

17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:****Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- *EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.*
- *Bioanalytical Method Validation Guidance for Industry FDA- May 2018.*
- *Electronic Data – 21 CFR 11*
- *Good Laboratory Practice -21 CFR 58, ISO 17025-2017*
- *ISO 9001:2015, Quality Management Systems*

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

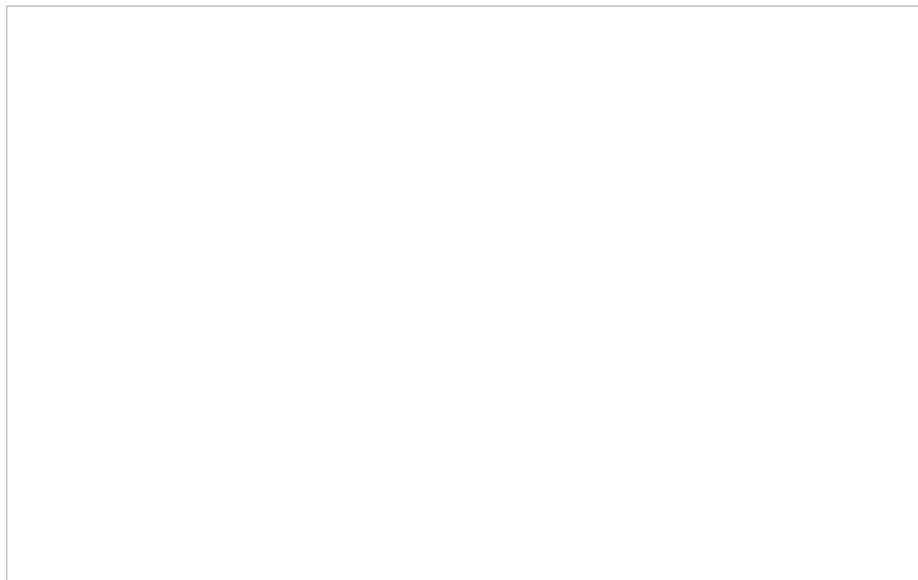
**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

**Process are described schematically as under for analysis:**

**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).****Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August'2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:  
Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.
- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
- **Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well

S. No.	Equipment	Qty.	Use	Specification
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- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)

**R.K. Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647



**Corporate Office:**  
D-39, 2nd Floor, Sector- 2, Noida  
Uttar Pradesh- 201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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We assure our best services and response to you all the time.

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



*World's first fully digital Automated Platform for  
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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9958632707

Voice: +91-120 411 0117; 4324647

**Corporate Office:**  
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Uttar Pradesh- 201301



Website: [www.rkassociates.org](http://www.rkassociates.org)

We assure our best services and response to you all the time.

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards  
  
For Skylimit Research Pvt Ltd  
  
Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
**(A Clinical Research Organization)**  
**VILLA-2/9, LAND 2, JAYPEE GREENS,**  
**GREATER NOIDA, UP-201306**  
**Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)**  
**Mobile: 9719193909**

Dt. 20.04.2024

To,  
  
M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,  
  
**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected

Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service, the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis. The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000

7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	<b>Head Clinical</b>	1	25,00,000.00
2	<b>Principal Investigators</b>	2	30,00,000.00

3	Research Associates for clinical department	4	16,00,000.00
4	Phlebotomists	5	12,50,000.00
5	Pharmacists	2	5,00,000.00
6	Trainee	4	8,00,000.00
7	Custodian and Recruiter	2	15,00,000.00
8	Head Bioanalytical	1	15,00,000.00
9	Team Leader	3	36,00,000.00
10	Research Associate	4	20,00,000.00
11	Trainee	4	10,00,000.00
12	Custodian	1	7,50,000.00
13	Clinical QA Associate	2	10,00,000.00
14	Bioanalytical QA	1	10,00,000.00
15	Bioanalytical QA Associate	2	10,00,000.00
16	Statistician	1	6,00,000.00
17	Report Writing team leader	1	7,50,000.00
18	Report Writing Research Associate	2	12,00,000.00
19	HR Manager	1	7,50,000.00
20	Head Quality Assurance	1	15,00,000.00
21	Clinical QA	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after

expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

#### **h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

#### **i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

#### **3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years

Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R 714667948713	Post Graduate	03 ears
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**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar

Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services. However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

**10. Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the Noida and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

**11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

**12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor

industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<u>Sr. No.</u>	<u>Content</u>	<u>Actual Study Subject Cost (INR)</u>	<u>Vendor Industry Cost (INR)</u>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>		5,40,000	7,65,000
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000  <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000  <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000  <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000  <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000  <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000  <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000  <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000  <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>		<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>



Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

**15. Loan disbursement schedule month wise.** The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

**16. GST certificate of the company** is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions & Projections** (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.

14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

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For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:  
Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of “**M/s Skylimit Research Private Limited**”, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
  - A. Land:**
    - a) Total Area of the land used for the project.
    - b) Layout Plan.
    - c) Sale/Lease Deed.
    - d) Current status/utilization of the land.
    - e) Address of the Unit
    - f) Google coordinates of the location.
    - g) Attach sale deed.
  - B. Building and Civil works:**
    - a) Total Area proposed for the Building.
    - b) Layout/ Site plan.
    - c) Site Map Approval/Sanctioned.
    - d) Details of the contractor's engaged.
    - e) Attach agreement with contractor.
  - C. Proposed Equipment:**
    - a) List of proposed equipment as per below heads:
      - Serial Number, if any
      - Equipment name
      - Manufacturer name
      - Specification/capacity
      - Expected Landed Price
      - Current status of the order
    - b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
    - c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:  
Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
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Website: [www.rkassociates.org](http://www.rkassociates.org)

Aneesh Mallick <aneesh.mallick@rkassociates.org>  
To: Gaurav Kumar <gaurav.kumar@rkassociates.org>

Fri, May 3, 2024 at 4:23 PM

Hi Gaurav

PFA revised model after considering bed capacity as 170, sample processing capacity as 25000 and rectifying an error in civil work cost (client has considered GST separately though quotation is including GST).

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Fri, May 3, 2024 at 4:00 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity is per month - 25,000.
- Total average Samples per subject - 60
- No of beds - 100 (170 from FY26)
- BA/BE studies capacity - 100 (170 from FY26)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:54 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity will be minimum per month - 12,000 which will be enhanced to 25000 samples per month or more as per the requirement.
- Total average Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:40 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000
- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**



With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of "M/s Skylimit Research Private Limited", we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**

and

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period is over after 7 to 25 days (depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

**Response**

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

**Response**

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000



8	Approximate cost for 50 Pilot studies (covering average number of 15 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5: As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.**

**Response**

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 : We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.**

**Response**

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA ,FDA for USA, EMEA for EU market, MHRA for UK , TGI for Australia and NPRA for Malaysia, and other ROW s, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 : Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.**

**Response**

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8 External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.**

**Response**

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.**

**Response**

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.**

**Response**

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :Kindly list down expenses which are linked to revenue and which are not linked with revenue.**

**Response**

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

**Query 12 :Proposed Shareholding Pattern.****Response**

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.****Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).****Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
- GST registration: Attached
- Pollution certificate: Applied and will be obtained in due course.
- Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
- Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.  
Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.
- EPFO registration: Will be obtained in due course
- ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).****Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format****Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
-------	--------------------------	----------	----------------	---------------

1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors
10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul

11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample dispensing, Bulk Spiking	1- channel, incl. Combitips advance rack, Combitips advance assortment pack Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:**

**Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- **EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.**
- **Bioanalytical Method Validation Guidance for Industry FDA- May 2018.**
- **Electronic Data – 21 CFR 11**
- **Good Laboratory Practice -21 CFR 58, ISO 17025-2017**
- **ISO 9001:2015, Quality Management Systems**

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

**Process are described schematically as under for analysis:**



**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).**

**Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August'2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:  
Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.
- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
- **Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well)

S. No.	Equipment	Qty.	Use	Specification
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- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

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Mobile No.- +91 9958632707

Voice: +91-120 411 0117; 4324647

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Uttar Pradesh- 201301

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/s ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: www.rkassociates.org

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service , the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.



The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies (52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	Head Clinical	1	25,00,000.00
2	Principal Investigators	2	30,00,000.00
3	Research Associates for clinical department	4	16,00,000.00
4	Phlebotomists	5	12,50,000.00
5	Pharmacists	2	5,00,000.00
6	Trainee	4	8,00,000.00
7	Custodian and Recruiter	2	15,00,000.00
8	Head Bioanalytical	1	15,00,000.00
9	Team Leader	3	36,00,000.00
10	Research Associate	4	20,00,000.00
11	Trainee	4	10,00,000.00
12	Custodian	1	7,50,000.00
13	Clinical QA Associate	2	10,00,000.00
14	Bioanalytical QA	1	10,00,000.00
15	Bioanalytical QA Associate	2	10,00,000.00
16	Statistician	1	6,00,000.00
17	Report Writing team leader	1	7,50,000.00
18	Report Writing Research Associate	2	12,00,000.00
19	HR Manager	1	7,50,000.00
20	Head Quality Assurance	1	15,00,000.00
21	Clinical QA	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control

Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

#### **g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

#### **h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

#### **i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

2. **Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat, Director	02/01/2000	08163436	GXWPS7371P 806698463827	Graduate	04 years
Yash Pratap Singh, Director	11/08/2001	10075889	MSCPS9247R 226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R 714667948713	Post Graduate	03 ears

4. **List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

5. **List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

6. **List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally,

clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.**

No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

**12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<u>Sr. No.</u>	<u>Content</u>	<u>Actual Study Subject Cost (INR)</u>	<u>Vendor Industry Cost (INR)</u>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>		5,40,000	7,65,000
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000

		<b>Sub-total = Rs. 3,22,50,000</b>	<b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	$5,40,000 \times 2 \times 25 = \text{Rs. } 2,70,00,000$ <b>Plus</b> $7,50,000 \times 2 \times 25 = \text{Rs. } 3,75,00,000$ <b>Sub-total = Rs. 6,45,00,000</b>	$7,65,000 \times 2 \times 25 = \text{Rs. } 3,82,50,000$ <b>Plus</b> $12,00,000 \times 2 \times 25 = \text{Rs. } 6,00,00,000$ <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

15. Loan disbursement schedule month wise. The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

16. GST certificate of the company is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

## Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**  
D-39, 2nd Floor, Sector- 2, Noida



Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

We assure our best services and response to you all the time.

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <shahid@rkassociates.org> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:

**A. Land:**

- a) Total Area of the land used for the project.
- b) Layout Plan.
- c) Sale/Lease Deed.
- d) Current status/utilization of the land.
- e) Address of the Unit
- f) Google coordinates of the location.
- g) Attach sale deed.

**B. Building and Civil works:**

- a) Total Area proposed for the Building.
- b) Layout/ Site plan.
- c) Site Map Approval/Sanctioned.
- d) Details of the contractor's engaged.
- e) Attach agreement with contractor.

**C. Proposed Equipment:**

- a) List of proposed equipment as per below heads:
  - Serial Number, if any
  - Equipment name
  - Manufacturer name

- Specification/capacity
  - Expected Landed Price
  - Current status of the order
- b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
- c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.

12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).

13. Pricing Strategy of the company along with selling & marketing plan.

14. Updated agreements for the proposed unit, if any.

15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).

16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.

17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

 Financial Model - SRPL\_v3.xlsx  
153K

Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

Mon, May 6, 2024 at 11:32 AM

To: m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)>

Cc: "Shahid ." <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>, "skylimitresearch@gmail.com" <[skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)>, roshni@skylimitresearch.com, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, "R.K Associates, The Valuers | LIE | TEV | ASM" <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, [clpc6277@pnb.co.in](mailto:clpc6277@pnb.co.in), "Business Operations R.K Associates" <[bo@rkassociates.org](mailto:bo@rkassociates.org)>, FA Team <[fateam@rkassociates.org](mailto:fateam@rkassociates.org)>, [bratati@skylimitresearch.com](mailto:bratati@skylimitresearch.com)

Sir

With reference to our meeting, please provide below details for report compilation -

- Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor.
- Project implementation schedule - dates/status (refer annexure 1)
- Regulatory approvals - dates/status and copy of application required (refer annexure 2)
- Quotations for P&M for s.no. 10,11,12,14,16,17,18,19,20,21,22,23 (refer annexure 3)

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Fri, May 3, 2024 at 4:00 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity is per month - 25,000.
- Total average Samples per subject - 60
- No of beds - 100 (170 from FY26)

- BA/BE studies capacity - 100 (170 from FY26)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:54 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity will be minimum per month - 12,000 which will be enhanced to 25000 samples per month or more as per the requirement.
- Total average Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:40 PM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:

Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000
- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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We assure our best services and response to you all the time.

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**

and

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period is over after 7 to 25 days (depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

**Response**

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

**Response**

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>



**Query 5: As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.**

**Response**

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 : We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.**

**Response**

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA ,FDA for USA, EMEA for EU market, MHRA for UK , TGI for Australia and NPRA for Malaysia, and other ROW s, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 : Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.**

**Response**

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8 External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.**

**Response**

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.**

**Response**

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.**

**Response**

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :Kindly list down expenses which are linked to revenue and which are not linked with revenue.**

**Response**

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

**Query 12 :Proposed Shareholding Pattern.**

**Response**

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.**

**Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical



Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).**

**Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- a. PAN Card: Attached
- b. GST registration: Attached
- c. Pollution certificate: Applied and will be obtained in due course.
- d. Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
- e. Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.  
Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.
- f. EPFO registration: Will be obtained in due course
- g. ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**

**Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format**

**Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers

6	SCIEX Triple Quad 5500+ System QTRAP Activated-Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated-Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors
10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample dispensing, Bulk Spiking	1- channel, incl. Combishops advance rack, Combishops advance assortment pack  Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range  Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS

18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent LCMSMS 6475		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:**

**Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- *EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.*
- *Bioanalytical Method Validation Guidance for Industry FDA- May 2018.*
- *Electronic Data – 21 CFR 11*
- *Good Laboratory Practice -21 CFR 58, ISO 17025-2017*
- *ISO 9001:2015, Quality Management Systems*

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

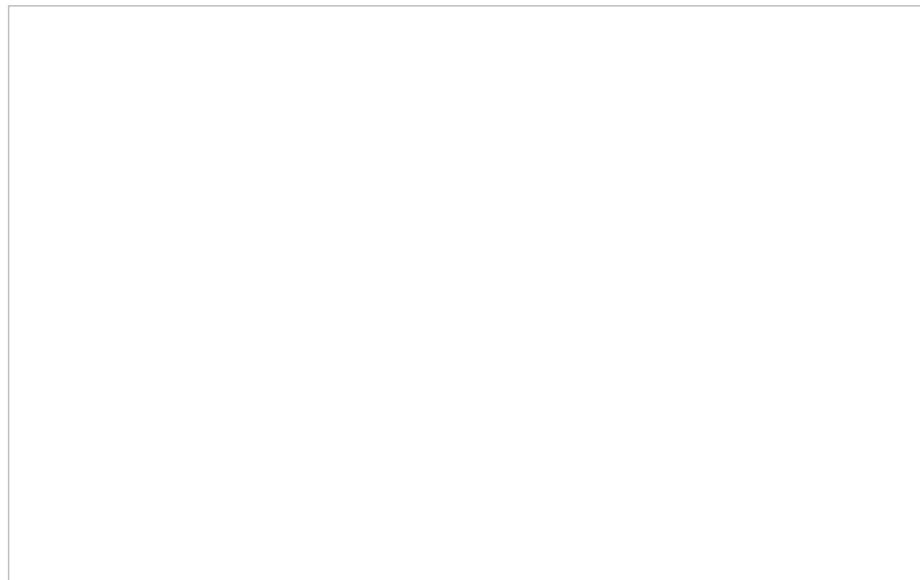
**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

**Process are described schematically as under for analysis:**



**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).**

**Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August'2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:  
Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
  - With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
  - Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
  - As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
  - As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
  - We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
  - Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
  - External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
  - In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
  - Financial Model of the Project in excel with proper assumptions & Projections and rationale.
  - Kindly list down expenses which are linked to revenue and which are not linked with revenue.
  - Proposed Shareholding Pattern.
  - Experience in the subject Industry of promoters/ directors.
  - Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
  - Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
  - Technical specifications of the proposed equipment in the below format (kindly mention the use as well)
- | S. No. | Equipment | Qty. | Use | Specification |
|--------|-----------|------|-----|---------------|
| •      |           |      |     |               |
- BA/BE study testing standards/parameters as per regulatory requirements.
  - Please mention the methods we will be using to establish BE.
  - Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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Uttar Pradesh- 201301

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We assure our best services and response to you all the time.

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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Uttar Pradesh- 201301

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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards  
  
For Skylimit Research Pvt Ltd  
  
Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 20.04.2024

To,  
  
M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,  
  
**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00

PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service, the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis. The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000

8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies (52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	<b>Head Clinical</b>	1	25,00,000.00
2	<b>Principal Investigators</b>	2	30,00,000.00
3	<b>Research Associates for clinical department</b>	4	16,00,000.00



4	Phlebotomists	5	12,50,000.00
5	Pharmacists	2	5,00,000.00
6	Trainee	4	8,00,000.00
7	Custodian and Recruiter	2	15,00,000.00
8	Head Bioanalytical	1	15,00,000.00
9	Team Leader	3	36,00,000.00
10	Research Associate	4	20,00,000.00
11	Trainee	4	10,00,000.00
12	Custodian	1	7,50,000.00
13	Clinical QA Associate	2	10,00,000.00
14	Bioanalytical QA	1	10,00,000.00
15	Bioanalytical QA Associate	2	10,00,000.00
16	Statistician	1	6,00,000.00
17	Report Writing team leader	1	7,50,000.00
18	Report Writing Research Associate	2	12,00,000.00
19	HR Manager	1	7,50,000.00
20	Head Quality Assurance	1	15,00,000.00
21	Clinical QA	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to

pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

#### **h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

#### **i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

#### **3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat, Director	02/01/2000	08163436	GXWPS7371P 806698463827	Graduate	04 years
Yash Pratap Singh, Director	11/08/2001	10075889	MSCPS9247R 226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R 714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.**

No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

12. **Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** -

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

13. **Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<u>Sr. No.</u>	<u>Content</u>	<u>Actual Study Subject Cost (INR)</u>	<u>Vendor Industry Cost (INR)</u>
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	Total Clinical Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected

to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

**15. Loan disbursement schedule month wise.** The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

**16. GST certificate of the company** is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.



2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
  - A. Land:**
    - a) Total Area of the land used for the project.
    - b) Layout Plan.
    - c) Sale/Lease Deed.
    - d) Current status/utilization of the land.
    - e) Address of the Unit
    - f) Google coordinates of the location.
    - g) Attach sale deed.
  - B. Building and Civil works:**
    - a) Total Area proposed for the Building.
    - b) Layout/ Site plan.
    - c) Site Map Approval/Sanctioned.
    - d) Details of the contractor's engaged.
    - e) Attach agreement with contractor.
  - C. Proposed Equipment:**
    - a) List of proposed equipment as per below heads:
      - Serial Number, if any
      - Equipment name
      - Manufacturer name
      - Specification/capacity
      - Expected Landed Price
      - Current status of the order
    - b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
    - c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

--

Thanks & Regards,  
Mohd Shahid,  
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Website: [www.rkassociates.org](http://www.rkassociates.org)

 **Annexures.xlsx**  
25K

m c bhatt pnb <mcbhatt13@gmail.com>

Mon, May 6, 2024 at 2:35 PM

To: Aneesh Mallick <aneesh.mallick@rkassociates.org>

Cc: "Shahid ." <shahid@rkassociates.org>, "skylimitresearch@gmail.com" <skylimitresearch@gmail.com>, roshni@skylimitresearch.com, Gaurav Kumar <gaurav.kumar@rkassociates.org>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <mohit.agarwal@rkassociates.org>, "R.K Associates, The Valuers | LIE | TEV | ASM" <valuers@rkassociates.org>, clpc6277@pnb.co.in, "Business Operations R.K Associates" <bo@rkassociates.org>, FA Team <fateam@rkassociates.org>, bratati@skylimitresearch.com

Dear Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor is attached herewith.
2. Project implementation schedule has been discussed in the meeting and it will be as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copies of applications are being provided.
4. Quotations for P&M for s.no. 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for s.no. 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 11:32 AM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:

Sir

With reference to our meeting, please provide below details for report compilation -

- Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor.
- Project implementation schedule - dates/status (refer annexure 1)
- Regulatory approvals - dates/status and copy of application required (refer annexure 2)
- Quotations for P&M for s.no. 10,11,12,14,16,17,18,19,20,21,22,23 (refer annexure 3)

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets





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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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On Fri, May 3, 2024 at 4:00 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity is per month - 25,000.
- Total average Samples per subject - 60
- No of beds - 100 (170 from FY26)
- BA/BE studies capacity - 100 (170 from FY26)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:54 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity will be minimum per month - 12,000 which will be enhanced to 25000 samples per month or more as per the requirement.
- Total average Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:40 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000
- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**

and

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period, is over after 7 to 25 days (depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

**Response**

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

**Response**

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Subject Cost (INR)	Study Cost	Vendor Cost	Industry /Revenues
---------	---------	------------------------------	---------------	----------------	-----------------------

			<b>expected (INR)</b>
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5: As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.**

#### **Response**

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 : We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.**

#### **Response**

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA, FDA for USA, EMEA for EU market, MHRA for UK, TGI for Australia and NPRA for Malaysia, and other ROWs, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 : Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises is 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.**

#### **Response**

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8 External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.**

**Response**

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.**

**Response**

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.**

**Response**

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :Kindly list down expenses which are linked to revenue and which are not linked with revenue.**

**Response**

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

**Query 12 :Proposed Shareholding Pattern.**

**Response**

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.**

**Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).**

**Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
- GST registration: Attached
- Pollution certificate: Applied and will be obtained in due course.
- Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
- Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.  
Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.
- EPFO registration: Will be obtained in due course



g. ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**

**Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format**

**Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)



8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors
10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample dispensing, Bulk Spiking	1- channel, incl. Combitips advance rack, Combitips advance assortment pack  Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range  Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:**

**Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- **EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.**
- **Bioanalytical Method Validation Guidance for Industry FDA- May 2018.**
- **Electronic Data – 21 CFR 11**
- **Good Laboratory Practice -21 CFR 58, ISO 17025-2017**
- **ISO 9001:2015, Quality Management Systems**

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

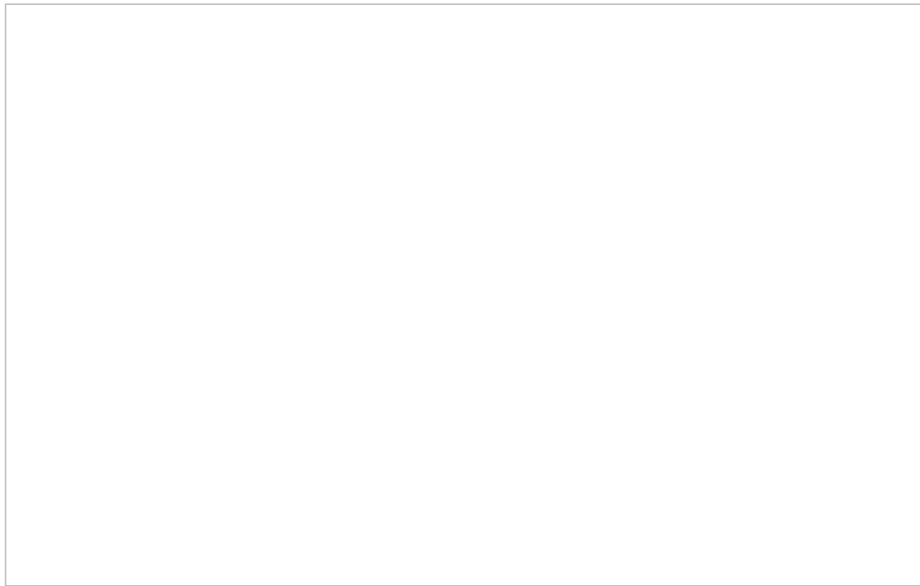
**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

Process are described schematically as under for analysis:

**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).****Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August'2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.

- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.
- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
- Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well

S. No.	Equipment	Qty.	Use	Specification
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- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9958632707

Voice: +91-120 411 0117; 4324647

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D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71

Average DSCR	2.20
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**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service, the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>

10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	Rs. 32,50,000	Rs. 32,50,000
11.Overall Cost	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	10,00,00,000	15,06,25,000

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	Head Clinical	1	25,00,000.00
2	Principal Investigators	2	30,00,000.00
3	Research Associates for clinical department	4	16,00,000.00
4	Phlebotomists	5	12,50,000.00
5	Pharmacists	2	5,00,000.00
6	Trainee	4	8,00,000.00
7	Custodian and Recruiter	2	15,00,000.00
8	Head Bioanalytical	1	15,00,000.00
9	Team Leader	3	36,00,000.00
10	Research Associate	4	20,00,000.00
11	Trainee	4	10,00,000.00
12	Custodian	1	7,50,000.00
13	Clinical QA Associate	2	10,00,000.00
14	Bioanalytical QA	1	10,00,000.00
15	Bioanalytical QA Associate	2	10,00,000.00
16	Statistician	1	6,00,000.00

17	<b>Report Writing team leader</b>	1	7,50,000.00
18	<b>Report Writing Research Associate</b>	2	12,00,000.00
19	<b>HR Manager</b>	1	7,50,000.00
20	<b>Head Quality Assurance</b>	1	15,00,000.00
21	<b>Clinical QA</b>	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

**h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

**i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company



enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

### 3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R  714667948713	Post Graduate	03 ears

### 4. List of the Raw material required with ratio, grade and specifications and cost:

The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables,

chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any): NA**

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

**7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.** The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

**8. Site layout Plan** is attached.

**9. Google coordinates of the location** are attached.

**10. Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase

II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

**11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.**

No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

**12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) -**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<u>Sr. No.</u>	<u>Content</u>	<u>Actual Study Subject Cost (INR)</u>	<u>Vendor Industry Cost (INR)</u>
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500

4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	Total Clinical Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000  <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000  <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000  <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000  <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000  <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000  <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000  <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000  <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

14. **Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

15. Loan disbursement schedule month wise. The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

16. GST certificate of the company is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

#### Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**  
D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <shahid@rkassociates.org> wrote:  
Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.

4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
  - A. Land:**
    - a) Total Area of the land used for the project.
    - b) Layout Plan.
    - c) Sale/Lease Deed.
    - d) Current status/utilization of the land.
    - e) Address of the Unit
    - f) Google coordinates of the location.
    - g) Attach sale deed.
  - B. Building and Civil works:**
    - a) Total Area proposed for the Building.
    - b) Layout/ Site plan.
    - c) Site Map Approval/Sanctioned.
    - d) Details of the contractor's engaged.
    - e) Attach agreement with contractor.
  - C. Proposed Equipment:**
    - a) List of proposed equipment as per below heads:
      - Serial Number, if any
      - Equipment name
      - Manufacturer name
      - Specification/capacity
      - Expected Landed Price
      - Current status of the order
    - b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
    - c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:  
Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,



Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

 **SRPL-Quotation Agilent -06.02.2024.pdf**  
975K

m c bhatt pnb <mcbhatt13@gmail.com>

Tue, May 7, 2024 at 1:32 PM

To: Aneesh Mallick <aneesh.mallick@rkassociates.org>

Cc: "Shahid ." <shahid@rkassociates.org>, "skylimitresearch@gmail.com" <skylimitresearch@gmail.com>, roshni@skylimitresearch.com, Gaurav Kumar <gaurav.kumar@rkassociates.org>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <mohit.agarwal@rkassociates.org>, "R.K Associates, The Valuers | LIE | TEV | ASM" <valuers@rkassociates.org>, clpc6277@pnb.co.in, "Business Operations R.K Associates" <bo@rkassociates.org>, FA Team <fateam@rkassociates.org>, bratati@skylimitresearch.com

Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative are as highlighted in map and area in each floor already submitted.
2. Project implementation schedule was discussed in the meeting and it is again submitted as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copy of NOC of Fire department is also attached.
4. Quotations for P&M for s.no. 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for s.no. 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report. Further, quotations for S.No.10,11,12 are from same supplier and all these are again attached.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 2:35 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor is attached herewith.
2. Project implementation schedule has been discussed in the meeting and it will be as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copies of applications are being provided.
4. Quotations for P&M for s.no. 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for s.no. 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 11:32 AM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:

Sir

With reference to our meeting, please provide below details for report compilation -

- Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor.
- Project implementation schedule - dates/status (refer annexure 1)
- Regulatory approvals - dates/status and copy of application required (refer annexure 2)
- Quotations for P&M for s.no. 10,11,12,14,16,17,18,19,20,21,22,23 (refer annexure 3)

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Assets



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Integrating Valuation Life Cycle -  
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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Fri, May 3, 2024 at 4:00 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity is per month - 25,000.
- Total average Samples per subject - 60
- No of beds - 100 (170 from FY26)
- BA/BE studies capacity - 100 (170 from FY26)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:54 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity will be minimum per month - 12,000 which will be enhanced to 25000 samples per month or more as per the requirement.
- Total average Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:40 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000
- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

--

Thanks & Warm Regards,

Aneesh Mallick

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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**

**and**

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period, is over after 7 to 25 days (depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

**Response**

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

**Response**

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are

Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5:** As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.

**Response**

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 :** We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.

**Response**

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA ,FDA for USA, EMEA for EU market, MHRA for UK , TGI for Australia and NPRA for Malaysia, and other ROW s, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 : Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.**

**Response**

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8 External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.**

**Response**

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.**

**Response**

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.**

**Response**

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :Kindly list down expenses which are linked to revenue and which are not linked with revenue.**

**Response**

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

**Query 12 :Proposed Shareholding Pattern.**

**Response**

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.**

**Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).**

**Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
- GST registration: Attached



- c. Pollution certificate: Applied and will be obtained in due course.
- d. Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
- e. Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.  
Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.
- f. EPFO registration: Will be obtained in due course
- g. ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**

**Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format**

**Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus

				TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors
10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample dispensing, Bulk Spiking	1- channel, incl. Combitips advance rack, Combitips advance assortment pack  Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer , standard weighing	Ultra micro balance :For 1mg to 1gm weighing range  Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included



**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:****Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- *EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.*
- *Bioanalytical Method Validation Guidance for Industry FDA- May 2018.*
- *Electronic Data – 21 CFR 11*
- *Good Laboratory Practice -21 CFR 58, ISO 17025-2017*
- *ISO 9001:2015, Quality Management Systems*

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

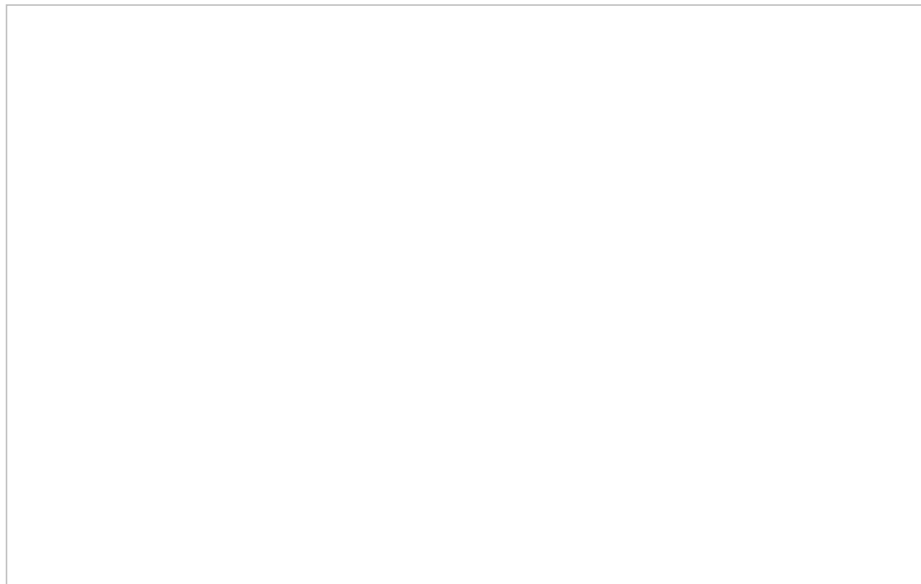
**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

**Process are described schematically as under for analysis:**

**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).****Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August'2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
  - With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
  - Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
  - As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
  - As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
  - We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
  - Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
  - External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
  - In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
  - Financial Model of the Project in excel with proper assumptions & Projections and rationale.
  - Kindly list down expenses which are linked to revenue and which are not linked with revenue.
  - Proposed Shareholding Pattern.
  - Experience in the subject Industry of promoters/ directors.
  - Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
  - **Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**
  - Technical specifications of the proposed equipment in the below format (kindly mention the use as well)
- | S. No. | Equipment   | Qty. | Use | Specification |
|--------|---|------|-----|---------------|
| •      | BA/BE study testing standards/parameters as per regulatory requirements.    |      |     |               |
| •      | Please mention the methods we will be using to establish BE.                |      |     |               |
| •      | Loan disbursement schedule month wise (% of loan to be disbursed by month). |      |     |               |

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9958632707

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75

Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service, the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000

		<b>Sub-total = Rs. 3,22,50,000</b>	<b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected to conduct around 104 studies (52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	<b>Head Clinical</b>	1	25,00,000.00
2	<b>Principal Investigators</b>	2	30,00,000.00
3	<b>Research Associates for clinical department</b>	4	16,00,000.00
4	<b>Phlebotomists</b>	5	12,50,000.00
5	<b>Pharmacists</b>	2	5,00,000.00
6	<b>Trainee</b>	4	8,00,000.00
7	<b>Custodian and Recruiter</b>	2	15,00,000.00

8	Head Bioanalytical	1	15,00,000.00
9	Team Leader	3	36,00,000.00
10	Research Associate	4	20,00,000.00
11	Trainee	4	10,00,000.00
12	Custodian	1	7,50,000.00
13	Clinical QA Associate	2	10,00,000.00
14	Bioanalytical QA	1	10,00,000.00
15	Bioanalytical QA Associate	2	10,00,000.00
16	Statistician	1	6,00,000.00
17	Report Writing team leader	1	7,50,000.00
18	Report Writing Research Associate	2	12,00,000.00
19	HR Manager	1	7,50,000.00
20	Head Quality Assurance	1	15,00,000.00
21	Clinical QA	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

**h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

**i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R  714667948713	Post Graduate	03 ears



**4. List of the Raw material required with ratio, grade and specifications and cost:**

The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any): NA**

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

12. **Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

13. **Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject

cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<u>Sr. No.</u>	<u>Content</u>	<u>Actual Study Subject Cost (INR)</u>	<u>Vendor Industry Cost (INR)</u>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>	<b>Total Clinical Study cost for 30 subjects</b>	<b>5,40,000</b>	<b>7,65,000</b>
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	$5,40,000 \times 25 = \text{Rs. } 1,35,00,000$ <b>Plus</b> $7,50,000 \times 25 = \text{Rs. } 1,87,50,000$ <b>Sub-total = Rs. 3,22,50,000</b>	$7,65,000 \times 25 = \text{Rs. } 1,91,25,000$ <b>Plus</b> $12,00,000 \times 25 = \text{Rs. } 3,00,00,000$ <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	$5,40,000 \times 2 \times 25 = \text{Rs. } 2,70,00,000$ <b>Plus</b> $7,50,000 \times 2 \times 25 = \text{Rs. } 3,75,00,000$ <b>Sub-total = Rs. 6,45,00,000</b>	$7,65,000 \times 2 \times 25 = \text{Rs. } 3,82,50,000$ <b>Plus</b> $12,00,000 \times 2 \times 25 = \text{Rs. } 6,00,00,000$ <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	<b>Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year</b>	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

**15. Loan disbursement schedule month wise.** The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

**16. GST certificate of the company** is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.

13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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A product of R.K. Associates  
[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <shahid@rkassociates.org> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of “**M/s Skylimit Research Private Limited**”, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
  - A. Land:**
    - a) Total Area of the land used for the project.
    - b) Layout Plan.
    - c) Sale/Lease Deed.
    - d) Current status/utilization of the land.
    - e) Address of the Unit
    - f) Google coordinates of the location.
    - g) Attach sale deed.
  - B. Building and Civil works:**
    - a) Total Area proposed for the Building.
    - b) Layout/ Site plan.
    - c) Site Map Approval/Sanctioned.
    - d) Details of the contractor's engaged.
    - e) Attach agreement with contractor.
  - C. Proposed Equipment:**
    - a) List of proposed equipment as per below heads:
      - Serial Number, if any
      - Equipment name
      - Manufacturer name
      - Specification/capacity
      - Expected Landed Price
      - Current status of the order
    - b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
    - c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)







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Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
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Corporate Office: -  
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Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

#### 6 attachments

-  **SRPL-TEV Reply Annexures.xlsx**  
30K
-  **SRPL-Fire NOC dated 08.02.2023.pdf**  
167K
-  **SRPL-Kirloskar genset.pdf**  
13600K
-  **SRPL-SB- Biochem.pdf**  
8174K
-  **SRPL-Quotation Uniair-1.pdf**  
160K
-  **SRPL-Qoutation Uniair.pdf**  
146K

m c bhatt pnb <mcbhatt13@gmail.com>

Tue, May 7, 2024 at 3:21 PM

To: Aneesh Mallick <aneesh.mallick@rkassociates.org>

Cc: "Shahid." <shahid@rkassociates.org>, "skylimitresearch@gmail.com" <skylimitresearch@gmail.com>, roshni@skylimitresearch.com, Gaurav Kumar <gaurav.kumar@rkassociates.org>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <mohit.agarwal@rkassociates.org>, "R.K Associates, The Valuers | LIE | TEV | ASM" <valuers@rkassociates.org>, clpc6277@pnb.co.in, "Business Operations R.K Associates" <bo@rkassociates.org>, FA Team <fateam@rkassociates.org>, bratati@skylimitresearch.com

Please find attached invoices in respect of [sl.no.](#) quotations for S.No.10,11 & 12 for kind reference.

Thanks & Regards

For Skylimit research Pvt Ltd

Authorized Signatory

On Tue, May 7, 2024 at 1:32 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative are as highlighted in map and area in each floor already submitted.
2. Project implementation schedule was discussed in the meeting and it is again submitted as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copy of NOC of Fire department is also attached.
4. Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for [s.no.](#) 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report. Further, quotations for S.No.10,11,12 are from same supplier and all these are again attached.



Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 2:35 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor is attached herewith.
2. Project implementation schedule has been discussed in the meeting and it will be as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copies of applications are being provided.
4. Quotations for P&M for s.no. 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for s.no. 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 11:32 AM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:

Sir

With reference to our meeting, please provide below details for report compilation -

- Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor.
- Project implementation schedule - dates/status (refer annexure 1)
- Regulatory approvals - dates/status and copy of application required (refer annexure 2)
- Quotations for P&M for s.no. 10,11,12,14,16,17,18,19,20,21,22,23 (refer annexure 3)

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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On Fri, May 3, 2024 at 4:00 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity is per month - 25,000.
- Total average Samples per subject - 60
- No of beds - 100 (170 from FY26)
- BA/BE studies capacity - 100 (170 from FY26)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:54 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity will be minimum per month - 12,000 which will be enhanced to 25000 samples per month or more as per the requirement.
- Total average Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:40 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000
- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets





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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

=====

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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**

**and**

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period, is over after 7 to 25 days (depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

**Response**

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

**Response**

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Subject Cost (INR)	Study Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000 X 25 = Rs. Rs. 1,87,50,000	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000 X 25 = Rs. Rs. 3,00,00,000

	subjects in each Pilot study) in a year	<b>Sub-total = Rs. 3,22,50,000</b>	<b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5: As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.**

**Response**

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 : We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.**

**Response**

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA ,FDA for USA, EMEA for EU market, MHRA for UK , TGI for Australia and NPRA for Malaysia, and other ROW s, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 : Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.**

**Response**

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8 External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.**

**Response**

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.**

**Response**

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.**

**Response**

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :Kindly list down expenses which are linked to revenue and which are not linked with revenue.**

**Response**

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

**Query 12 :Proposed Shareholding Pattern.****Response**

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.****Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).****Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
- GST registration: Attached
- Pollution certificate: Applied and will be obtained in due course.
- Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
- Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.

Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.

- EPFO registration: Will be obtained in due course
- ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).****Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format****Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer Capacity : 828 Litres

2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors
10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample dispensing, Bulk Spiking	1- channel, incl. Combipips advance rack, Combipips advance assortment pack  Variable range for Volume range for 500-5000 ul



12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:**

**Response:**

All the activities of BABB will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- *EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.*
- *Bioanalytical Method Validation Guidance for Industry FDA- May 2018.*
- *Electronic Data – 21 CFR 11*
- *Good Laboratory Practice -21 CFR 58, ISO 17025-2017*
- *ISO 9001:2015, Quality Management Systems*

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABB:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

**Process are described schematically as under for analysis:**





**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).**

**Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August’2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:  
Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.
- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
- **Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well)

S. No.	Equipment	Qty.	Use	Specification
--------	-----------	------	-----	---------------

- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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Mobile No.- +91 9958632707

Voice: +91-120 411 0117; 4324647

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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)

Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: www.rkassociates.org

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service , the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the

average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for

Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected to conduct around 104 studies (52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	<b>Head Clinical</b>	1	25,00,000.00
2	<b>Principal Investigators</b>	2	30,00,000.00
3	<b>Research Associates for clinical department</b>	4	16,00,000.00
4	<b>Phlebotomists</b>	5	12,50,000.00
5	<b>Pharmacists</b>	2	5,00,000.00
6	<b>Trainee</b>	4	8,00,000.00
7	<b>Custodian and Recruiter</b>	2	15,00,000.00
8	<b>Head Bioanalytical</b>	1	15,00,000.00
9	<b>Team Leader</b>	3	36,00,000.00
10	<b>Research Associate</b>	4	20,00,000.00
11	<b>Trainee</b>	4	10,00,000.00
12	<b>Custodian</b>	1	7,50,000.00
13	<b>Clinical QA Associate</b>	2	10,00,000.00
14	<b>Bioanalytical QA</b>	1	10,00,000.00
15	<b>Bioanalytical QA Associate</b>	2	10,00,000.00
16	<b>Statistician</b>	1	6,00,000.00
17	<b>Report Writing team leader</b>	1	7,50,000.00
18	<b>Report Writing Research Associate</b>	2	12,00,000.00
19	<b>HR Manager</b>	1	7,50,000.00
20	<b>Head Quality Assurance</b>	1	15,00,000.00
21	<b>Clinical QA</b>	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

#### **g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

#### **h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

#### **i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

2. **Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat, Director	02/01/2000	08163436	GXWPS7371P 806698463827	Graduate	04 years
Yash Pratap Singh, Director	11/08/2001	10075889	MSCPS9247R 226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R 714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:**

The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and



are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

**11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

**12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) -** The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<u>Sr. No.</u>	<u>Content</u>	<u>Actual Study Subject Cost (INR)</u>	<u>Vendor Industry Cost (INR)</u>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>		5,40,000	7,65,000
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
	Average cost for a single subject		

6	analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	$5,40,000 \times 25 = \text{Rs. } 1,35,00,000$ <b>Plus</b> $7,50,000 \times 25 = \text{Rs. } 1,87,50,000$ <b>Sub-total = Rs. 3,22,50,000</b>	$7,65,000 \times 25 = \text{Rs. } 1,91,25,000$ <b>Plus</b> $12,00,000 \times 25 = \text{Rs. } 3,00,00,000$ <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	$5,40,000 \times 2 \times 25 = \text{Rs. } 2,70,00,000$ <b>Plus</b> $7,50,000 \times 2 \times 25 = \text{Rs. } 3,75,00,000$ <b>Sub-total = Rs. 6,45,00,000</b>	$7,65,000 \times 2 \times 25 = \text{Rs. } 3,82,50,000$ <b>Plus</b> $12,00,000 \times 2 \times 25 = \text{Rs. } 6,00,00,000$ <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>		<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing

will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

15. Loan disbursement schedule month wise. The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

16. GST certificate of the company is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

### Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst





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**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <shahid@rkassociates.org> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).

9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
- A. Land:**
- a) Total Area of the land used for the project.
  - b) Layout Plan.
  - c) Sale/Lease Deed.
  - d) Current status/utilization of the land.
  - e) Address of the Unit
  - f) Google coordinates of the location.
  - g) Attach sale deed.
- B. Building and Civil works:**
- a) Total Area proposed for the Building.
  - b) Layout/ Site plan.
  - c) Site Map Approval/Sanctioned.
  - d) Details of the contractor's engaged.
  - e) Attach agreement with contractor.
- C. Proposed Equipment:**
- a) List of proposed equipment as per below heads:
    - Serial Number, if any
    - Equipment name
    - Manufacturer name
    - Specification/capacity
    - Expected Landed Price
    - Current status of the order
  - b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
  - c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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 **SRPL-Eppendorf-Misc equipments.pdf**  
146K

**Aneesh Mallick** <aneesh.mallick@rkassociates.org>

Thu, May 9, 2024 at 12:23 PM

To: bratati@skylimitresearch.com

Cc: m c bhatt pnb <mcbhatt13@gmail.com>, Gaurav Kumar <gaurav.kumar@rkassociates.org>

Dear Dr. Sanyal

Request you to provide a brief writeup on our recruitment plan and database of volunteers for conducting BS/BE studies.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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Voice: +91-120 411 0117; 4324647

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, May 7, 2024 at 3:21 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Please find attached invoices in respect of [sl.no.](#) quotations for S.No.10,11 & 12 for kind reference.

Thanks & Regards

For Skylimit research Pvt Ltd

Authorized Signatory

On Tue, May 7, 2024 at 1:32 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative are as highlighted in map and area in each floor already submitted.
2. Project implementation schedule was discussed in the meeting and it is again submitted as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copy of NOC of Fire department is also attached.
4. Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for [s.no.](#) 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report. Further, quotations for S.No.10,11,12 are from same supplier and all these are again attached.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 2:35 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor is attached herewith.
2. Project implementation schedule has been discussed in the meeting and it will be as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copies of applications are being provided.
4. Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for [s.no.](#) 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 11:32 AM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

With reference to our meeting, please provide below details for report compilation -

- Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor.
- Project implementation schedule - dates/status (refer annexure 1)
- Regulatory approvals - dates/status and copy of application required (refer annexure 2)
- Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 (refer annexure 3)

--

Thanks & Warm Regards,

Aneesh Mallick

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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Fri, May 3, 2024 at 4:00 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity is per month - 25,000.
- Total average Samples per subject - 60
- No of beds - 100 (170 from FY26)
- BA/BE studies capacity - 100 (170 from FY26)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:54 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity will be minimum per month - 12,000 which will be enhanced to 25000 samples per month or more as per the requirement.
- Total average Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:40 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000
- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of "M/s Skylimit Research Private Limited"**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of "M/s Skylimit Research Private Limited", we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year  
and**

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period, is over after 7 to 25 days (depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

**Response**

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

**Response**

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5:** As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.

#### Response

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 :** We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.

#### Response

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA ,FDA for USA, EMEA for EU market, MHRA for UK , TGI for Australia and NPRA for Malaysia, and other ROW s, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 :** Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.

**Response**

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8 External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.**

**Response**

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.**

**Response**

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.**

**Response**

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :Kindly list down expenses which are linked to revenue and which are not linked with revenue.**

**Response**

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

**Query 12 :Proposed Shareholding Pattern.**

**Response**

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.**

**Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).**

**Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
- GST registration: Attached
- Pollution certificate: Applied and will be obtained in due course.
- Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
- Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.

Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.

f. EPFO registration: Will be obtained in due course

g. ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**

**Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format**

**Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers



7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors
10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample dispensing, Bulk Spiking	1- channel, incl. Combitips advance rack, Combitips advance assortment pack Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:****Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- **EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.**



- *Bioanalytical Method Validation Guidance for Industry FDA- May 2018.*
- *Electronic Data – 21 CFR 11*
- *Good Laboratory Practice -21 CFR 58, ISO 17025-2017*
- *ISO 9001:2015, Quality Management Systems*

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BAE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

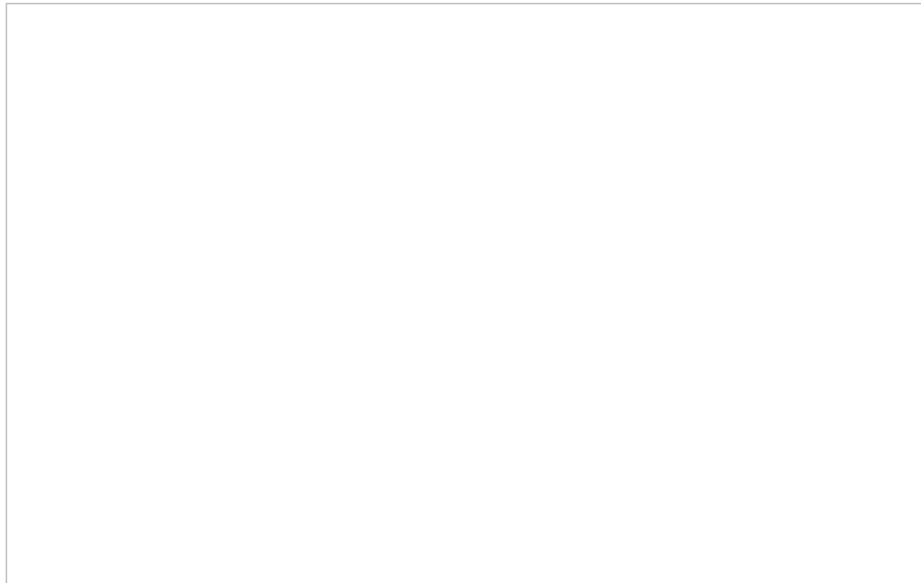
**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

Process are described schematically as under for analysis:

**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).****Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August'2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).

- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.
- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
- **Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well

S. No.	Equipment	Qty.	Use	Specification
--------	-----------	------	-----	---------------

- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards  
  
For Skylimit Research Pvt Ltd  
  
Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 20.04.2024

To,  
  
M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,  
  
**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**  
  
With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75

Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service, the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis. The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
	Approximate cost for 25 Pivotal studies	5,40,000 X 2 X 25 = Rs. 2,70,00,000	7,65,000 X 2 X 25 = Rs. 3,82,50,000

9	(covering average number of 60 subjects in each Pivotal study) in a year	<b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	<b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies (52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	<b>Head Clinical</b>	1	25,00,000.00
2	<b>Principal Investigators</b>	2	30,00,000.00
3	<b>Research Associates for clinical department</b>	4	16,00,000.00
4	<b>Phlebotomists</b>	5	12,50,000.00
5	<b>Pharmacists</b>	2	5,00,000.00
6	<b>Trainee</b>	4	8,00,000.00
7	<b>Custodian and Recruiter</b>	2	15,00,000.00
8	<b>Head Bioanalytical</b>	1	15,00,000.00
9	<b>Team Leader</b>	3	36,00,000.00
10	<b>Research Associate</b>	4	20,00,000.00
11	<b>Trainee</b>	4	10,00,000.00

12	<b>Custodian</b>	1	7,50,000.00
13	<b>Clinical QA Associate</b>	2	10,00,000.00
14	<b>Bioanalytical QA</b>	1	10,00,000.00
15	<b>Bioanalytical QA Associate</b>	2	10,00,000.00
16	<b>Statistician</b>	1	6,00,000.00
17	<b>Report Writing team leader</b>	1	7,50,000.00
18	<b>Report Writing Research Associate</b>	2	12,00,000.00
19	<b>HR Manager</b>	1	7,50,000.00
20	<b>Head Quality Assurance</b>	1	15,00,000.00
21	<b>Clinical QA</b>	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

#### **f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

#### **g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

#### **h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

**i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R  714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent



regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any): NA**

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

12. **Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

13. **Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing

the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<u>Sr. No.</u>	<u>Content</u>	<u>Actual Study Subject Cost (INR)</u>	<u>Vendor Industry Cost (INR)</u>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>	<b>Total Clinical Study cost for 30 subjects</b>	<b>5,40,000</b>	<b>7,65,000</b>
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	<b>Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year</b>	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

**15. Loan disbursement schedule month wise.** The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

**16. GST certificate of the company** is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.

12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards  
For Skylimit research Private Limited  
Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,  
  
Kindly find attached the reply and other annexures for your kind perusal and necessary action please.  
  
Thanks & Regards  
For Skylimit research Private Limited  
Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,  
  
Kindly find attached the reply and other annexures for your kind perusal and necessary action please.  
  
Thanks & Regards  
For Skylimit research Private Limited  
Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,  
  
Kindly find attached the reply and other annexures for your kind perusal and necessary action please.  
  
Thanks & Regards  
For Skylimit research Private Limited  
Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,  
  
Kindly find attached the reply and other annexures for your kind perusal and necessary action please.  
  
Thanks & Regards  
For Skylimit research Private Limited  
Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,  
  
Kindly find attached the reply and other annexures for your kind perusal and necessary action please.  
  
Thanks & Regards  
For Skylimit research Private Limited  
Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,  
  
Kindly find attached the reply and other annexures for your kind perusal and necessary action please.  
  
Thanks & Regards  
For Skylimit research Private Limited  
Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <shahid@rkassociates.org> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of "**M/s Skylimit Research Private Limited**", kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
  - A. **Land:**
    - a) Total Area of the land used for the project.
    - b) Layout Plan.
    - c) Sale/Lease Deed.
    - d) Current status/utilization of the land.
    - e) Address of the Unit
    - f) Google coordinates of the location.
    - g) Attach sale deed.
  - B. **Building and Civil works:**
    - a) Total Area proposed for the Building.
    - b) Layout/ Site plan.
    - c) Site Map Approval/Sanctioned.
    - d) Details of the contractor's engaged.
    - e) Attach agreement with contractor.
  - C. **Proposed Equipment:**
    - a) List of proposed equipment as per below heads:
      - Serial Number, if any
      - Equipment name
      - Manufacturer name
      - Specification/capacity
      - Expected Landed Price
      - Current status of the order
    - b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
    - c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

6/10/24, 1:19 PM

Rkassociates.org Mail - Re: Quotation for TEV Study of M/s Skylimit Research Pvt. Ltd.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

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Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

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Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Dr. Bratati Sanyal <[bratati@skylimitresearch.com](mailto:bratati@skylimitresearch.com)>

To: Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

Cc: m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)>, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>

Thu, May 9, 2024 at 12:48 PM

Greetings!!

Refer Following

**For BA/BE study ,Skylimit Research Private Limited will enroll volunteers from the data bank , so far Skylimit has 20K+ (male and female) volunteer data bank containing all the informations of local volunteers. For screening process and volunteer management, we will recruit experienced staff. Screening Executive/Designee will coordinate with the Principal Investigator regarding study dates. Screening Executive/Designee will inform the volunteers about the date and time to report for undergoing the screening process.**

Regards

On 2024-05-09 12:23, Aneesh Mallick wrote:

Dear Dr. Sanyal

Request you to provide a brief writeup on our recruitment plan and database of volunteers for conducting BS/BE studies.

--

Thanks & Warm Regards,

Aneesh Mallick

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Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, May 7, 2024 at 3:21 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Please find attached invoices in respect of [sl.no.](#) quotations for S.No.10,11 & 12 for kind reference.

Thanks & Regards

For Skylimit research Pvt Ltd

Authorized Signatory

On Tue, May 7, 2024 at 1:32 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative are as highlighted in map and area in each floor already submitted.
2. Project implementation schedule was discussed in the meeting and it is again submitted as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copy of NOC of Fire department is also attached.
4. Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for [s.no.](#) 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report. Further, quotations for S.No.10,11,12 are from same supplier and all these are again attached.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 2:35 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor is attached herewith.
2. Project implementation schedule has been discussed in the meeting and it will be as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copies of applications are being provided.
4. Quotations for P&M for s.no. 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for s.no. 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 11:32 AM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:

Sir

With reference to our meeting, please provide below details for report compilation -

- Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor.
- Project implementation schedule - dates/status (refer annexure 1)
- Regulatory approvals - dates/status and copy of application required (refer annexure 2)
- Quotations for P&M for s.no. 10,11,12,14,16,17,18,19,20,21,22,23 (refer annexure 3)

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Fri, May 3, 2024 at 4:00 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity is per month - 25,000.
- Total average Samples per subject - 60
- No of beds - 100 (170 from FY26)
- BA/BE studies capacity - 100 (170 from FY26)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:54 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity will be minimum per month - 12,000 which will be enhanced to 25000 samples per month or more as per the requirement.
- Total average Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:40 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000
- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets





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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of "M/s Skylimit Research Private Limited"**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of "M/s Skylimit Research Private Limited", we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**

and

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period, is over after 7 to 25 days (depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

**Response**

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

**Response**

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Subject Cost (INR)	Study Vendor Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
	Approximate cost for 50 Pilot studies	5,40,000 X 25 = Rs. 1,35,00,000	7,65,000 X 25 = Rs. 1,91,25,000

8	(covering average number of 15 subjects in each Pilot study) in a year	<b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs.</b> <b>3,22,50,000</b>	<b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs.</b> <b>4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs.</b> <b>6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs.</b> <b>9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5: As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.**

#### **Response**

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 : We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.**

#### **Response**

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA ,FDA for USA, EMEA for EU market, MHRA for UK , TGI for Australia and NPRA for Malaysia, and other ROW s, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 : Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises is 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.**

#### **Response**

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8 External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.**

#### **Response**

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.**

#### **Response**

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.**

#### **Response**

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.



**Query 11 :Kindly list down expenses which are linked to revenue and which are not linked with revenue.**

**Response**

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

**Query 12 :Proposed Shareholding Pattern.**

**Response**

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.**

**Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).**

**Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
- GST registration: Attached
- Pollution certificate: Applied and will be obtained in due course.
- Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
- Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.

Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.

- EPFO registration: Will be obtained in due course
- ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**

**Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format**

**Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors



10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample dispensing, Bulk Spiking	1- channel, incl. Combitips advance rack, Combitips advance assortment pack Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:**

**Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- **EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.**
- **Bioanalytical Method Validation Guidance for Industry FDA- May 2018.**
- **Electronic Data – 21 CFR 11**
- **Good Laboratory Practice -21 CFR 58, ISO 17025-2017**
- **ISO 9001:2015, Quality Management Systems**

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

Process are described schematically as under for analysis:



**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).**

**Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August'2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.
- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
- Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well

S. No.	Equipment	Qty.	Use	Specification
--------	-----------	------	-----	---------------

- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

=====

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**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9958632707

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of "M/s Skylimit Research Private Limited"**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of "M/s Skylimit Research Private Limited", we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements), we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service, the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 18,75,00,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>

10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies (52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	<b>Head Clinical</b>	1	25,00,000.00
2	<b>Principal Investigators</b>	2	30,00,000.00
3	<b>Research Associates for clinical department</b>	4	16,00,000.00
4	<b>Phlebotomists</b>	5	12,50,000.00
5	<b>Pharmacists</b>	2	5,00,000.00
6	<b>Trainee</b>	4	8,00,000.00
7	<b>Custodian and Recruiter</b>	2	15,00,000.00
8	<b>Head Bioanalytical</b>	1	15,00,000.00
9	<b>Team Leader</b>	3	36,00,000.00
10	<b>Research Associate</b>	4	20,00,000.00
11	<b>Trainee</b>	4	10,00,000.00
12	<b>Custodian</b>	1	7,50,000.00
13	<b>Clinical QA Associate</b>	2	10,00,000.00
14	<b>Bioanalytical QA</b>	1	10,00,000.00
15	<b>Bioanalytical QA Associate</b>	2	10,00,000.00
16	<b>Statistician</b>	1	6,00,000.00
17	<b>Report Writing team leader</b>	1	7,50,000.00



18	<b>Report Writing Research Associate</b>	2	12,00,000.00
19	<b>HR Manager</b>	1	7,50,000.00
20	<b>Head Quality Assurance</b>	1	15,00,000.00
21	<b>Clinical QA</b>	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

**h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

**i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as



soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

### 3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R  714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence.

There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

**7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.** The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

12. **Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

13. **Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost (INR)
---------	---------	---------------------------------	----------------------------

<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>		5,40,000	7,65,000
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>		<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

**15. Loan disbursement schedule month wise.** The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

**16. GST certificate of the company** is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.



14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <shahid@rkassociates.org> wrote:  
Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of "**M/s Skylimit Research Private Limited**", kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:

**A. Land:**

- a) Total Area of the land used for the project.
- b) Layout Plan.
- c) Sale/Lease Deed.
- d) Current status/utilization of the land.
- e) Address of the Unit
- f) Google coordinates of the location.
- g) Attach sale deed.

**B. Building and Civil works:**

- a) Total Area proposed for the Building.
- b) Layout/ Site plan.
- c) Site Map Approval/Sanctioned.
- d) Details of the contractor's engaged.
- e) Attach agreement with contractor.

**C. Proposed Equipment:**

- a) List of proposed equipment as per below heads:
  - Serial Number, if any
  - Equipment name
  - Manufacturer name
  - Specification/capacity
  - Expected Landed Price
  - Current status of the order
- b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
- c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.

12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study



report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
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Website: [www.rkassociates.org](http://www.rkassociates.org)

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--  
Dr Bratati Sanyal  
Head Technical Operations  
Skylimit Research Pvt.Ltd.  
9811290091  
Phase 2  
Sector 153  
Noida, U.P.

Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

Thu, May 9, 2024 at 7:04 PM

To: [clpc6277@pnb.co.in](mailto:clpc6277@pnb.co.in)

Cc: "Shahid ." <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, "R.K Associates, The Valuers | LIE | TEV | ASM" <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, "Business Operations R.K Associates" <[bo@rkassociates.org](mailto:bo@rkassociates.org)>, FA Team <[fateam@rkassociates.org](mailto:fateam@rkassociates.org)>

Sir

Please find attached draft TEV report of CRO unit being setup by M/s Skylimit. This report is subject to final review.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, May 7, 2024 at 3:21 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Please find attached invoices in respect of [sl.no.](#) quotations for S.No.10,11 & 12 for kind reference.

Thanks & Regards

For Skylimit research Pvt Ltd

Authorized Signatory

On Tue, May 7, 2024 at 1:32 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative are as highlighted in map and area in each floor already submitted.
2. Project implementation schedule was discussed in the meeting and it is again submitted as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copy of NOC of Fire department is also attached.
4. Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for [s.no.](#) 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report. Further, quotations for S.No.10,11,12 are from same supplier and all these are again attached.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 2:35 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor is attached herewith.
2. Project implementation schedule has been discussed in the meeting and it will be as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copies of applications are being provided.
4. Quotations for P&M for s.no. 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for s.no. 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 11:32 AM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:

Sir

With reference to our meeting, please provide below details for report compilation -

- Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor.
- Project implementation schedule - dates/status (refer annexure 1)
- Regulatory approvals - dates/status and copy of application required (refer annexure 2)
- Quotations for P&M for s.no. 10,11,12,14,16,17,18,19,20,21,22,23 (refer annexure 3)

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Fri, May 3, 2024 at 4:00 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity is per month - 25,000.
- Total average Samples per subject - 60
- No of beds - 100 (170 from FY26)
- BA/BE studies capacity - 100 (170 from FY26)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:54 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity will be minimum per month - 12,000 which will be enhanced to 25000 samples per month or more as per the requirement.
- Total average Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:40 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000
- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets





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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**  
**and**

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period, is over after 7 to 25 days (depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

**Response**

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

**Response**

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000 X 25 = Rs. Rs. 1,87,50,000	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000 X 25 = Rs. Rs. 3,00,00,000

	subjects in each Pilot study) in a year	<b>Sub-total = Rs. 3,22,50,000</b>	<b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5: As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.**

**Response**

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 : We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.**

**Response**

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA ,FDA for USA, EMEA for EU market, MHRA for UK , TGI for Australia and NPRA for Malaysia, and other ROW s, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 : Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.**

**Response**

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8 External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.**

**Response**

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.**

**Response**

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.**

**Response**

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :Kindly list down expenses which are linked to revenue and which are not linked with revenue.**

**Response**



All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

#### Query 12 :Proposed Shareholding Pattern.

##### Response

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

#### Query 13: Experience in the subject Industry of promoters/ directors.

##### Response

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

#### Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).

##### Response

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
- GST registration: Attached
- Pollution certificate: Applied and will be obtained in due course.
- Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
- Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.  
Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.
- EPFO registration: Will be obtained in due course
- ESIC registration: Will be obtained in due course

#### Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).

##### Response

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

#### Query 16: Technical specifications of the proposed equipment in the below format

##### Response

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C



				ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors
10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample	1- channel, incl. Combitips advance rack, Combitips advance assortment pack

			dispensing, Bulk Spiking	Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range  Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:**

**Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- *EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.*
- *Bioanalytical Method Validation Guidance for Industry FDA- May 2018.*
- *Electronic Data – 21 CFR II*
- *Good Laboratory Practice -21 CFR 58, ISO 17025-2017*
- *ISO 9001:2015, Quality Management Systems*

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

**Process are described schematically as under for analysis:**



**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).**

**Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August’2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:  
Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.
- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
- **Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well

S. No.	Equipment	Qty.	Use	Specification
•				

- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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Mobile No.- +91 9958632707

Voice: +91-120 411 0117; 4324647

**Corporate Office:**  
D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)

Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: www.rkassociates.org

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service , the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80

lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs.

15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected to conduct around 104 studies (52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	Head Clinical	1	25,00,000.00
2	Principal Investigators	2	30,00,000.00
3	Research Associates for clinical department	4	16,00,000.00
4	Phlebotomists	5	12,50,000.00
5	Pharmacists	2	5,00,000.00
6	Trainee	4	8,00,000.00
7	Custodian and Recruiter	2	15,00,000.00
8	Head Bioanalytical	1	15,00,000.00
9	Team Leader	3	36,00,000.00
10	Research Associate	4	20,00,000.00
11	Trainee	4	10,00,000.00
12	Custodian	1	7,50,000.00
13	Clinical QA Associate	2	10,00,000.00
14	Bioanalytical QA	1	10,00,000.00
15	Bioanalytical QA Associate	2	10,00,000.00
16	Statistician	1	6,00,000.00
17	Report Writing team leader	1	7,50,000.00
18	Report Writing Research Associate	2	12,00,000.00
19	HR Manager	1	7,50,000.00
20	Head Quality Assurance	1	15,00,000.00
21	Clinical QA	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from December,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**



The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

#### **g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

#### **h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

#### **i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat, Director	02/01/2000	08163436	GXWPS7371P 806698463827	Graduate	04 years
Yash Pratap Singh, Director	11/08/2001	10075889	MSCPS9247R 226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R 714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and

Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

**11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

**12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) -** The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<u>Sr. No.</u>	<u>Content</u>	<u>Actual Study Subject Cost (INR)</u>	<u>Vendor Industry Cost (INR)</u>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>		5,40,000	7,65,000
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800

6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000  <b>Plus</b>  7,50,000X 25 = Rs. Rs. 1,87,50,000  <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000  <b>Plus</b>  12,00,000X 25 = Rs. Rs. 3,00,00,000  <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000  <b>Plus</b>  7,50,000X 2 X 25 = Rs. 3,75,00,000  <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000  <b>Plus</b>  12,00,000X 2 X 25 = Rs. 6,00,00,000  <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>		<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug

Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

15. Loan disbursement schedule month wise. The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

16. GST certificate of the company is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

### Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst





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**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <shahid@rkassociates.org> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.



8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
  - A. Land:**
    - a) Total Area of the land used for the project.
    - b) Layout Plan.
    - c) Sale/Lease Deed.
    - d) Current status/utilization of the land.
    - e) Address of the Unit
    - f) Google coordinates of the location.
    - g) Attach sale deed.
  - B. Building and Civil works:**
    - a) Total Area proposed for the Building.
    - b) Layout/ Site plan.
    - c) Site Map Approval/Sanctioned.
    - d) Details of the contractor's engaged.
    - e) Attach agreement with contractor.
  - C. Proposed Equipment:**
    - a) List of proposed equipment as per below heads:
      - Serial Number, if any
      - Equipment name
      - Manufacturer name
      - Specification/capacity
      - Expected Landed Price
      - Current status of the order
    - b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
    - c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216


Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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Website: [www.rkassociates.org](http://www.rkassociates.org)

 **Ms. Skylimit Research Private Limited Draft TEV Report.pdf**  
4182K

**Aneesh Mallick** <aneesh.mallick@rkassociates.org>

Tue, May 14, 2024 at 11:12 AM

To: clpc6277@pnb.co.in

Cc: "Shahid ." <shahid@rkassociates.org>, Gaurav Kumar <gaurav.kumar@rkassociates.org>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <mohit.agarwal@rkassociates.org>, "R.K Associates, The Valuers | LIE | TEV | ASM" <valuers@rkassociates.org>, "Business Operations R.K Associates" <bo@rkassociates.org>, FA Team <fateam@rkassociates.org>

Sir

Please find attached revised TEV report after extending the loan tenure to 10 years and moratorium period to 2 years.

---

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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We assure our best services and response to you all the time.

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, May 9, 2024 at 7:04 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

Please find attached draft TEV report of CRO unit being setup by M/s Skylimit. This report is subject to final review.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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On Tue, May 7, 2024 at 3:21 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Please find attached invoices in respect of [sl.no.](#) quotations for S.No.10,11 & 12 for kind reference.

Thanks & Regards

For Skylimit research Pvt Ltd

Authorized Signatory

On Tue, May 7, 2024 at 1:32 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative are as highlighted in map and area in each floor already submitted.
2. Project implementation schedule was discussed in the meeting and it is again submitted as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copy of NOC of Fire department is also attached.
4. Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for [s.no.](#) 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report. Further, quotations for S.No.10,11,12 are from same supplier and all these are again attached.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 2:35 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor is attached herewith.
2. Project implementation schedule has been discussed in the meeting and it will be as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copies of applications are being provided.
4. Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for [s.no.](#) 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 11:32 AM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

With reference to our meeting, please provide below details for report compilation -

- Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor.
- Project implementation schedule - dates/status (refer annexure 1)
- Regulatory approvals - dates/status and copy of application required (refer annexure 2)
- Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 (refer annexure 3)

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets





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On Fri, May 3, 2024 at 4:00 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity is per month - 25,000.
- Total average Samples per subject - 60
- No of beds - 100 (170 from FY26)
- BA/BE studies capacity - 100 (170 from FY26)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:54 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity will be minimum per month - 12,000 which will be enhanced to 25000 samples per month or more as per the requirement.
- Total average Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:40 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000
- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**

and

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period, is over after 7 to 25 days (depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

**Response**

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

**Response**

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:



Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5:** As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.

#### Response

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 :** We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.

#### Response

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA ,FDA for USA, EMEA for EU market, MHRA for UK , TGI for Australia and NPRA for Malaysia, and other ROW s, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 :** Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.



**Response**

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8 External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.**

**Response**

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.**

**Response**

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.**

**Response**

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :Kindly list down expenses which are linked to revenue and which are not linked with revenue.**

**Response**

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

**Query 12 :Proposed Shareholding Pattern.**

**Response**

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.**

**Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).**

**Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
- GST registration: Attached
- Pollution certificate: Applied and will be obtained in due course.
- Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
- Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.

Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.

f. EPFO registration: Will be obtained in due course

g. ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**

**Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format**

**Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers

7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors
10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample dispensing, Bulk Spiking	1- channel, incl. Combitips advance rack, Combitips advance assortment pack Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:**

**Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- **EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.**

- **Bioanalytical Method Validation Guidance for Industry FDA- May 2018.**
- **Electronic Data – 21 CFR 11**
- **Good Laboratory Practice -21 CFR 58, ISO 17025-2017**
- **ISO 9001:2015, Quality Management Systems**

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

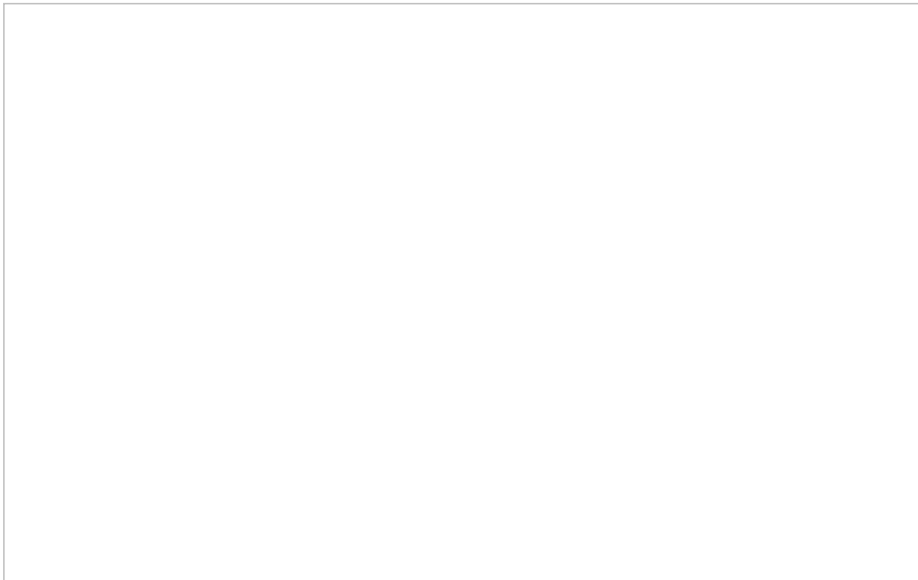
**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

**Process are described schematically as under for analysis:**

**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).****Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August'2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).

- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.
- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
- **Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well)

S. No.	Equipment	Qty.	Use	Specification
--------	-----------	------	-----	---------------

- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9958632707

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to by conducted in the CRO.

Thanks & Regards  
  
For Skylimit Research Pvt Ltd  
  
Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 20.04.2024

To,  
  
M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,  
  
**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75

Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service, the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000



8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	<b>Head Clinical</b>	1	25,00,000.00
2	<b>Principal Investigators</b>	2	30,00,000.00
3	<b>Research Associates for clinical department</b>	4	16,00,000.00

4	Phlebotomists	5	12,50,000.00
5	Pharmacists	2	5,00,000.00
6	Trainee	4	8,00,000.00
7	Custodian and Recruiter	2	15,00,000.00
8	Head Bioanalytical	1	15,00,000.00
9	Team Leader	3	36,00,000.00
10	Research Associate	4	20,00,000.00
11	Trainee	4	10,00,000.00
12	Custodian	1	7,50,000.00
13	Clinical QA Associate	2	10,00,000.00
14	Bioanalytical QA	1	10,00,000.00
15	Bioanalytical QA Associate	2	10,00,000.00
16	Statistician	1	6,00,000.00
17	Report Writing team leader	1	7,50,000.00
18	Report Writing Research Associate	2	12,00,000.00
19	HR Manager	1	7,50,000.00
20	Head Quality Assurance	1	15,00,000.00
21	Clinical QA	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease

agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

#### **h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

#### **i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

#### **3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat, Director	02/01/2000	08163436	GXWPS7371P 806698463827	Graduate	04 years
Yash Pratap Singh, Director	11/08/2001	10075889	MSCPS9247R 226536725538	Graduate	04 years

Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R 714667948713	Post Graduate	03 ears
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**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be

conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

12. **Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been

implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<b>- Sr. No.</b>	<b>- Content</b>	<b>Actual Study Subject Cost (INR)</b>	<b>Vendor Industry Cost (INR)</b>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>		5,40,000	7,65,000
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000  <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000  <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000  <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000  <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000  <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000  <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000  <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000  <b>Sub-total = Rs. 9,82,50,000</b>

10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

**15. Loan disbursement schedule month wise.** The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

**16. GST certificate of the company** is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying

- assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
  3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
  4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
  5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
  6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
  7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
  8. Site layout Plan.
  9. Google coordinates of the location.
  10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
  11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
  12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
  13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
  14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
  15. Loan disbursement schedule month wise.
  16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023



**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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**Note** : The e-mail content is intended for the sole use of the intended recipient/s and may contain material that is **CONFIDENTIAL AND PRIVATE COMPANY INFORMATION**. Any review or reliance by others or copying or distribution or forwarding of any or all of the contents in this message is **STRICTLY PROHIBITED**. If you have erroneously received this message, please delete it immediately and notify the sender. Before opening any attachments please check them for viruses and defects.

On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards  
For Skylimit research Private Limited  
Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards  
For Skylimit research Private Limited  
Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards  
For Skylimit research Private Limited  
Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards  
For Skylimit research Private Limited  
Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards  
For Skylimit research Private Limited  
Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards  
For Skylimit research Private Limited  
Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <shahid@rkassociates.org> wrote:  
Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
  - A. Land:**
    - a) Total Area of the land used for the project.
    - b) Layout Plan.
    - c) Sale/Lease Deed.
    - d) Current status/utilization of the land.
    - e) Address of the Unit
    - f) Google coordinates of the location.
    - g) Attach sale deed.

**B. Building and Civil works:**

- a) Total Area proposed for the Building.
- b) Layout/ Site plan.
- c) Site Map Approval/Sanctioned.
- d) Details of the contractor's engaged.
- e) Attach agreement with contractor.

**C. Proposed Equipment:**

- a) List of proposed equipment as per below heads:
  - Serial Number, if any
  - Equipment name
  - Manufacturer name
  - Specification/capacity
  - Expected Landed Price
  - Current status of the order
- b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.

c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.

12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:  
Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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Thanks & Regards,  
Mohd Shahid,  
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+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

 **Ms. Skylimit Research Private Limited Draft TEV Report\_v2.pdf**  
4219K

Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

Mon, May 20, 2024 at 5:13 PM

To: m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)>

Cc: clpc6277@pnb.co.in, "Shahid ." <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, "R.K Associates, The Valuers | LIE | TEV | ASM" <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, "Business Operations R.K Associates" <[bo@rkassociates.org](mailto:bo@rkassociates.org)>, FA Team <[fateam@rkassociates.org](mailto:fateam@rkassociates.org)>

Sir

This is with reference to our discussion with the bank wherein they have permitted us to share the draft TEV report with you for your comments/reference.  
Please find attached copy of final draft of TEV report.

--

Thanks &amp; Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Assets



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9958632707

Voice: +91-120 411 0117; 4324647

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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, May 14, 2024 at 11:12 AM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

Please find attached revised TEV report after extending the loan tenure to 10 years and moratorium period to 2 years.

--

Thanks &amp; Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Assets



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**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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On Thu, May 9, 2024 at 7:04 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

Please find attached draft TEV report of CRO unit being setup by M/s Skylimit. This report is subject to final review.

---

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets





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On Tue, May 7, 2024 at 3:21 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Please find attached invoices in respect of [sl.no.](#) quotations for S.No.10,11 & 12 for kind reference.

Thanks & Regards

For Skylimit research Pvt Ltd

Authorized Signatory

On Tue, May 7, 2024 at 1:32 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative are as highlighted in map and area in each floor already submitted.
2. Project implementation schedule was discussed in the meeting and it is again submitted as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copy of NOC of Fire department is also attached.
4. Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for [s.no.](#) 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report. Further, quotations for S.No.10,11,12 are from same supplier and all these are again attached.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 2:35 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor is attached herewith.
2. Project implementation schedule has been discussed in the meeting and it will be as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copies of applications are being provided.
4. Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for [s.no.](#) 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 11:32 AM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to our meeting, please provide below details for report compilation -

- Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor.
- Project implementation schedule - dates/status (refer annexure 1)
- Regulatory approvals - dates/status and copy of application required (refer annexure 2)
- Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 (refer annexure 3)

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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On Fri, May 3, 2024 at 4:00 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity is per month - 25,000.
- Total average Samples per subject - 60
- No of beds - 100 (170 from FY26)
- BA/BE studies capacity - 100 (170 from FY26)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:54 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity will be minimum per month - 12,000 which will be enhanced to 25000 samples per month or more as per the requirement.
- Total average Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:40 PM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:  
Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000
- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

--

Thanks & Warm Regards,

Aneesh Mallick

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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**

and

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period, is over after 7 to 25 days (depending on the

drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

**Response**

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

**Response**

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subjectanalysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>

	25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study		
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5:** As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.

#### Response

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 :** We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.

#### Response

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA ,FDA for USA, EMEA for EU market, MHRA for UK , TGI for Australia and NPRA for Malaysia, and other ROW s, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 :** Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.

#### Response

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8** External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.

#### Response

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :**In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.

#### Response

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10:** Financial Model of the Project in excel with proper assumptions & Projections and rationale.

#### Response

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :**Kindly list down expenses which are linked to revenue and which are not linked with revenue.

#### Response

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

**Query 12 :**Proposed Shareholding Pattern.

#### Response

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000

Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.**

**Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).**

**Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
- GST registration: Attached
- Pollution certificate: Applied and will be obtained in due course.
- Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
- Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.  
Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.
- EPFO registration: Will be obtained in due course
- ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**

**Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format**

**Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus

4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated-Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated-Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors
10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample dispensing, Bulk Spiking	1- channel, incl. Combitips advance rack, Combitips advance assortment pack  Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range

	Micro Analytical balance			Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:**

**Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- **EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.**
- **Bioanalytical Method Validation Guidance for Industry FDA- May 2018.**
- **Electronic Data – 21 CFR 11**
- **Good Laboratory Practice -21 CFR 58, ISO 17025-2017**
- **ISO 9001:2015, Quality Management Systems**

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

**Process are described schematically as under for analysis:**



**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).**

**Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August’2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.
- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
- Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well

S. No.	Equipment	Qty.	Use	Specification
--------	-----------	------	-----	---------------

- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

--

Thanks & Warm Regards,  
Aneesh Mallick

Consultant-Securities & Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst





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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306

Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)

Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service , the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is

expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>

<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>
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The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	<b>Head Clinical</b>	1	25,00,000.00
2	<b>Principal Investigators</b>	2	30,00,000.00
3	<b>Research Associates for clinical department</b>	4	16,00,000.00
4	<b>Phlebotomists</b>	5	12,50,000.00
5	<b>Pharmacists</b>	2	5,00,000.00
6	<b>Trainee</b>	4	8,00,000.00
7	<b>Custodian and Recruiter</b>	2	15,00,000.00
8	<b>Head Bioanalytical</b>	1	15,00,000.00
9	<b>Team Leader</b>	3	36,00,000.00
10	<b>Research Associate</b>	4	20,00,000.00
11	<b>Trainee</b>	4	10,00,000.00
12	<b>Custodian</b>	1	7,50,000.00
13	<b>Clinical QA Associate</b>	2	10,00,000.00
14	<b>Bioanalytical QA</b>	1	10,00,000.00
15	<b>Bioanalytical QA Associate</b>	2	10,00,000.00
16	<b>Statistician</b>	1	6,00,000.00
17	<b>Report Writing team leader</b>	1	7,50,000.00
18	<b>Report Writing Research Associate</b>	2	12,00,000.00
19	<b>HR Manager</b>	1	7,50,000.00
20	<b>Head Quality Assurance</b>	1	15,00,000.00
21	<b>Clinical QA</b>	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

**h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

**i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

### **3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R  714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any): NA**

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

**7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.** The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

**8. Site layout Plan is attached.**

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

12. **Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

13. **Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost (INR)
---------	---------	---------------------------------	----------------------------



<b>Clinical</b>	-	-	-
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	Total Clinical Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	$5,40,000 \times 25 = \text{Rs. } 1,35,00,000$ <b>Plus</b> $7,50,000 \times 25 = \text{Rs. } 1,87,50,000$ <b>Sub-total = Rs. 3,22,50,000</b>	$7,65,000 \times 25 = \text{Rs. } 1,91,25,000$ <b>Plus</b> $12,00,000 \times 25 = \text{Rs. } 3,00,00,000$ <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	$5,40,000 \times 2 \times 25 = \text{Rs. } 2,70,00,000$ <b>Plus</b> $7,50,000 \times 2 \times 25 = \text{Rs. } 3,75,00,000$ <b>Sub-total = Rs. 6,45,00,000</b>	$7,65,000 \times 2 \times 25 = \text{Rs. } 3,82,50,000$ <b>Plus</b> $12,00,000 \times 2 \times 25 = \text{Rs. } 6,00,00,000$ <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

**15. Loan disbursement schedule month wise.** The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

**16. GST certificate of the company** is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.

14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

**We assure our best services and response to you all the time.**

**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

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Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:  
Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **“M/s Skylimit Research Private Limited”**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:

**A. Land:**

- a) Total Area of the land used for the project.
- b) Layout Plan.
- c) Sale/Lease Deed.
- d) Current status/utilization of the land.
- e) Address of the Unit
- f) Google coordinates of the location.
- g) Attach sale deed.

**B. Building and Civil works:**

- a) Total Area proposed for the Building.
- b) Layout/ Site plan.
- c) Site Map Approval/Sanctioned.
- d) Details of the contractor's engaged.
- e) Attach agreement with contractor.

**C. Proposed Equipment:**

- a) List of proposed equipment as per below heads:
  - Serial Number, if any
  - Equipment name
  - Manufacturer name
  - Specification/capacity
  - Expected Landed Price
  - Current status of the order
- b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
- c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.

12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV

study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,


Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

--

Thanks & Regards,  
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Senior Coordinator Business Operation  
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Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

 **Ms. Skylimit Research Private Limited Draft TEV Report\_v3.pdf**  
4107K

Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>

Mon, May 27, 2024 at 1:36 PM

To: [clpc6277@pnb.co.in](mailto:clpc6277@pnb.co.in), [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)

Cc: Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, "R.K Associates, The Valuers | LIE | TEV | ASM" <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, "Business Operations R.K Associates" <[bo@rkassociates.org](mailto:bo@rkassociates.org)>, FA Team <[fateam@rkassociates.org](mailto:fateam@rkassociates.org)>, "Accounts R.K Associates" <[accounts@rkassociates.org](mailto:accounts@rkassociates.org)>, Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

Dear Sir,

Please find the attached Final Tax Invoice for TEV Study of M/s Skylimit Research Ltd. Please make remaining payment asap.

On Mon, May 20, 2024 at 5:13 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

This is with reference to our discussion with the bank wherein they have permitted us to share the draft TEV report with you for your comments/reference. Please find attached copy of final draft of TEV report.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets





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Uttar Pradesh- 201301

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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On Tue, May 14, 2024 at 11:12 AM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

Please find attached revised TEV report after extending the loan tenure to 10 years and moratorium period to 2 years.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets





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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

=====

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On Thu, May 9, 2024 at 7:04 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

Please find attached draft TEV report of CRO unit being setup by M/s Skylimit. This report is subject to final review.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets







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Integrating Valuation Life Cycle -  
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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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We assure our best services and response to you all the time.

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, May 7, 2024 at 3:21 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Please find attached invoices in respect of [sl.no.](#) quotations for S.No.10,11 & 12 for kind reference.

Thanks & Regards

For Skylimit research Pvt Ltd

Authorized Signatory

On Tue, May 7, 2024 at 1:32 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative are as highlighted in map and area in each floor already submitted.
2. Project implementation schedule was discussed in the meeting and it is again submitted as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copy of NOC of Fire department is also attached.
4. Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for [s.no.](#) 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report. Further, quotations for S.No.10,11,12 are from same supplier and all these are again attached.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 2:35 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor is attached herewith.
2. Project implementation schedule has been discussed in the meeting and it will be as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copies of applications are being provided.
4. Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for [s.no.](#) 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 11:32 AM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to our meeting, please provide below details for report compilation -

- Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor.
- Project implementation schedule - dates/status (refer annexure 1)
- Regulatory approvals - dates/status and copy of application required (refer annexure 2)
- Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 ( refer annexure 3)

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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On Fri, May 3, 2024 at 4:00 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity is per month - 25,000.
- Total average Samples per subject - 60
- No of beds - 100 (170 from FY26)
- BA/BE studies capacity - 100 (170 from FY26)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:54 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity will be minimum per month - 12,000 which will be enhanced to 25000 samples per month or more as per the requirement.
- Total average Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:40 PM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:  
Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000
- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**

and

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria , the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period ,is over after 7 to 25

days(depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

#### Response

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

#### Response

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subjectanalysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>

	25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study		
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5:** As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.

#### Response

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 :** We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.

#### Response

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA ,FDA for USA, EMEA for EU market, MHRA for UK , TGI for Australia and NPRA for Malaysia, and other ROW s, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 :** Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.

#### Response

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8** External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.

#### Response

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :**In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.

#### Response

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.**

#### Response

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :**Kindly list down expenses which are linked to revenue and which are not linked with revenue.

#### Response

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

**Query 12 :Proposed Shareholding Pattern.**

#### Response

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000



Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.**

**Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).**

**Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
- GST registration: Attached
- Pollution certificate: Applied and will be obtained in due course.
- Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
- Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.  
Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.
- EPFO registration: Will be obtained in due course
- ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**

**Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format**

**Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus

4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated-Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated-Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors
10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample dispensing, Bulk Spiking	1- channel, incl. Combipips advance rack, Combipips advance assortment pack  Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range



	Micro Analytical balance			Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:**

**Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- **EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.**
- **Bioanalytical Method Validation Guidance for Industry FDA- May 2018.**
- **Electronic Data – 21 CFR 11**
- **Good Laboratory Practice -21 CFR 58, ISO 17025-2017**
- **ISO 9001:2015, Quality Management Systems**

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

**Process are described schematically as under for analysis:**



**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).**

**Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August’2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:  
Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
  - With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
  - Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
  - As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
  - As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
  - We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
  - Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
  - External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
  - In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
  - Financial Model of the Project in excel with proper assumptions & Projections and rationale.
  - Kindly list down expenses which are linked to revenue and which are not linked with revenue.
  - Proposed Shareholding Pattern.
  - Experience in the subject Industry of promoters/ directors.
  - Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
  - Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
  - Technical specifications of the proposed equipment in the below format (kindly mention the use as well
- | S. No. | Equipment | Qty. | Use | Specification |
|--------|-----------|------|-----|---------------|
| •      |           |      |     |               |
- BA/BE study testing standards/parameters as per regulatory requirements.
  - Please mention the methods we will be using to establish BE.
  - Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

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Thanks & Warm Regards,  
Aneesh Mallick

Consultant-Securities & Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



*World's first fully digital Automated Platform for  
Integrating Valuation Life Cycle -  
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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
 (A Clinical Research Organization)  
 VILLA-2/9, LAND 2, JAYPEE GREENS,  
 GREATER NOIDA, UP-201306

Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)

Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements), we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service, the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for

the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>

<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>
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The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	<b>Head Clinical</b>	1	25,00,000.00
2	<b>Principal Investigators</b>	2	30,00,000.00
3	<b>Research Associates for clinical department</b>	4	16,00,000.00
4	<b>Phlebotomists</b>	5	12,50,000.00
5	<b>Pharmacists</b>	2	5,00,000.00
6	<b>Trainee</b>	4	8,00,000.00
7	<b>Custodian and Recruiter</b>	2	15,00,000.00
8	<b>Head Bioanalytical</b>	1	15,00,000.00
9	<b>Team Leader</b>	3	36,00,000.00
10	<b>Research Associate</b>	4	20,00,000.00
11	<b>Trainee</b>	4	10,00,000.00
12	<b>Custodian</b>	1	7,50,000.00
13	<b>Clinical QA Associate</b>	2	10,00,000.00
14	<b>Bioanalytical QA</b>	1	10,00,000.00
15	<b>Bioanalytical QA Associate</b>	2	10,00,000.00
16	<b>Statistician</b>	1	6,00,000.00
17	<b>Report Writing team leader</b>	1	7,50,000.00
18	<b>Report Writing Research Associate</b>	2	12,00,000.00
19	<b>HR Manager</b>	1	7,50,000.00
20	<b>Head Quality Assurance</b>	1	15,00,000.00
21	<b>Clinical QA</b>	1	10,00,000.00

	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>
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The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

**h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

**i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.



All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R  714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials

management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any): NA**

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

**7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised**

unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

**10. Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

**11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/23-24/752 dated 03.01.2024.

**12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed

evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<u>Sr. No.</u>	<u>Content</u>	<u>Actual Study Subject Cost (INR)</u>	<u>Vendor Industry Cost (INR)</u>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>		5,40,000	7,65,000
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year		

<b>Overall Cost</b>		<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>
---------------------	--	------------------------	------------------------

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

#### 14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) –

The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

15. Loan disbursement schedule month wise. The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

16. GST certificate of the company is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions & Projections** (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.

10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst -  
[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) -  
[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:

**A. Land:**

- a) Total Area of the land used for the project.
- b) Layout Plan.
- c) Sale/Lease Deed.
- d) Current status/utilization of the land.
- e) Address of the Unit
- f) Google coordinates of the location.
- g) Attach sale deed.

**B. Building and Civil works:**

- a) Total Area proposed for the Building.
- b) Layout/ Site plan.
- c) Site Map Approval/Sanctioned.
- d) Details of the contractor's engaged.
- e) Attach agreement with contractor.

**C. Proposed Equipment:**

- a) List of proposed equipment as per below heads:
    - Serial Number, if any
    - Equipment name
    - Manufacturer name
    - Specification/capacity
    - Expected Landed Price
    - Current status of the order
  - b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
  - c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
  13. Pricing Strategy of the company along with selling & marketing plan.
  14. Updated agreements for the proposed unit, if any.
  15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).



16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:  
Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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Website: [www.rkassociates.org](http://www.rkassociates.org)

 Invoice for Skylimit Research.pdf  
189K

Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>Mon, Jun 3, 2024 at 12:06 PM

To: [clpc6277@pnb.co.in](mailto:clpc6277@pnb.co.in)

Cc: "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, "Shahid ." <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, "R.K Associates, The Valuers | LIE | TEV | ASM" <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, "Business Operations R.K Associates" <[bo@rkassociates.org](mailto:bo@rkassociates.org)>, FA Team <[fateam@rkassociates.org](mailto:fateam@rkassociates.org)>

Sir

As requested, please find attached financial model of SRPL.

Request you to not share the model further.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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Voice: +91-120 411 0117; 4324647

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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Mon, May 27, 2024 at 1:38 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:  
Dear Sir,

Please find the attached Final Tax Invoice for TEV Study of M/s Skylimit Research Ltd. Please make remaining payment asap.

On Mon, May 20, 2024 at 5:13 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

This is with reference to our discussion with the bank wherein they have permitted us to share the draft TEV report with you for your comments/reference. Please find attached copy of final draft of TEV report.

--

Thanks & Warm Regards,  
Aneesh Mallick

Consultant-Securities & Financial Assets



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**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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On Tue, May 14, 2024 at 11:12 AM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

Please find attached revised TEV report after extending the loan tenure to 10 years and moratorium period to 2 years.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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On Thu, May 9, 2024 at 7:04 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

Please find attached draft TEV report of CRO unit being setup by M/s Skylimit. This report is subject to final review.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets





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**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, May 7, 2024 at 3:21 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Please find attached invoices in respect of [sl.no.](#) quotations for S.No.10,11 & 12 for kind reference.

Thanks & Regards

For Skylimit research Pvt Ltd

Authorized Signatory

On Tue, May 7, 2024 at 1:32 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative are as highlighted in map and area in each floor already submitted.
2. Project implementation schedule was discussed in the meeting and it is again submitted as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copy of NOC of Fire department is also attached.
4. Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for [s.no.](#) 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report. Further, quotations for S.No.10,11,12 are from same supplier and all these are again attached.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 2:35 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor is attached herewith.
2. Project implementation schedule has been discussed in the meeting and it will be as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copies of applications are being provided.

4. Quotations for P&M for s.no. 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for s.no. 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 11:32 AM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to our meeting, please provide below details for report compilation -

- Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor.
- Project implementation schedule - dates/status (refer annexure 1)
- Regulatory approvals - dates/status and copy of application required (refer annexure 2)
- Quotations for P&M for s.no. 10,11,12,14,16,17,18,19,20,21,22,23 (refer annexure 3)

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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this message is **STRICTLY PROHIBITED**. If you have erroneously received this message, please delete it immediately and notify the sender. Before opening any attachments please check them for viruses and defects.

On Fri, May 3, 2024 at 4:00 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity is per month - 25,000.
- Total average Samples per subject - 60
- No of beds - 100 (170 from FY26)
- BA/BE studies capacity - 100 (170 from FY26)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:54 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity will be minimum per month - 12,000 which will be enhanced to 25000 samples per month or more as per the requirement.
- Total average Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:40 PM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:  
Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000
- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**

**and**

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per



protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period, is over after 7 to 25 days (depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

#### Response

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

#### Response

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000 X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000 X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000 X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000 X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>

10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5: As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.**

**Response**

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 : We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.**

**Response**

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA ,FDA for USA, EMEA for EU market, MHRA for UK , TGI for Australia and NPRA for Malaysia, and other ROW s, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 : Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.**

**Response**

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8 External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.**

**Response**

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.**

**Response**

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.**

**Response**

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :Kindly list down expenses which are linked to revenue and which are not linked with revenue.**

**Response**

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

**Query 12 :Proposed Shareholding Pattern.**

**Response**

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.**

**Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).**

**Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
- GST registration: Attached
- Pollution certificate: Applied and will be obtained in due course.
- Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
- Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.  
Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.
- EPFO registration: Will be obtained in due course
- ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**

**Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format**

**Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus

3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors
10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample dispensing, Bulk Spiking	1- channel, incl. Combipips advance rack, Combipips advance assortment pack Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA

13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:****Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- *EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.*
- *Bioanalytical Method Validation Guidance for Industry FDA- May 2018.*
- *Electronic Data – 21 CFR 11*
- *Good Laboratory Practice -21 CFR 58, ISO 17025-2017*
- *ISO 9001:2015, Quality Management Systems*

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

**Process are described schematically as under for analysis:**



**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).**

**Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August'2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.
- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
- Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well

S. No.	Equipment	Qty.	Use	Specification
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- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

--

Thanks &amp; Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Analyst



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Integrating Valuation Life Cycle -  
A product of R.K. Associates  
[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

--

Thanks &amp; Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Analyst



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Integrating Valuation Life Cycle -  
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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks &amp; Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
**(A Clinical Research Organization)**



VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service , the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete

1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>		<b>Total Clinical</b> Study cost for 30 subjects	5,40,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>

<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>
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The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	<b>Head Clinical</b>	1	25,00,000.00
2	<b>Principal Investigators</b>	2	30,00,000.00
3	<b>Research Associates for clinical department</b>	4	16,00,000.00
4	<b>Phlebotomists</b>	5	12,50,000.00
5	<b>Pharmacists</b>	2	5,00,000.00
6	<b>Trainee</b>	4	8,00,000.00
7	<b>Custodian and Recruiter</b>	2	15,00,000.00
8	<b>Head Bioanalytical</b>	1	15,00,000.00
9	<b>Team Leader</b>	3	36,00,000.00
10	<b>Research Associate</b>	4	20,00,000.00
11	<b>Trainee</b>	4	10,00,000.00
12	<b>Custodian</b>	1	7,50,000.00
13	<b>Clinical QA Associate</b>	2	10,00,000.00
14	<b>Bioanalytical QA</b>	1	10,00,000.00
15	<b>Bioanalytical QA Associate</b>	2	10,00,000.00
16	<b>Statistician</b>	1	6,00,000.00
17	<b>Report Writing team leader</b>	1	7,50,000.00
18	<b>Report Writing Research Associate</b>	2	12,00,000.00
19	<b>HR Manager</b>	1	7,50,000.00
20	<b>Head Quality Assurance</b>	1	15,00,000.00

21	<b>Clinical QA</b>	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

**h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

**i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are

bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

### 3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat, Director	02/01/2000	08163436	GXWPS7371P 806698463827	Graduate	04 years
Yash Pratap Singh, Director	11/08/2001	10075889	MSCPS9247R 226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R 714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical

device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P.)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

12. **Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in

the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<b>- Sr. No.</b>	<b>- Content</b>	<b>Actual Study Subject Cost (INR)</b>	<b>Vendor Industry Cost (INR)</b>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>		5,40,000	7,65,000
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000  <b>Plus</b>  7,50,000X 25 = Rs. Rs. 1,87,50,000  <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000  <b>Plus</b>  12,00,000X 25 = Rs. Rs. 3,00,00,000  <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000  <b>Plus</b>  7,50,000X 2 X 25 = Rs. 3,75,00,000  <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000  <b>Plus</b>  12,00,000X 2 X 25 = Rs. 6,00,00,000  <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>



	Pivotal study) in a year @ 65000/- per study		
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

#### 14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) –

The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

15. Loan disbursement schedule month wise. The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

16. GST certificate of the company is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.

5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst -  
[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

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Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:

**A. Land:**

- a) Total Area of the land used for the project.
- b) Layout Plan.
- c) Sale/Lease Deed.
- d) Current status/utilization of the land.
- e) Address of the Unit
- f) Google coordinates of the location.
- g) Attach sale deed.

**B. Building and Civil works:**

- a) Total Area proposed for the Building.
- b) Layout/ Site plan.
- c) Site Map Approval/Sanctioned.
- d) Details of the contractor's engaged.
- e) Attach agreement with contractor.

**C. Proposed Equipment:**

- a) List of proposed equipment as per below heads:
  - Serial Number, if any
  - Equipment name
  - Manufacturer name
  - Specification/capacity
  - Expected Landed Price
  - Current status of the order
- b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
- c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.

12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:  
Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

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Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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Website: [www.rkassociates.org](http://www.rkassociates.org)

 **Financial Model - SRPL\_Final (10Y).xlsx**  
70K

Aneesh Mallick <aneesh.mallick@rkassociates.org>

Mon, Jun 3, 2024 at 3:54 PM

To: clpc6277@pnb.co.in

Cc: "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <mohit.agarwal@rkassociates.org>, "Shahid ." <shahid@rkassociates.org>, Gaurav Kumar <gaurav.kumar@rkassociates.org>, "R.K Associates, The Valuers | LIE | TEV | ASM" <valuers@rkassociates.org>, "Business Operations R.K Associates" <bo@rkassociates.org>, FA Team <fateam@rkassociates.org>

As requested, please find attached complete financial model.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Mon, Jun 3, 2024 at 12:06 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

As requested, please find attached financial model of SRPL.

Request you to not share the model further.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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On Mon, May 27, 2024 at 1:38 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Please find the attached Final Tax Invoice for TEV Study of M/s Skylimit Research Ltd. Please make remaining payment asap.

On Mon, May 20, 2024 at 5:13 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

This is with reference to our discussion with the bank wherein they have permitted us to share the draft TEV report with you for your comments/reference. Please find attached copy of final draft of TEV report.

--

Thanks & Warm Regards,  
Aneesh Mallick

Consultant-Securities & Financial Assets



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On Tue, May 14, 2024 at 11:12 AM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

Please find attached revised TEV report after extending the loan tenure to 10 years and moratorium period to 2 years.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets





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On Thu, May 9, 2024 at 7:04 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

Please find attached draft TEV report of CRO unit being setup by M/s Skylimit. This report is subject to final review.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets





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**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, May 7, 2024 at 3:21 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Please find attached invoices in respect of [sl.no.](#) quotations for S.No.10,11 & 12 for kind reference.

Thanks & Regards

For Skylimit research Pvt Ltd

Authorized Signatory

On Tue, May 7, 2024 at 1:32 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative are as highlighted in map and area in each floor already submitted.
2. Project implementation schedule was discussed in the meeting and it is again submitted as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copy of NOC of Fire department is also attached.
4. Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for [s.no.](#) 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report. Further, quotations for S.No.10,11,12 are from same supplier and all these are again attached.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 2:35 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor is attached herewith.
2. Project implementation schedule has been discussed in the meeting and it will be as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copies of applications are being provided.

4. Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for [s.no.](#) 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 11:32 AM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to our meeting, please provide below details for report compilation -

- Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor.
- Project implementation schedule - dates/status (refer annexure 1)
- Regulatory approvals - dates/status and copy of application required (refer annexure 2)
- Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 (refer annexure 3)

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Fri, May 3, 2024 at 4:00 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity is per month - 25,000.
- Total average Samples per subject - 60
- No of beds - 100 (170 from FY26)
- BA/BE studies capacity - 100 (170 from FY26)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:54 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity will be minimum per month - 12,000 which will be enhanced to 25000 samples per month or more as per the requirement.
- Total average Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:40 PM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:

Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000
- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

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Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**

and

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection

for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period ,is over after 7 to 25 days(depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

#### Response

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

#### Response

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000

	Pivotal study) in a year	<b>Sub-total = Rs. 6,45,00,000</b>	<b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5:** As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.

#### Response

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 :** We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.

#### Response

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA, FDA for USA, EMEA for EU market, MHRA for UK, TGI for Australia and NPRA for Malaysia, and other ROWs, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 :** Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises is 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.

#### Response

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8** External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.

#### Response

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :**In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.

#### Response

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10:** Financial Model of the Project in excel with proper assumptions & Projections and rationale.

#### Response

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :**Kindly list down expenses which are linked to revenue and which are not linked with revenue.

#### Response

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.



**Query 12 :Proposed Shareholding Pattern.****Response**

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.****Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).****Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
- GST registration: Attached
- Pollution certificate: Applied and will be obtained in due course.
- Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
- Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.  
Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.
- EPFO registration: Will be obtained in due course
- ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).****Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format****Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C



				ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors
10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample	1- channel, incl. Combipips advance rack, Combipips advance assortment pack

			dispensing, Bulk Spiking	Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range  Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:**

**Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- *EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.*
- *Bioanalytical Method Validation Guidance for Industry FDA- May 2018.*
- *Electronic Data – 21 CFR 11*
- *Good Laboratory Practice -21 CFR 58, ISO 17025-2017*
- *ISO 9001:2015, Quality Management Systems*

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

**Process are described schematically as under for analysis:**

**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).**

**Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August’2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:  
 Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.
- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
- Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well

S. No.	Equipment	Qty.	Use	Specification
--------	-----------	------	-----	---------------

- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

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Thanks &amp; Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Analyst



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A product of R.K. Associates  
[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

--

Thanks &amp; Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Analyst



*World's first fully digital Automated Platform for  
Integrating Valuation Life Cycle -  
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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks &amp; Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)**

VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306

Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)

Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements), we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service, the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in

complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>

10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	Rs. 32,50,000	Rs. 32,50,000
11.Overall Cost	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	10,00,00,000	15,06,25,000

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	Head Clinical	1	25,00,000.00
2	Principal Investigators	2	30,00,000.00
3	Research Associates for clinical department	4	16,00,000.00
4	Phlebotomists	5	12,50,000.00
5	Pharmacists	2	5,00,000.00
6	Trainee	4	8,00,000.00
7	Custodian and Recruiter	2	15,00,000.00
8	Head Bioanalytical	1	15,00,000.00
9	Team Leader	3	36,00,000.00
10	Research Associate	4	20,00,000.00
11	Trainee	4	10,00,000.00
12	Custodian	1	7,50,000.00
13	Clinical QA Associate	2	10,00,000.00
14	Bioanalytical QA	1	10,00,000.00



15	<b>Bioanalytical QA Associate</b>	2	10,00,000.00
16	<b>Statistician</b>	1	6,00,000.00
17	<b>Report Writing team leader</b>	1	7,50,000.00
18	<b>Report Writing Research Associate</b>	2	12,00,000.00
19	<b>HR Manager</b>	1	7,50,000.00
20	<b>Head Quality Assurance</b>	1	15,00,000.00
21	<b>Clinical QA</b>	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

**h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs.

30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

#### **i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

#### **3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R  714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical

studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

12. **Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced

the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<u>Sr. No.</u>	<u>Content</u>	<u>Actual Study Subject Cost (INR)</u>	<u>Vendor Industry Cost (INR)</u>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>	<b>Total Clinical Study cost for 30 subjects</b>	<b>5,40,000</b>	<b>7,65,000</b>
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000 X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000 X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000 X 2 X 25 = Rs. 3,75,00,000	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000 X 2 X 25 = Rs. 6,00,00,000

		<b>Sub-total = Rs. 6,45,00,000</b>	<b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) –**

The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

15. Loan disbursement schedule month wise. The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

16. GST certificate of the company is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

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Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory



On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <shahid@rkassociates.org> wrote:  
Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:

**A. Land:**

- a) Total Area of the land used for the project.
- b) Layout Plan.
- c) Sale/Lease Deed.
- d) Current status/utilization of the land.
- e) Address of the Unit
- f) Google coordinates of the location.
- g) Attach sale deed.

**B. Building and Civil works:**

- a) Total Area proposed for the Building.
- b) Layout/ Site plan.
- c) Site Map Approval/Sanctioned.
- d) Details of the contractor's engaged.
- e) Attach agreement with contractor.

**C. Proposed Equipment:**

- a) List of proposed equipment as per below heads:
- Serial Number, if any
  - Equipment name
  - Manufacturer name
  - Specification/capacity
  - Expected Landed Price
  - Current status of the order
- b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
- c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.

12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd.  
Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

--

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Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

 **Financial Model - SRPL\_v6 (10Y).xlsx**  
163K

**Aneesh Mallick** <aneesh.mallick@rkassociates.org>

Mon, Jun 3, 2024 at 4:08 PM

To: m c bhatt pnb <mcbhatt13@gmail.com>

Cc: clpc6277@pnrb.co.in, "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <mohit.agarwal@rkassociates.org>, "Shahid ." <shahid@rkassociates.org>, Gaurav Kumar <gaurav.kumar@rkassociates.org>, "R.K Associates, The Valuers | LIE | TEV | ASM" <valuers@rkassociates.org>, "Business Operations R.K Associates" <bo@rkassociates.org>, FA Team <fateam@rkassociates.org>

Sir

As requested, please find attached financial model of SRPL.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Mon, Jun 3, 2024 at 3:54 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
As requested, please find attached complete financial model.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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On Mon, Jun 3, 2024 at 12:06 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

As requested, please find attached financial model of SRPL.

Request you to not share the model further.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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On Mon, May 27, 2024 at 1:38 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:  
Dear Sir,

Please find the attached Final Tax Invoice for TEV Study of M/s Skylimit Research Ltd. Please make remaining payment asap.

On Mon, May 20, 2024 at 5:13 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

This is with reference to our discussion with the bank wherein they have permitted us to share the draft TEV report with you for your comments/reference. Please find attached copy of final draft of TEV report.

--

Thanks &amp; Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Assets



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On Tue, May 14, 2024 at 11:12 AM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

Please find attached revised TEV report after extending the loan tenure to 10 years and moratorium period to 2 years.

--

Thanks &amp; Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Assets



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On Thu, May 9, 2024 at 7:04 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

Please find attached draft TEV report of CRO unit being setup by M/s Skylimit. This report is subject to final review.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets





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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, May 7, 2024 at 3:21 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Please find attached invoices in respect of [sl.no.](#) quotations for S.No.10,11 & 12 for kind reference.

Thanks & Regards

For Skylimit research Pvt Ltd

Authorized Signatory

On Tue, May 7, 2024 at 1:32 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative are as highlighted in map and area in each floor already submitted.
2. Project implementation schedule was discussed in the meeting and it is again submitted as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copy of NOC of Fire department is also attached.
4. Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for [s.no.](#) 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report. Further, quotations for S.No.10,11,12 are from same supplier and all these are again attached.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 2:35 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor is attached herewith.
2. Project implementation schedule has been discussed in the meeting and it will be as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copies of applications are being provided.



4. Quotations for P&M for [s.no. 10,11,12,14,16,17,18,19,20,21,22,23](#) are attached. The quotation for [s.no. 17,18,19,20,21 & 22](#) is same as we have provided the equipment details separately in the proposal/project report.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 11:32 AM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to our meeting, please provide below details for report compilation -

- Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor.
- Project implementation schedule - dates/status (refer annexure 1)
- Regulatory approvals - dates/status and copy of application required (refer annexure 2)
- Quotations for P&M for [s.no. 10,11,12,14,16,17,18,19,20,21,22,23](#) ( refer annexure 3)

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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On Fri, May 3, 2024 at 4:00 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity is per month - 25,000.
- Total average Samples per subject - 60
- No of beds - 100 (170 from FY26)
- BA/BE studies capacity - 100 (170 from FY26)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:54 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity will be minimum per month - 12,000 which will be enhanced to 25000 samples per month or more as per the requirement.
- Total average Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:40 PM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:

Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000
- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**

**and**

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for

sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period, is over after 7 to 25 days (depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

#### Response

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

#### Response

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000 X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000 X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000 X 2 X 25 = Rs. 3,75,00,000	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000 X 2 X 25 = Rs. 6,00,00,000

	Pivotal study) in a year	<b>Sub-total = Rs. 6,45,00,000</b>	<b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5: As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.**

**Response**

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 : We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.**

**Response**

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA, FDA for USA, EMEA for EU market, MHRA for UK, TGI for Australia and NPRA for Malaysia, and other ROWs, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 : Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises is 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.**

**Response**

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to the fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8 External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.**

**Response**

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.**

**Response**

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.**

**Response**

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :Kindly list down expenses which are linked to revenue and which are not linked with revenue.**

**Response**

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

**Query 12 :Proposed Shareholding Pattern.****Response**

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.****Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).****Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
- GST registration: Attached
- Pollution certificate: Applied and will be obtained in due course.
- Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
- Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.  
Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.
- EPFO registration: Will be obtained in due course
- ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).****Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format****Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright -

				86°C ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated-Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated-Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors
10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample	1- channel, incl. Combipips advance rack, Combipips advance assortment pack



			dispensing, Bulk Spiking	Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer , standard weighing	Ultra micro balance :For 1mg to 1gm weighing range  Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:****Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- **EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.**
- **Bioanalytical Method Validation Guidance for Industry FDA- May 2018.**
- **Electronic Data – 21 CFR 11**
- **Good Laboratory Practice -21 CFR 58, ISO 17025-2017**
- **ISO 9001:2015, Quality Management Systems**

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

**Process are described schematically as under for analysis:**





**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).**

**Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August’2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.
- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
- **Completion schedule of the Project (List down high level milestones and to be achieved date, COD).**
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well

S. No.	Equipment	Qty.	Use	Specification
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- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

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Thanks &amp; Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

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Thanks &amp; Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Analyst



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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks & Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)**

VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306

Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)

Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service , the company expects to garner total 50 studies (25 Pilot and 25

Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 18,75,00,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study)	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>

	in a year @ 65000/- per study		
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	<b>Head Clinical</b>	1	25,00,000.00
2	<b>Principal Investigators</b>	2	30,00,000.00
3	<b>Research Associates for clinical department</b>	4	16,00,000.00
4	<b>Phlebotomists</b>	5	12,50,000.00
5	<b>Pharmacists</b>	2	5,00,000.00
6	<b>Trainee</b>	4	8,00,000.00
7	<b>Custodian and Recruiter</b>	2	15,00,000.00
8	<b>Head Bioanalytical</b>	1	15,00,000.00
9	<b>Team Leader</b>	3	36,00,000.00
10	<b>Research Associate</b>	4	20,00,000.00
11	<b>Trainee</b>	4	10,00,000.00
12	<b>Custodian</b>	1	7,50,000.00
13	<b>Clinical QA Associate</b>	2	10,00,000.00
14	<b>Bioanalytical QA</b>	1	10,00,000.00
15	<b>Bioanalytical QA Associate</b>	2	10,00,000.00
16	<b>Statistician</b>	1	6,00,000.00
17	<b>Report Writing team leader</b>	1	7,50,000.00
18	<b>Report Writing Research Associate</b>	2	12,00,000.00

19	<b>HR Manager</b>	1	7,50,000.00
20	<b>Head Quality Assurance</b>	1	15,00,000.00
21	<b>Clinical QA</b>	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

**h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

**i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

### 3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R  714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence



studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any): NA**

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique

advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

12. **Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** -

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several

exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<u>Sr. No.</u>	<u>Content</u>	<u>Actual Study Subject Cost (INR)</u>	<u>Vendor Industry Cost (INR)</u>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>	<b>Total Clinical Study cost for 30 subjects</b>	<b>5,40,000</b>	<b>7,65,000</b>
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000

		<b>Sub-total = Rs. 6,45,00,000</b>	<b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

#### 14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) –

The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

15. Loan disbursement schedule month wise. The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

16. GST certificate of the company is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

## Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

=====

We assure our best services and response to you all the time.

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

=====

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

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Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <shahid@rkassociates.org> wrote:  
Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:
  - A. Land:**
    - a) Total Area of the land used for the project.
    - b) Layout Plan.
    - c) Sale/Lease Deed.
    - d) Current status/utilization of the land.
    - e) Address of the Unit
    - f) Google coordinates of the location.
    - g) Attach sale deed.
  - B. Building and Civil works:**
    - a) Total Area proposed for the Building.
    - b) Layout/ Site plan.
    - c) Site Map Approval/Sanctioned.
    - d) Details of the contractor's engaged.
    - e) Attach agreement with contractor.

**C. Proposed Equipment:**

a) List of proposed equipment as per below heads:

- Serial Number, if any
- Equipment name
- Manufacturer name
- Specification/capacity
- Expected Landed Price
- Current status of the order

b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.

c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.

12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).

13. Pricing Strategy of the company along with selling & marketing plan.

14. Updated agreements for the proposed unit, if any.

15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).

16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.

17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

---

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

--

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Website: [www.rkassociates.org](http://www.rkassociates.org)

 **Financial Model - SRPL\_v6 (10Y).xlsx**  
163K

**Aneesh Mallick** <aneesh.mallick@rkassociates.org>  
To: m c bhatt pnb <mcbhatt13@gmail.com>

Mon, Jun 3, 2024 at 4:12 PM

Forwarding the report again which we had shared earlier.

--  
Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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Uttar Pradesh- 201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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----- Forwarded message -----

From: **Aneesh Mallick** <aneesh.mallick@rkassociates.org>

Date: Mon, May 20, 2024 at 5:13 PM

Subject: Re: Quotation for TEV Study of M/s Skylimit Research Pvt. Ltd.

To: m c bhatt pnb <mcbhatt13@gmail.com>

Cc: <clpc6277@pnb.co.in>, Shahid . <shahid@rkassociates.org>, Gaurav Kumar <gaurav.kumar@rkassociates.org>, Mohit Agarwal (Executive Sr. Vice President), R.K Associates <mohit.agarwal@rkassociates.org>, R.K Associates, The Valuers | LIE | TEV | ASM <valuers@rkassociates.org>, Business Operations R.K Associates <bo@rkassociates.org>, FA Team <fateam@rkassociates.org>

Sir

This is with reference to our discussion with the bank wherein they have permitted us to share the draft TEV report with you for your comments/reference. Please find attached copy of final draft of TEV report.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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**PROHIBITED.** If you have erroneously received this message, please delete it immediately and notify the sender. Before opening any attachments please check them for viruses and defects.

On Tue, May 14, 2024 at 11:12 AM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

Please find attached revised TEV report after extending the loan tenure to 10 years and moratorium period to 2 years.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

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On Thu, May 9, 2024 at 7:04 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

Please find attached draft TEV report of CRO unit being setup by M/s Skylimit. This report is subject to final review.

--

Thanks & Warm Regards,  
Aneesh Mallick

Consultant-Securities & Financial Assets



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**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, May 7, 2024 at 3:21 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Please find attached invoices in respect of [sl.no.](#) quotations for S.No.10,11 & 12 for kind reference.

Thanks & Regards

For Skylimit research Pvt Ltd

Authorized Signatory

On Tue, May 7, 2024 at 1:32 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative are as highlighted in map and area in each floor already submitted.
2. Project implementation schedule was discussed in the meeting and it is again submitted as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copy of NOC of Fire department is also attached.
4. Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for [s.no.](#) 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report. Further, quotations for S.No.10,11,12 are from same supplier and all these are again attached.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 2:35 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor is attached herewith.
2. Project implementation schedule has been discussed in the meeting and it will be as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copies of applications are being provided.
4. Quotations for P&M for s.no. 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for s.no. 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 11:32 AM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:

Sir

With reference to our meeting, please provide below details for report compilation -

- Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor.
- Project implementation schedule - dates/status (refer annexure 1)
- Regulatory approvals - dates/status and copy of application required (refer annexure 2)
- Quotations for P&M for s.no. 10,11,12,14,16,17,18,19,20,21,22,23 (refer annexure 3)

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Fri, May 3, 2024 at 4:00 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity is per month - 25,000.
- Total average Samples per subject - 60
- No of beds - 100 (170 from FY26)
- BA/BE studies capacity - 100 (170 from FY26)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:54 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity will be minimum per month - 12,000 which will be enhanced to 25000 samples per month or more as per the requirement.
- Total average Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:40 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000
- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

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Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets





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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**

**and**



**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period, is over after 7 to 25 days (depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

**Response**

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

**Response**

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b>



	subjects in each Pilot study) in a year	7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5: As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.**

**Response**

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 : We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.**

**Response**

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA ,FDA for USA, EMEA for EU market, MHRA for UK , TGI for Australia and NPRA for Malaysia, and other ROW s, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 : Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.**

**Response**

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8 External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.**

**Response**

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.**

**Response**

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10: Financial Model of the Project in excel with proper assumptions & Projections and rationale.**

**Response**

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :Kindly list down expenses which are linked to revenue and which are not linked with revenue.**

**Response**

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.

**Query 12 :Proposed Shareholding Pattern.****Response**

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.****Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).****Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
- GST registration: Attached
- Pollution certificate: Applied and will be obtained in due course.
- Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
- Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.  
Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.
- EPFO registration: Will be obtained in due course
- ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).****Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format****Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors

10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample dispensing, Bulk Spiking	1- channel, incl. Combipits advance rack, Combipits advance assortment pack  Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range  Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:**

**Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- **EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.**
- **Bioanalytical Method Validation Guidance for Industry FDA- May 2018.**
- **Electronic Data – 21 CFR 11**
- **Good Laboratory Practice -21 CFR 58, ISO 17025-2017**
- **ISO 9001:2015, Quality Management Systems**

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

Process are described schematically as under for analysis:



**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).**

**Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August’2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:  
Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.
- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
- Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well

S. No.	Equipment	Qty.	Use	Specification
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- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Analyst



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Integrating Valuation Life Cycle -  
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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**  
D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

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Thanks &amp; Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Analyst



*World's first fully digital Automated Platform for  
Integrating Valuation Life Cycle -  
A product of R.K. Associates  
[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks &amp; Regards

For Skylimit Research Pvt Ltd

## Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**

(A Clinical Research Organization)

VILLA-2/9, LAND 2, JAYPEE GREENS,

GREATER NOIDA, UP-201306

Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)

Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers &amp; Techno Engineering Consultants (P) Ltd.,

Corporate Office : D-39, Second Floor, Sector-2,

Noida, Uttar Pradesh-201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements) , we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**



**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service, the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>

	Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study		
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected to conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	<b>Head Clinical</b>	1	25,00,000.00
2	<b>Principal Investigators</b>	2	30,00,000.00
3	<b>Research Associates for clinical department</b>	4	16,00,000.00
4	<b>Phlebotomists</b>	5	12,50,000.00
5	<b>Pharmacists</b>	2	5,00,000.00
6	<b>Trainee</b>	4	8,00,000.00
7	<b>Custodian and Recruiter</b>	2	15,00,000.00
8	<b>Head Bioanalytical</b>	1	15,00,000.00
9	<b>Team Leader</b>	3	36,00,000.00
10	<b>Research Associate</b>	4	20,00,000.00
11	<b>Trainee</b>	4	10,00,000.00
12	<b>Custodian</b>	1	7,50,000.00
13	<b>Clinical QA Associate</b>	2	10,00,000.00
14	<b>Bioanalytical QA</b>	1	10,00,000.00
15	<b>Bioanalytical QA Associate</b>	2	10,00,000.00
16	<b>Statistician</b>	1	6,00,000.00
17	<b>Report Writing team leader</b>	1	7,50,000.00

18	<b>Report Writing Research Associate</b>	2	12,00,000.00
19	<b>HR Manager</b>	1	7,50,000.00
20	<b>Head Quality Assurance</b>	1	15,00,000.00
21	<b>Clinical QA</b>	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

**h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs. 30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

**i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are

bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

### 3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R  714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida, which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

12. **Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

13. **Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking**

**done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<u>Sr. No.</u>	<u>Content</u>	<u>Actual Study Subject Cost (INR).</u>	<u>Vendor Industry Cost (INR).</u>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>	<b>Total Clinical Study cost for 30 subjects</b>	<b>5,40,000</b>	<b>7,65,000</b>
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
	Approximate cost for 50 studies (25 Pilot		

<b>Overall Cost</b>	and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>
---------------------	---------------------------	------------------------	------------------------

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD)** – The entire physical set up of the CRO will be completed by September’2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September’2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months’ time by December’2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September’2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December’2024.

**15.** Loan disbursement schedule month wise. The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December’2024.

**16.** GST certificate of the company is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.



10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

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Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:

**A. Land:**

- a) Total Area of the land used for the project.
- b) Layout Plan.
- c) Sale/Lease Deed.
- d) Current status/utilization of the land.
- e) Address of the Unit
- f) Google coordinates of the location.
- g) Attach sale deed.

**B. Building and Civil works:**

- a) Total Area proposed for the Building.
- b) Layout/ Site plan.
- c) Site Map Approval/Sanctioned.
- d) Details of the contractor's engaged.
- e) Attach agreement with contractor.

**C. Proposed Equipment:**

- a) List of proposed equipment as per below heads:
  - Serial Number, if any
  - Equipment name
  - Manufacturer name
  - Specification/capacity
  - Expected Landed Price
  - Current status of the order
- b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
- c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.

12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).

16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.

17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd. Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

--

Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

--

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 **Ms. Skylimit Research Private Limited Draft TEV Report\_v3.pdf**  
4107K

**Aneesh Mallick** <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)>

Mon, Jun 10, 2024 at 1:16 PM

To: [clpc6277@pnb.co.in](mailto:clpc6277@pnb.co.in)

Cc: "Mohit Agarwal (Executive Sr. Vice President), R.K Associates" <[mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org)>, "Shahid ." <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)>, Gaurav Kumar <[gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org)>, "R.K Associates, The Valuers | LIE | TEV | ASM" <[valuers@rkassociates.org](mailto:valuers@rkassociates.org)>, "Business Operations R.K Associates" <[bo@rkassociates.org](mailto:bo@rkassociates.org)>, FA Team <[fateam@rkassociates.org](mailto:fateam@rkassociates.org)>

Sir

As requested, please find attached revised financial model of SRPL.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Mon, Jun 3, 2024 at 12:06 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

As requested, please find attached financial model of SRPL.

Request you to not share the model further.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets





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**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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On Mon, May 27, 2024 at 1:38 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Please find the attached Final Tax Invoice for TEV Study of M/s Skylimit Research Ltd. Please make remaining payment asap.

On Mon, May 20, 2024 at 5:13 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

This is with reference to our discussion with the bank wherein they have permitted us to share the draft TEV report with you for your comments/reference. Please find attached copy of final draft of TEV report.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets





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On Tue, May 14, 2024 at 11:12 AM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

Please find attached revised TEV report after extending the loan tenure to 10 years and moratorium period to 2 years.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets





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On Thu, May 9, 2024 at 7:04 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

Please find attached draft TEV report of CRO unit being setup by M/s Skylimit. This report is subject to final review.

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets







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On Tue, May 7, 2024 at 3:21 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Please find attached invoices in respect of [sl.no.](#) quotations for S.No.10,11 & 12 for kind reference.

Thanks & Regards

For Skylimit research Pvt Ltd

Authorized Signatory

On Tue, May 7, 2024 at 1:32 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative are as highlighted in map and area in each floor already submitted.
2. Project implementation schedule was discussed in the meeting and it is again submitted as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copy of NOC of Fire department is also attached.
4. Quotations for P&M for [s.no.](#) 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for [s.no.](#) 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report. Further, quotations for S.No.10,11,12 are from same supplier and all these are again attached.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 2:35 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Dear Sir,

We submit the requisite information as under:

1. Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor is attached herewith.
2. Project implementation schedule has been discussed in the meeting and it will be as per the dates/status given in the referred annexure 1.
3. Regulatory approvals dates and status is as per referred annexure 2. Copies of applications are being provided.

4. Quotations for P&M for s.no. 10,11,12,14,16,17,18,19,20,21,22,23 are attached. The quotation for s.no. 17,18,19,20,21 & 22 is same as we have provided the equipment details separately in the proposal/project report.

Thanks and regards

For Skylimit Research Pvt. Ltd

Authorised Signatory

On Mon, May 6, 2024 at 11:32 AM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to our meeting, please provide below details for report compilation -

- Layout plan with clinical, bioanalytical, and administrative areas highlighted in map and area in each floor.
- Project implementation schedule - dates/status (refer annexure 1)
- Regulatory approvals - dates/status and copy of application required (refer annexure 2)
- Quotations for P&M for s.no. 10,11,12,14,16,17,18,19,20,21,22,23 (refer annexure 3)

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

**In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.**

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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in this message is **STRICTLY PROHIBITED**. If you have erroneously received this message, please delete it immediately and notify the sender. Before opening any attachments please check them for viruses and defects.

On Fri, May 3, 2024 at 4:00 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity is per month - 25,000.
- Total average Samples per subject - 60
- No of beds - 100 (170 from FY26)
- BA/BE studies capacity - 100 (170 from FY26)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:54 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:

Dear Sir,

We confirm having discussed and and consented on the following the facts in the meeting dated 29.04.2024-

- Sample processing capacity will be minimum per month - 12,000 which will be enhanced to 25000 samples per month or more as per the requirement.
- Total average Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- Average No of subjects per pilot study - 15
- Average No of subjects per pivotal study - 60

Thanks & Regards

For Skylimit Research Pvt. Ltd

Authorized Signatory

On Fri, May 3, 2024 at 3:40 PM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:

Sir

This is with reference to our face to face meeting on 29th April 2024. Request you to please confirm the facts stated below as discussed in the meeting -

- Sample processing capacity per month - 12,000
- Samples per subject - 60
- No of beds - 150 (170 from FY27)
- BA/BE studies capacity - 150 (170 from FY27)
- In house subject days per study - 4 days
- No of subjects per pilot study - 15
- No of subjects per pivotal study - 60

--

Thanks & Warm Regards,

Aneesh Mallick

Consultant-Securities & Financial Assets



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In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Sat, Apr 27, 2024 at 4:15 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

M/S SKYLIMIT RESEARCH PRIVATE LIMITED  
(A Clinical Research Organization)  
VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306  
Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)  
Mobile: 9719193909

Dt. 26.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office: D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 24.04.2024 regarding Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information/clarification as below:

**Query 1 : Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year**

**and**

**Query 2 : With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.**

**Response:**

Normally there are only 4 in house subject days for a pilot/pivotal study. The volunteers are first screened in the clinical department and the blood profile, KFT, LFT, BMI, RBC, CBC etc are conducted and if found as per SOP acceptance criteria, the subjects/volunteers are enrolled in the CPU Department where the Reference/Test drug is given to the subject and after dosing, samples are collected which may be number 25 or even more depending upon the molecules of the drug given as different drugs have different sampling points as per their Pharmacokinetic profile. After the drug is taken by the subject, he is kept in the CRO under monitoring & for sample collection

for 48 hours/ 2 days only i.e. inhouse sampling. After inhouse sampling ambulatory samples might be taken as per protocol. Samples will be stored in deepfreezer at CPU unit. After complete sampling for period 1 cycle samples will be shifted to Bioanalytical Department. After the wash out period of the first period ,is over after 7 to 25 days(depending on the drug profile), the subject is again called and the same procedure is repeated for period 2 cycle. The subject is again kept in the CRO under monitoring & for sample collection for 48 hours/ 2 days. The samples obtained are analysed in the Bioanalytical department by using LC/MS and other equipment and the data is sent to the statistical department who will analyse the data. As such, on an average, the in house subject days for a pilot/pivotal study are only 04 days and not 10 days which results in actual capacity of 100 BA/BE studies in a year with 100 beds. It is also submitted that after the total set up of the CRO, there is ample vacant space in the 2<sup>nd</sup> floor of the rented premises which will be used for providing 60 more beds.

**Query 3 : Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).**

#### Response

The BA/BE studies will be conducted by different types of generic drugs namely Small Molecule Drugs, hormones, endogenous molecules, Single and multiple dose (steady kinetics), FDCs, Immediate and Modified release formulations etc. We are offering services for ANDA and NDA applications for all over the globe and regulatory.

**Query 4: As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.**

#### Response

Average number of subjects (Healthy Volunteers/ Patients) of pilot BE study for a generic drug are 12 to 18 and for pivotal BE study for a generic drug, the average number of subjects are 30 to 180 depending on the drug and its variability. There are Highly variable drugs for which the within-subject variability (WSV) equals or exceeds 30% of the maximum concentration (C<sub>max</sub>) and/or the area under the concentration versus time curve (AUC). The bioequivalence of their formulations is a problem because the high variability means that large numbers of subjects are required to give adequate statistical power. Considering these facts, average number of subjects for pivotal BE study for a generic drug is given 60. As such considering above facts, in case of the pilot BE study for a generic drug, the number of subjects is revised to 15 (with standby subjects) only against the reported as 30 in the proposal submitted by us and the revised yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 75 studies (50 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Subject Cost (INR)	Study Vendor Cost /Industry Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 50 Pilot studies (covering average number of 15 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000

	Pivotal study) in a year	<b>Sub-total = Rs. 6,45,00,000</b>	<b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>11.Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

**Query 5:** As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.

#### Response

The average time for pilot and pivotal BE study and report generation is 2.50 months only for a small molecule generic drug which includes the time taken on screening, clinicals, Bioanalytical analysis and reports.

**Query 6 :** We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.

#### Response

We have not considered any export revenue in our model as initially the CRO will be working as per the approval and NOC provided by the Indian Regulator i.e. DCGI. However, the company has planned to apply and pursue for the ANDA/NDA, FDA for USA, EMEA for EU market, MHRA for UK, TGI for Australia and NPRA for Malaysia, and other ROWs, which will take substantial time and efforts. Therefore we have not considered any export revenue initially. However, the company expects to derive substantial revenue from the export market in addition to the domestic burgeoning market.

**Query 7 :** Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises is 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.

#### Response

Quotation for interior work shared is for 30,000 sq ft only against the carpet area 32,000 sqft. of leased premises due to fact that the 2000 square feet area is not covered for interior work. Entire amount of the quotation is inclusive of GST.

**Query 8** External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.

#### Response

We have negotiated with the EPC contractor M/S ADHARSHILA POWER CORPORATION for inclusion of the External civil work, lab set up and beds in the interior scope of work and it will be get done accordingly.

**Query 9 :**In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.

#### Response

In the CMA data shared, the EBITDA margins are initially decreasing and then increasing again in later years due to the fact that the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period which has resulted in the EBITDA margins initially decreasing and then increasing again in later years.

**Query 10:** Financial Model of the Project in excel with proper assumptions & Projections and rationale.

#### Response

Financial Model of the Project is already submitted in excel with proper assumptions & Projections and rationale.

**Query 11 :**Kindly list down expenses which are linked to revenue and which are not linked with revenue.

#### Response

All the expenses are mandatorily linked to revenue except the pre-operative/preliminary expenses have been capitalized initially and the amortization amount is being adjusted in revenues expenses over the period.



**Query 12 :Proposed Shareholding Pattern.****Response**

The company is limited by Shares with authorized capital of Rs.10.00 lacs and paid up capital of Rs.1.00 lac. The present shareholding of paid up Rs. 1.00 lacs is held as under:

Name of Shareholder	No. of shares held	Amount of holding in INR
Mr Karan Pratap Rawat	4000	40000
Miss Sandeepika Sharma	500	5000
Mrs Poonam Rawat	2000	20000
Mr.Yash Pratap Rawat	2500	25000
Mr Arjun Singh Rawat	1000	10000

The company has proceeded for increase of the authorized capital to Rs. 12.00 crores. The company will raise the paid up capital to Rs. 10.00 crores in due course.

**Query 13: Experience in the subject Industry of promoters/ directors.****Response**

Experience in the subject Industry of promoters/ directors: The company has already employed requisite staff for the preliminary work on the project which includes medical, administrative, accounts departments for assisting in the timely implementation of the project. The company has also enrolled Dr. Bratati Sanyal who has almost 20 years of experience working in the Clinical Research Industry and the requisite number of experienced & qualified staff are being recruited. Profile of Dr. Bratati Sanyal, who is supervising the project, is attached.

**Query 14: Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).****Response**

Status of Certificates/statutory approvals obtained and list of statutory approval need to be obtained:

- PAN Card: Attached
- GST registration: Attached
- Pollution certificate: Applied and will be obtained in due course.
- Statutory approval from Central Drug Standards Control Organization (CDSCO), India: The NOC & approval for conducting BA/BE will be initiated as soon as the physical set up of the CRO done and the requisite qualified staff are engaged in the CRO. Site registration process is ongoing.
- Statutory approval from Food and Drug administration(FDA) USA: Site is registered for USFDA ,ANDA and NDA submission. FDA Establishment Identification (FEI) of the site is **3030539257**, Data Universal Numbering System Number (DUNS) of site is: **644175087**.  
Statutory approval from other overseas regulatory bodies: The company will approach the respective Regulatory Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established and positioning of the requisite staff of the CRO.
- EPFO registration: Will be obtained in due course
- ESIC registration: Will be obtained in due course

**Query 15: Completion schedule of the Project (List down high level milestones and to be achieved date, COD).****Response**

Completion schedule of the Project. The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1st/2nd week of December'2024.

**Query 16: Technical specifications of the proposed equipment in the below format****Response**

Technical specifications of the proposed equipment in the format (kindly mention the use as well):

S.No.	Details of the equipment	Quantity	Use in the CRO	Specification
1	Haier make Freezer,	1	Sample Storage	230V/50 Hz. Model : DW-86L828J Type Upright - 86°C

				ULT Freezer Capacity : 828 Litres
2	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
3	600 bar HPLC	1	Analysis of samples	600 bar HPLC with DAD with Openlab CDS 2.7 Workstation plus
4	FLD single wavelength	1	Sample Detection	Single wavelength detection
5	SCIEX Triple Quad 4500 System	2	Analysis of samples	SCIEX Triple Quad 4500 System Upgradeable to QTRAP functionality with PN 5049829 Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer.- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
6	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap	2	Analysis of samples	SCIEX Triple Quad 5500+ System QTRAP Activated- Enhanced high performance triple quadrupole LC-MS/MS mass spectrometer with activated linear ion trap- Two Numbers Plus TQ/QT Software Starter Kit - with SCIEX OS-MQ 3.3- Two Numbers Plus CABLE* POWER INDIA 10A/250V- Twenty Numbers
7	Logan Water Jacketed Automated Transdermal Diffusion Cell System(24CellSystem)	1	For IVRT/IVPT sample analysis	System(24CellSystem)
8	Bio-eVap DP Nitrogen Evaporator	1	For Sample Processing	(Dual Press 144 Position) one set plus speX Series 144 Position Solid Phase Extraction one set plus Multitube Vortexer Main Unit two sets
9	5702 R with A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors	2	Sample separations	A-4-38 rotor incl. adaptor for 13/16 mm blood collection tubes, 2 set of 2 adaptors
10	Micropipettes	NA	Pipetting Device ,for aliquoting, sample dispensing, stock and dilution preparation.	Fixed and Variable range for Volume range 10-100 ul, 20-200 ul , 100-1000 ul and 500-5000 ul
11	Multipette M4 Starter kit , 1- channel,	NA	Pipetting Device ,for aliquoting, sample	1- channel, incl. Combipips advance rack, Combipips advance assortment pack



			dispensing, Bulk Spiking	Variable range for Volume range for 500-5000 ul
12	Kirloskar 125 KVA water cooled Genset three phase	1	Backup of electricity	125 KVA
13	Entris II Analytical balance and Cubis II Micro Analytical balance	1	Buffer standard weighing	Ultra micro balance :For 1mg to 1gm weighing range  Analytical Balance : For 20 mg to 220 gm weighing range
14	Agilent ICPMS – 7850	1	IVRT /IVPT sample analysis	Agilent ICPMS – 7850; • PC and Printer are included • Microwave Digestion Included • IQ/OQ included • Autosampler Included
15	Non Agilent Product Microwave Digestion system	1	Sample Incubation	NA
16	Agilent 600 Bar HPLC – 1260 Infinity II	1	Analysis of samples	1260 Infinity II with UV detector and Autosampler • IQ/OQ included
17	Agilent ECM – XT □ IQ/OQ included	1	Data Storage	XT Server to connect HPLC/LCMS and ICPMS
18	Agilent 1260 Infinity II HPLC	1	Analysis of samples	system with 800 bar pressure, Autosampler with chiller, Multicolumn compartment with thermostat and UV Detector.
19	Agilent 6475 LCMSMS		Analysis of samples	Nitrogen Generator included

**Query 17: BA/BE study testing standards/parameters as per regulatory requirements:**

**Response:**

All the activities of BABE will be conducted as per Standard Operating Procedures (SOP) based on various regulatory guidelines mentioned below:

- *EMA/CHMP/ICH/172948/2019 Committee for Medicinal Products for Human Use ICH guideline M10 on bioanalytical method validation and study sample analysis.*
- *Bioanalytical Method Validation Guidance for Industry FDA- May 2018.*
- *Electronic Data – 21 CFR 11*
- *Good Laboratory Practice -21 CFR 58, ISO 17025-2017*
- *ISO 9001:2015, Quality Management Systems*

**Query 18: Please mention the methods we will be using to establish BE**

Following Lab procedures will be followed to establish BABE:

**1.Optimization of Instrument Parameters:** In this process Instrument (MS) parameters are optimized as per molecule based on their polarities, Source parameter Optimizations, Compound Parameter Optimizations. Further LC parameters will be optimized comprising column, mobile phase, sample volume, temperature of analysis etc.

**2.Wet lab methods:** Before analysis samples are process to avoid contaminations. Three methods are used for that as per molecule chemistry.

**Protein Precipitation (PP)-** Protein Precipitation is suitable for highly water-soluble drugs and having low pKa values. Precipitating agents used are perchloric acid (PCA) (5-28 % solution), trichloro acetic acid (TCA) (5-25 solution), acetonitrile (1-3 fold of sample volume) and methanol (1-3 fold of sample volume), etc.

**Liquid-Liquid Extraction (LLE)** Liquid-liquid extraction is based on distribution coefficient of analyte(s), preferable organic solvents employed are, diethyl ether (DEE), dichloro methane (DCM), hexane, tertiary butyl methyl ether (TBME), ethyl acetate, isopropyl alcohol (1-5 % IPA in hexane), etc. and/or their appropriate mixtures.

**Solid Phase Extraction (SPE)** Select suitable SPE cartridge based on partition coefficient/ion exchange of analyte(s) (HLB, MAX, MCX etc.)

**Process are described schematically as under for analysis:**

**Query 19: Loan disbursement schedule month wise (% of loan to be disbursed by month).**

**Response**

Loan disbursement schedule month wise: Entire term loan amount Rs. 30.00 crores will be disbursed @ 25% each month i.e. entire amount of term loan will be disbursed by August’2024.

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Wed, Apr 24, 2024 at 2:37 PM Aneesh Mallick <aneesh.mallick@rkassociates.org> wrote:  
 Sir

Based on the data shared by you, please find below list of queries/requirements -

- Sample processing capacity in a year to compute maximum no of studies that can be conducted in a year
- With 100 beds, 10 in house subject days and 30 subjects for a pilot study and 60 subjects for a pivotal study, maximum no of tests that can be conducted are 40 in a year. We have considered our capacity as 100 BA/BE studies in a year.
- Please provide BA/BE studies to be conducted by type of generic drug (Small Molecule Drugs, Topical Drugs, Narrow Therapeutic Index (NTI) Drugs, Inhalers, Liposomes, Dendrimers, Polymeric Micelles, Iron Carbohydrate Complexes, Glatiramoids, Ophthalmic Emulsions, etc).
- As per research, average no of subjects (Healthy Volunteers/ Patients) for a small molecule for pilot and pivotal BE study for a generic drug are 10 and 30 respectively. We have considered the same as 30 and 60 respectively in revenue analysis.
- As per research, average time for pilot and pivotal BE study and report generation is ~7 months for a small molecule generic drug whereas we have considered the average time for BA/BE study as 2.5 months per study.
- We have not considered any export revenue in our model though most of our revenue is expected to be derived from the export market.
- Quotation for interior work shared for 30,000 sq ft whereas carpet area of leased premises in 32,000 sqft. Also, quotation is inclusive of GST whereas we have considered GST separately in capital cost.
- External civil work, lab set up and beds are not included in the interior scope of work. Please let us know the estimated cost for the same.
- In the CMA data shared, EBITDA margins are in the range of 16% to 41%. No clear trend in projections. Margins are initially decreasing and then increasing again in later years.
- Financial Model of the Project in excel with proper assumptions & Projections and rationale.
- Kindly list down expenses which are linked to revenue and which are not linked with revenue.
- Proposed Shareholding Pattern.
- Experience in the subject Industry of promoters/ directors.
- Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals/applications).
- Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
- Technical specifications of the proposed equipment in the below format (kindly mention the use as well

S. No.	Equipment	Qty.	Use	Specification
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- BA/BE study testing standards/parameters as per regulatory requirements.
- Please mention the methods we will be using to establish BE.
- Loan disbursement schedule month wise (% of loan to be disbursed by month).

Also, we have prepared a financial model encompassing balance sheet, statement of profit and loss and cash flow statement. We will be needing certain inputs from you to prepare detailed schedules on key line items and underlying assumptions for TEV purposes.

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Thanks &amp; Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Analyst



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Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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**We assure our best services and response to you all the time.**

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Tue, Apr 23, 2024 at 12:55 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

Kindly find the attachments

On Tue, Apr 23, 2024 at 12:17 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:

Sir

The attachments are missing in the email sent by you. Request you to please attach the files and send them again.

Thanks

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Thanks &amp; Warm Regards,

Aneesh Mallick

Consultant-Securities &amp; Financial Analyst



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**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9958632707

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

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**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 999597597

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On Tue, Apr 23, 2024 at 11:51 AM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly take reference of telephonic conversation held on 22.03.2024. We attach herewith quotations/work orders from M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307 and ARCHITECTS ATELIER H-123, Delta-2, Greater Noida regarding the entire interiors to be conducted in the CRO.

Thanks &amp; Regards

For Skylimit Research Pvt Ltd

Authorized Signatory

On Mon, Apr 22, 2024 at 1:07 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:

**M/S SKYLIMIT RESEARCH PRIVATE LIMITED**  
**(A Clinical Research Organization)**

VILLA-2/9, LAND 2, JAYPEE GREENS,  
GREATER NOIDA, UP-201306

Email: [skylimitresearch@gmail.com](mailto:skylimitresearch@gmail.com)

Mobile: 9719193909

Dt. 20.04.2024

To,

M/S R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,  
Corporate Office : D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

Sir,

**Reg: Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”**

With reference to your email dated 19.04.2024 regarding the work order for Techno-Economic Viability (TEV) study of “M/s Skylimit Research Private Limited”, we submit the requisite data/information as below:

1. Financial Model of the Project in excel is already submitted as per the CMA data. Regarding proper assumptions & Projections (balance sheet, statement of profit & loss and cash flow statements), we submit the detailed notes/schedules on key line items and underlying assumptions and rationale considered for forecasting as under:

The key financial projections of the company for next 03 years are as under:

Amount Rs. in crores

Particulars	31.03.25	31.03.26	31.03.27	31.03.28	31.03.29	31.03.30	31.03.31	31.03.32	31.03.33
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
Gross Revenue	4.00	22.00	35.00	42.00	50.00	59.50	66.35	79.62	95.55
% wise rise/fall in total sales	NA	450.00	59.09	20.00	19.04	19.00	11.51	20.00	20.00
PBDIT	1.85	8.30	10.15	11.90	11.55	12.20	13.10	19.99	30.64
PBT	0.55	1.30	3.45	5.50	5.45	6.60	8.00	15.29	26.34
PAT	0.41	0.98	2.58	4.12	4.09	4.95	6.00	11.47	19.75
Cash Accruals	1.41	4.97	6.58	8.12	8.09	8.95	10.00	15.47	23.75
Paid up capital	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
Tangible Net worth	10.41	10.97	12.59	14.12	14.08	14.95	16.00	21.47	29.75
Unsecured loans by promoters/relatives	2.00	4.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
Current Ratio	1.57	1.33	1.59	1.15	1.28	1.17	1.48	2.22	2.38
NWC	1.98	1.20	2.48	0.69	1.32	0.85	2.57	8.70	13.65
DSCR	1.73	1.80	2.05	2.71	2.70	2.98	3.31	5.06	7.71
Average DSCR	2.20								

**Justification for the above projections and assumptions is as under:**

**a. Revenues from operations:** The company is expected to start commercial operations in next 06 months after the establishment of full set up of the CRO and obtaining the mandatory approvals from the respective agencies. Based on the proposed Clinical Research Organization setup and the assumptions regarding the persistently growing demand for the service, the company expects to garner total 50 studies (25 Pilot and 25 Pivotal) in

complete 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As the revenue generation for the operations is expected to start from December'2024, the Company is expected to garner around 26.55% of the total 50 studies (25 Pilot and 25 Pivotal) in complete 1st year of the operations. The average revenue generation/billing for each Pilot study covering average number of 30 subjects in each study is Rs. 19.80 lacs and the average revenue generation/billing for each Pivotal study covering average number of 60 subjects in each study is Rs. 39.97 lacs on a conservative basis.

The yearly cost comparisons for actual study subject costs vis-à-vis vendor industry costs and expected revenues are outlined below for 50 studies (25 Pilot and 25 Pivotal) in a year:

Sr. No.	Content	Actual Study Subject Cost (INR)	Vendor Industry Cost /Revenues expected (INR)
<b>Clinical</b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30subjects	30,000	45,000
<b>Total Clinical</b>	<b>Total Clinical</b> Study cost for 30 subjects	5,40,000	7,65,000
<b>Bioanalytical</b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000X 25 = Rs. Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000X 25 = Rs. Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000X 2 X 25 = Rs. 3,75,00,000 <b>Sub-total = Rs. 6,45,00,000</b>	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000X 2 X 25 = Rs. 6,00,00,000 <b>Sub-total = Rs. 9,82,50,000</b>

10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	Rs. 32,50,000	Rs. 32,50,000
<b>11.Overall Cost</b>	Approximate cost for 50 studies(25 Pilot and 25 Pivotal) in a year	<b>10,00,00,000</b>	<b>15,06,25,000</b>

The above-mentioned Actual Study Subject Cost and Vendor Industry Cost /Revenues expected are expected to increase at the rate of around 6% annually which means that the above figures for overall cost will be Rs. 10.60 crores of Actual Study Subject Cost and Rs. 15.96 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2025-26. Further, the overall cost will be Rs. 11.23 crores of Actual Study Subject Cost and Rs. 16.92 crores for Vendor Industry Cost /Revenues expected for conducting 50 studies (25 Pilot and 25 Pivotal) in FY 2026-27.

The company expects to achieve total operational revenue generation of Rs. 4.00 crores in the 1<sup>st</sup> year of operations i.e. FY 2024-25 which represents around 26.60% of the total revenue for initially conducting 50 studies (25 Pilot and 25 Pivotal) in a year by conducting commercial operations during Dec'2024 to 31.03.2025. The company is expected to conduct around 70 studies (35 Pilot and 35 Pivotal) which will result in increase in total revenue of the company to Rs. 22.00 crores during the FY' 2025-26. During FY'2026-27, the company is expected conduct around 104 studies(52 Pilot and 52 Pivotal) which will result in increase in total revenue of the company to Rs. 35.00 crores during the FY' 2026-27.

**b. Paid up Capital & Net Worth:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

**c. Unsecured Loans:** To meet the substantial amount of pre-operative/preliminary expenses, the company has proposed to induce unsecured loans from friends and relative to the extent of Rs. 2.00 crores which will be enhanced to Rs. 4.00 crores in FY 2025-26.

**d. Expenses to be incurred in the operation of the CRO:**

**e. Manpower cost/Total annual salary bill during the 1<sup>st</sup> year of full operation:**

The company will have to employ minimum 45 number of highly or semi-skilled staff which will entail yearly staff cost of Rs. 2.88 crores as under:

S.No.	Designation of staff	No. of staff	Total annual salary
1	Head Clinical	1	25,00,000.00
2	Principal Investigators	2	30,00,000.00
3	Research Associates for clinical department	4	16,00,000.00
4	Phlebotomists	5	12,50,000.00
5	Pharmacists	2	5,00,000.00
6	Trainee	4	8,00,000.00
7	Custodian and Recruiter	2	15,00,000.00
8	Head Bioanalytical	1	15,00,000.00
9	Team Leader	3	36,00,000.00
10	Research Associate	4	20,00,000.00
11	Trainee	4	10,00,000.00
12	Custodian	1	7,50,000.00
13	Clinical QA Associate	2	10,00,000.00
14	Bioanalytical QA	1	10,00,000.00

15	<b>Bioanalytical QA Associate</b>	2	10,00,000.00
16	<b>Statistician</b>	1	6,00,000.00
17	<b>Report Writing team leader</b>	1	7,50,000.00
18	<b>Report Writing Research Associate</b>	2	12,00,000.00
19	<b>HR Manager</b>	1	7,50,000.00
20	<b>Head Quality Assurance</b>	1	15,00,000.00
21	<b>Clinical QA</b>	1	10,00,000.00
	<b>Total</b>	<b>45</b>	<b>2,88,00,000.00</b>

The company will have to spend Rs. 1.00 crores in partially recruited staff during the implementation period upto November'2024 and full staff deployment in full operations from Deceber,2024 to 31.03.2025. However, from 1<sup>st</sup> year onwards the staff cost will start to rise due to additional deployment of more competent/experienced staff and as such the staff costs are projected at Rs. 4.00 crores in FY 2025-26 and Rs. 5.00 crores in FY 2026-27, which are reasonable estimations.

**f. Expenses on Regulatory approvals to be incurred by the CRO:**

The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines.

Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India. and the company will have to spend/provide for significant amount of funds to the tune of Rs. 1.00 crores for obtaining the various Applicable Regulatory Approvals, Accreditations & Certifications from the concerned authorities.

**g. Lease Rentals:**

The Company has executed lease agreement on 29.01.2024 the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. At this rate the company will have to pay Rs. 76,80,000.00 to the lessor during the 1st year. In addition to it, the company has deposited a sum of Rs. 12,80,000.00 to the Lessor as Interest Free Security Deposit as per the terms of the lease.

**h. Interest on term loan:**

The company will have to pay monthly interest approximately @ 10% pa during the 1st year which will be covered in the Implementation stage and on the term loan limit of Rs.



30.00 crores, the approximate interest amount for the 1st year will be around Rs. 2.00 crores.

#### **i. General miscellaneous/operational expenses of the CRO**

The general operational expenses viz electricity, municipal taxes, housekeeping, watch & ward, conveyance charges, general maintenance, food & beverages, general medicines, necessary chemicals, compounds, consumables and other miscellaneous expenses to the tune of Rs. 1.00 crores have been stipulated during the Implementation period which are bound to rise as soon as the company enters the commercial operations phase as it also carries the stipends/fee/charges and other expenses to be incurred.

All the expenses enumerated above are subject to continuous increase over the years and the company envisages to incur total Rs. 335.00 lacs during FY 2024-25, Rs. 1800.00 lacs during 2026-27 and Rs. 2905.00 lacs during 2027-28 which are reasonable estimations.

**j. Profitability:** The company will be able to turn into net/cash profit in the 1<sup>st</sup> year of working with net profit(after tax) Rs. 0.41 crores in the FY 2024-25 and the company expects increase in net profit(after tax) to Rs. 0.97 crores in year 2025-26 which is expected to increase to Rs. 2.58 crores in year 2026-27 which is quite reasonable and achievable.

**k. Current Ratio:** The current ratio is expected to be 1.57 as on 31.03.2025 and it is expected to remain at 1.33 and 1.59 as at 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**l. NWC:** The NWC of the company is expected to be Rs. 1.90 crores as on 31.03.2024 and it is expected to remain at Rs. 1.98 crores, Rs. 1.21 crores and Rs. 2.48 crores as at 31.03.2025, 31.03.2026 and 31.03.2027 respectively which is reasonable and acceptable.

**m. DSCR:** The DSCR is expected to be 1.73 as on 31.03.2024 which is further expected to increase to 1.80, 2.05 and 2.71 as on 31.03.2025, 31.03.2026 and 31.03.2027 respectively due to increased profitability and the average DSCR is expected to remain at 2.20 which gives sustainable repaying capability of the company against long term advances.

**2. Proposed Shareholding Pattern:** The Company has authorized capital of Rs. 10.00 lacs which is being enhanced to Rs. 12.00 crores and the paid up capital is being enhanced to Rs. 10.00 crores during the year. With the retention of the net profits in the company, the net worth is projected to increase to Rs. 10.41 crores as on 31.03.2025, Rs. 10.98 crores as on 31.03.2026 and Rs. 12.98 crores as on 31.03.2027 as per projected financial data attached which is quite reasonable and achievable considering the strong prospectives of the sector.

#### **3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry):**

Name/ Designation	Date of birth	UDIN No.	PAN/ Aadhar No.	Qualification	Experience
Karan Pratap Rawat,  Director	02/01/2000	08163436	GXWPS7371P  806698463827	Graduate	04 years
Yash Pratap Singh,  Director	11/08/2001	10075889	MSCPS9247R  226536725538	Graduate	04 years
Sandeepika Sharma/ Director	20/07/2000	10399143	LXRPS6218R  714667948713	Post Graduate	03 ears

**4. List of the Raw material required with ratio, grade and specifications and cost:** The project is for setting up a Clinical Research Organization (CRO) unit for conducting Bioavailability/Bioequivalence studies dictated for the drug/medicine/pharmaceutical companies/manufacturers by the stringent regulatory guidelines. The contract research organization (CRO) provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

The CRO will provide such services as biopharmaceutical development, biological assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence. There is no manufacturing involved in the process and the CRO only requires various consumables, chemicals and other general working capital items which are mentioned in the detailed project report.

**5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any):** NA

**6. List of the expected customer-line** - The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. The clinical trials are performed to evaluate the safety and efficacy of new drugs and medical devices on human beings. Clinical trials are mandatory to introduce new drugs in the market place. All clinical trials go through four phases. Phase I trials test a drug's safety on healthy volunteers. Phase II and III trials test the drug's efficacy on patients. Phase IV trials are conducted once the drug is marketed to monitor for its safety in larger populations. Most of the clinical trial business in the global market originates from the US and Europe and are directed to countries such as India, China and those in Eastern Europe. The global clinical research sector is exploring India by increasingly outsourcing clinical trials. Analysts are projecting that total clinical research spending in India will increase by more than 50% annually by 2028.

Clinical research and development of a new drug comprises about two thirds of the total development costs. With increased focus on cost control across the global pharma companies, speedier, low-cost and reliable clinical trials are the major thrust of the manufacturers. Globally, clinical research is becoming a thrust research area as it is essential for the development of not only new drugs but also for new formulations and Drug Delivery Systems (DDS). With the advent of high throughput screening and bioinformatics tools, drug discovery processes have speeded up markedly making clinical evaluation and development as the rate-limiting controlling step towards final drug development. The global pharmaceutical market estimated at US\$ 1185.19 bn in 2023, is forecast to grow at a compounded annual rate of 5.9% to 2028, with global prescription drug sales predicted to be worth \$1.6 trillion in five years, according to the latest World Preview report published by Evaluate Ltd. In 2023, research and development spending in the pharmaceutical industry totaled some 244 billion U.S. dollars globally. There has been a paradigm shift in the pharmaceutical market, and nearly 66% of the R&D costs go towards drug development, i.e., approximately US \$146 bn. And clinical trials account for 70% of time and money spent in drug development. It is the most significant direct cost factor related to drug discovery and development process. On an average, it costs \$282 mn and takes about seven years to complete. Irrespective of the origin of a drug or whether its preliminary clinical research studies have already been conducted abroad, every new drug needs evidence from clinical research before it enters the market place. Thus, whether it is a new chemical compound or an existing drug that is being marketed for new indication, clinical research studies have to be conducted. Similarly, the launch of new drug formulations, DDS or even new fixed dose combination, requires clinical data before it can be marketed to users. Hence, it is obvious that the area of clinical research holds immense scope and potential, for without the supporting clinical data, market launches of drugs are not feasible. Clinical research should not be viewed merely as a subsidiary to pre-clinical research. On the contrary, it is of prime importance as it has to be conducted even in cases where pre-clinical

studies are not warranted, e.g., new formulations, fixed dose combinations or bioequivalence study.

India has become the most preferred destination for global clinical trials because of significant cost advantage and other resource advantages. The unique advantages that make India so attractive are the 3 'P's— Population, Patients and Physicians.

As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

However, there are no agreements/contracts or proposals from any user groups/entities at this stage.

7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site. The company has already started work on the project for which the company has already raised unsecured loan of Rs. 1,40,55,100.00 which is spent on the various fixed assets items electrical fitting materials, elevators, furniture, payment of salaries etc.

8. Site layout Plan is attached.

9. Google coordinates of the location are attached.

10. **Building and Civil works (leasehold improvements)** - The Company has executed lease agreement on 29.01.2024 for the premises situated at Plot no. 28, Sector 155, Phase II, Noida , which is a 04 story building constructed on a plot area 1000 square meters and the entire leasable area is 32000 square feet which is sufficient for the setting up of the CRO. The monthly lease rent is Rs. 6,40,000.00 and the initial lease period is for 5 years with 5% annual increase in rent after expiry of 12 months of lease period and the lease agreement shall be automatically renewed for next 05 years after the expiry of the agreement as per the agreed terms. The proposed site of the CRO is well connected with the rest of the NOIDA and Greater Noida and easily approachable to the leading hospitals in the Delhi/NCR area. The Leased premises having 32000 square feet of carpet area is sufficient to house the 100 beds for the subjects, clinical department, statistical/archive department, administrative, bioanalytical, screening, pharmacy and other areas. The leased premises are sufficient to smoothly conduct upto 250 studies each year. A copy of the registered lease deed is attached.

11. **Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.** No, The project is being implemented internally. However the entire interior work including false ceiling, wall partitioning, flooring, painting, internal electrical work including internal conduit wiring, fixtures/equipment's, lights, power, CCTV, camera, heating, ventilation, air conditioning, plumbing, fire fighting equipments, has been assigned/contracted to M/S ADHARSHILA POWER CORPORATION G- 200, Sector-63, Noida (U.P)-201307, a leading Techno-Commercial MEP & Interior work EPC entity vide contract no. APC/MRC/OFFER/ 23-24/752 dated 03.01.2024.

12. **Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals)** - The regulatory landscape in the pharmaceutical industry is complex and constantly & continuously evolving. CROs in India, need to navigate a multitude of regulatory requirements imposed by different regulatory bodies, starting from approvals from Central Drug Standards Control Organization (CDSCO), India to overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities. Regulatory requirements and approval processes can vary significantly across different regions and countries. CROs operating globally have to navigate these regional variations and adapt their strategies accordingly. Each region may have unique documentation requirements, local safety reporting obligations, and specific regulatory approval timelines. Regulatory reforms post 2013 and the introduction of New Drugs and Clinical Trial Rules of 2019 have partially streamlined the approval processes, reduced

the timelines by 30-40%, and introduced several exemptions and provisions to improve the overall efficiency of conducting clinical trials. In addition, some other initiatives like Audio Visual consenting of patients, Ethics committee registration, new compensation law and robust scrutiny system for the Clinical Trial applications have been implemented. These are aimed at streamlining the processes and making the systems transparent.

The company will approach the respective Regulating Authorities for the requisite Approvals, Accreditations & Certifications after the CRO is fully established consisting of the complete infra setup and positioning of the requisite staff of the CRO, which will take 06 months' time and another 03 months' time will be spent in the process of getting the Approvals, Accreditations & Certifications from the respective Regulating Authorities in India.

**13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.** The financial calculation encompasses a detailed evaluation, comparing the actual study subject cost with the vendor industry cost. The cost comparisons for actual study subject costs vis-à-vis vendor industry costs are outlined below:

<u>Sr. No.</u>	<u>Content</u>	<u>Actual Study Subject Cost (INR)</u>	<u>Vendor Industry Cost (INR)</u>
<b><u>Clinical</u></b>			
1	Clinical per subject cost	17,000	24,000
2	Study considering 30 subjects	5,10,000	7,20,000
3	Clinical test	1,000	1,500
4	Clinical test considering 30 subjects	30,000	45,000
<b><u>Total Clinical</u></b>	<b>Total Clinical Study cost for 30 subjects</b>	<b>5,40,000</b>	<b>7,65,000</b>
<b><u>Bioanalytical</u></b>			
5	Average cost for a single bioanalytical sample	500	800
6	Average cost for a single subject analysis for 50 tests	25,000	40,000
7	Average cost for a 30 subject analysis for 50 tests	7,50,000	12,00,000
8	Approximate cost for 25 Pilot studies (covering average number of 30 subjects in each Pilot study) in a year	5,40,000 X 25 = Rs. 1,35,00,000 <b>Plus</b> 7,50,000 X 25 = Rs. 1,87,50,000 <b>Sub-total = Rs. 3,22,50,000</b>	7,65,000 X 25 = Rs. 1,91,25,000 <b>Plus</b> 12,00,000 X 25 = Rs. 3,00,00,000 <b>Sub-total = Rs. 4,91,25,000</b>
9	Approximate cost for 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year	5,40,000 X 2 X 25 = Rs. 2,70,00,000 <b>Plus</b> 7,50,000 X 2 X 25 = Rs. 3,75,00,000	7,65,000 X 2 X 25 = Rs. 3,82,50,000 <b>Plus</b> 12,00,000 X 2 X 25 = Rs. 6,00,00,000

		<b>Sub-total = Rs. 6,45,00,000</b>	<b>Sub-total = Rs. 9,82,50,000</b>
10	Other Miscellaneous cost for 25 Pilot and 25 Pivotal studies (covering average number of 60 subjects in each Pivotal study) in a year @ 65000/- per study	<b>Rs. 32,50,000</b>	<b>Rs. 32,50,000</b>
<b>Overall Cost</b>	Approximate cost for 50 studies (25 Pilot and 25 Pivotal) in a year	<b>Rs.10,00,00,000</b>	<b>Rs.15,06,25,000</b>

Based on the proposed Clinical Research Organization setup and the above assumptions, there is gross profit margin of approximately 50%. The company expects to garner total 50 studies (25 Pilot and 25 Pivotal studies) in 1st year of the operations and the number of studies are expected to increase to 100 and 150 with 50% share of Pilot and Pivotal studies in the 2nd and 3rd year of operations. As far as, the prospective client line is concerned, there are around 1000 drug and medicines manufacturing companies/units in state of Himanchal Pradesh, Uttarakhand, Haryana and Uttar Pradesh which normally require services of the CROs for introducing any bio-equivalent and bio-acceptable medicine in the market. Presently most of the CROs are concentrated in the states of Maharashtra, Tamilnadu and Karnataka. As such there is strong demand of the services.

**14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) –**

The entire physical set up of the CRO will be completed by September'2024 and entire machineries/equipments will be made fully operational. All the key staff positions will be deployed and simultaneously formal application will be filed for obtaining the mandatory/requisite Approvals, Accreditations & Certifications from Central Drug Standards Control Organization (CDSCO), India, which is the prime regulatory body in India during August/September'2024. The company expects getting all the requisite Approvals, Accreditations & Certifications from the Regulating Authorities/ Central Drug Standards Control Organization within 03 months' time by December'2024. The approvals from other overseas regulatory bodies such as the U.S. Food and Drug Administration (FDA), the European medicines Agency (EMA), and other national regulatory authorities will be pursued thereafter. At the above stage in August/September'2024, requisite marketing will be initiated from the prospective clients in India and the normal commercial operations of the CRO will start from 1<sup>st</sup>/2<sup>nd</sup> week of December'2024.

15. Loan disbursement schedule month wise. The company has already decided the purchase contracts/work contracts with all the suppliers/service providers and the loan disbursement will start immediately alongwith the requisite margin to be provided by the company on pro-rata basis. Entire term loan will be fully disbursed by December'2024.

16. GST certificate of the company is attached .

Thanks,

Yours faithfully

For Skylimit Research Private Limited

Authorized Signatory

On Fri, Apr 19, 2024 at 3:07 PM Aneesh Mallick <[aneesh.mallick@rkassociates.org](mailto:aneesh.mallick@rkassociates.org)> wrote:  
Sir

With reference to the trailing email, please provide below details/documents -

1. Financial Model of the Project in excel **with proper assumptions** & Projections (balance sheet, statement of profit & loss and cash flow statements) - please provide detailed schedules on key line items and underlying assumptions and rationale considered for forecasting.
2. Proposed Shareholding Pattern.
3. Details of the Directors/Promoters (Name, Age, Qualification, DIN, **Experience in the subject Industry**) - please provide writeup on experience and qualifications.
4. List of the Raw material required with ratio, grade and specifications and cost - please provide detailed write up of consumables, etc required with expected consumption, cost and inventory holding period.
5. List of the expected suppliers of the raw material (kindly share the agreement/contract etc. if any).
6. List of the expected customer-line - please provide detailed analysis of end users (biopharmaceutical companies, research entities, etc) we expect to tap in India and abroad. (kindly share the agreement/contract/proposal etc. if any).
7. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, **water etc.**) at the proposed site.
8. Site layout Plan.
9. Google coordinates of the location.
10. Building and Civil works (**leasehold improvements**) - Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
11. Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.
12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals) - please provide a list of statutory approvals required (India and other countries) with date/expected date of approval. Kindly attach the approvals obtained/ copy of applications.
13. Pricing Strategy of the company along with selling & marketing plan - please provide details of type of services to be offered (pre-clinical, clinical, BA/BE studies, etc) and vendor industry cost backup/source of benchmarking done in detailed project report. Please provide details for India and other countries we expect to tap.
14. Completion schedule of the Project (List down high level milestones and to be achieved date, COD) - please list down high level milestones and expected date of completion of each milestone.
15. Loan disbursement schedule month wise.
16. GST certificate.

Thanks & Warm Regards,

Aneesh Mallick

Sr. Financial Analyst



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[www.valuationintelligentsystem.com](http://www.valuationintelligentsystem.com)*

**R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,**

Mobile No.- +91 9560630318

Voice: +91-120 411 0117; 4324647

**Corporate Office:**

D-39, 2nd Floor, Sector- 2, Noida

Uttar Pradesh- 201301

Website: [www.rkassociates.org](http://www.rkassociates.org)

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We assure our best services and response to you all the time.

In case of any concern regarding our services, you may refer to the escalation matrix below to reach out to my manager/ supervisor or write to us at [valuers@rkassociates.org](mailto:valuers@rkassociates.org) regarding your concern.

**First Level Escalation** - Mr Gaurav Kumar – Sr. Financial & Market Research Analyst - [gaurav.kumar@rkassociates.org](mailto:gaurav.kumar@rkassociates.org) – 9611908023

**Second Level Escalation** - Mr Mohit Agarwal – Sr. Vice President (Projects, Business Planning & Strategy Group) - [mohit.agarwal@rkassociates.org](mailto:mohit.agarwal@rkassociates.org) – 9999597597

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On Thu, Apr 18, 2024 at 12:28 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:26 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

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Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:25 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:24 PM m c bhatt pnb <[mcbhatt13@gmail.com](mailto:mcbhatt13@gmail.com)> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:22 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Thu, Apr 18, 2024 at 12:19 PM m c bhatt pnb <mcbhatt13@gmail.com> wrote:  
Dear Sir/Madam,

Kindly find attached the reply and other annexures for your kind perusal and necessary action please.

Thanks & Regards

For Skylimit research Private Limited

Authorized Signatory

On Wed, Apr 17, 2024 at 11:27 PM Shahid . <shahid@rkassociates.org> wrote:  
Dear Sir/ Ma'am,

Hope this email finds you well.

With reference to the work order for Techno-Economic Viability (TEV) study of **"M/s Skylimit Research Private Limited"**, kindly provide authentic & verified required data/information as per the below documents checklist:

1. Detailed Project Report of the Proposed Clinical Research Organization (CRO) Unit.
2. If no DPR, kindly provided the Information memorandum containing the detailed description about the project along with, Background, proposed capacity, expected capacity utilization & pricing strategies etc.
3. Financial Model of the Project in excel with proper assumptions & Projections.
4. Incorporation details of the Company along with organizational structure, MOA, AOA, GST, PAN, TAN etc. and brief write up of historical milestones/Financials or profitability statement (if any).
5. Proposed Shareholding Pattern.
6. Details of the Directors/Promoters (Name, Age, Qualification, DIN, Experience in the subject Industry).
7. List of the Raw material required with ratio, grade and specifications and cost.
8. List of the expected suppliers of the raw material (kindly share the agreement/contact etc. if any).
9. List of the expected customer-line.
10. Information regarding the Current Physical Status of the project along with current status of utilities (Electricity, water etc.) at the proposed site.
11. Details of the manufacturing facility/Infrastructures:

**A. Land:**

- a) Total Area of the land used for the project.
- b) Layout Plan.
- c) Sale/Lease Deed.
- d) Current status/utilization of the land.
- e) Address of the Unit
- f) Google coordinates of the location.
- g) Attach sale deed.

**B. Building and Civil works:**

- a) Total Area proposed for the Building.
- b) Layout/ Site plan.
- c) Site Map Approval/Sanctioned.
- d) Details of the contractor's engaged.
- e) Attach agreement with contractor.

**C. Proposed Equipment:**



- a) List of proposed equipment as per below heads:
- Serial Number, if any
  - Equipment name
  - Manufacturer name
  - Specification/capacity
  - Expected Landed Price
  - Current status of the order
- b) Kindly Attach Bills/ Invoices/ Purchase Order/ Any agreement with the suppliers/ Quotations.
- c) Is Project implemented through any EPC consultant? If yes then Details of the same like Name of the consultant, its website. Attach contract agreement with EPC consultant.

12. Certificates of statutory approvals obtained and list of statutory approval need to be obtained (Kindly attach the copy of approvals).
13. Pricing Strategy of the company along with selling & marketing plan.
14. Updated agreements for the proposed unit, if any.
15. Completion schedule of the Project (List down high level milestones and to be achieved date, COD).
16. Any market study performed at your end during planning of the product or any other relevant data for the assignment in your view.
17. Proposed manpower details (Semi-skilled, skilled, Un-skilled) along with proposed salary and wages.

Kindly provide the primary data as per the above checklist in an organised manner. We will further keep you posted in case of any data/information required during the preparation of TEV study report.

If any query/ concern please contact us.

On Mon, Apr 15, 2024 at 7:02 PM Shahid . <[shahid@rkassociates.org](mailto:shahid@rkassociates.org)> wrote:

Dear Sir,

Greetings for the day!!

Please find the attached quotation for TEV Study of M/s Skylimit Research Pvt. Ltd.  
Proposed plant situated at Plot No. 28, Sector-155, Phase-II, Noida

Please acknowledge the same over the mail so that we can proceed further.

Please make advance payment so that we can start the work.

If any query please contact to us

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Thanks & Regards,  
Mohd Shahid,  
Senior Coordinator Business Operation  
+91-9350027216

Mobile: +91-9350027216 | Voice: 91-120-4110117, 4324647  
R.K Associates Valuers & Techno Engineering Consultants (P) Ltd.,

Corporate Office: -  
D-39, Second Floor, Sector-2,  
Noida, Uttar Pradesh-201301  
Website: [www.rkassociates.org](http://www.rkassociates.org)

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## 2 attachments



**Financial Model - SRPL\_v7 (10Y).xlsx**  
162K



**Ms. Skylimit Research Private Limited Draft TEV Report\_v4.pdf**  
4081K