Innovating for affordable healthcare

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

30 August 2022

Corporate Relationship Department,
BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Fort,
Mumbai-400 001

National Stock Exchange of India Limited
Exchange Plaza, 5th Floor,
Plot No.C/1, G Block
Bandra Kurla Complex, Bandra (E)
MUMBAI-400 051

Dear Sir/Madam,

Sub: Intimation U/R 30 of the SEBI(LODR) Regulations - Transcript of Q1 FY23 Conference Call
Ref: Stock Code: NSE: SHILPAMED/BSE-530549

In furtherance to our intimation dated 23 August 2022 & 25 August 2022 with regard to the Q1 FY23 Conference Call held on Wednesday, August 24, 2022 at 03:45 PM IST, please find the enclosed transcript of the call.

With Regards,

For **SHILPA MEDICARE LIMITED**

Ritu Tiwary
Company Secretary & Compliance Officer

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

SHILPA MEDICARE

Q1-FY23 EARNINGS CONFERENCE CALL TRANSCRIPT
AUGUST 24, 2022

Mit Shah Thank you. Good afternoon everyone, and welcome to the concall hosted by management of Shilpa Medicare to discuss the quarterly performance and strategic initiatives underway.

The management is being represented by Mr. Omprakash Innani – Chairman of Shilpa Medicare; Mr. Vishnukant Bhutada – Managing Director; and Mr. Alpesh Dalal – Chief Financial Officer.

Mr. Vishnukant Bhutada will lead the discussion with the thoughts on the business model and strategy. He will be followed by Mr. Alpesh Dalal who will elaborate on the financial performance. There will be an opportunity to get queries addressed at the end of the opening remarks from the management.

I would like to state that certain statements made on today's call could be forward-looking in nature and a detailed disclaimer in this regard is mentioned in the earnings presentation which is available on the stock exchange's website.

I would like to invite Mr. Vishnukant to take the discussion forward. Thank you, and over to you, sir.

Vishnukant Bhutada Thank you. Thank you all for joining us on this call to discuss the first quarter performance of Shilpa Medicare and discuss the strategic development associated with the business. I hope that each of you is doing well and keeping safe. We have started this new initiative to keep in touch with all of you and provide regular updates about our operations.

I will try to give some brief introductions of our business and share my thoughts on the growth initiative and planned development, and then we will cover the highlights of the latest performance.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Introduction of the Shilpa Group

We have various segments like API, formulations, the film formulation, biologic. So, I will take one by one where the most important and the oldest was the API. In API, we were working majorly on the onco, non-onco, peptide, polymers, CDMO, and intermediates. I will take one by one.

Our API business is focused on challenging, of course, the complex oncology and high-end non-oncology products. We have distinctions of various firsts in API business. So, I will just give the latest. Fresh one is the like we were the first company to introduce the isolator technology in the API in oncology to manufacture. We were the first company to start the Tranexamic Acid. We were first to have a dedicated oncology, nine dedicated blocks in this segment.

So, see, the company's focus initially was on onco and working on a CDMO where we used to work with the ICE S.P.A., which is, of course, in a joint venture, and subsequently, it has been hived off.

As on 30th June '22, we had about we had about 40 onco APIs and 18 non-onco APIs in the market along with 212 DMFs filed across geographies including the US, Europe, GCC, RoW, and Canada, Japan, Russia, LATAM and China, and we are creating the presence in Polymers where a new R&D set up has been commissioned and the GMP facility for small and medium volume development has also been established

I am happy to share that we are the first company to be qualified by the DRDO to supply a fully indigenous high energy polymers to the Government of India. We have also received recently an award from these including the cash prize from the Government in recognition of our efforts in this direction.

And then we have a non-oncology segment where the various non-onco API have been taken into the portfolio. While taking the non-oncology portfolio, we are cautiously working because we know generic competitions is there, but three or four major criteria we are seeing on that. One is the capabilities of selling, scaling of this is possibility or not, backward integration including the entire intermediate, particularly depending on the China, can we crack that? And yield improvements.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

These are the four, five factors we are checking before selecting the non-oncology portfolio. Of course, oncology being our prominent area, and we are working since long. So, oncology we know very well where we have specifically developed the non-infringing processes, and globally, it is known that if Shilpa gives the product, then it is compliant with all global standards including the non-infringement if it is required.

What we are trying to do is whilst API industry is going through the difficult phase with declining selling prices and increased costs, we have been proactively working on various measures to ease out the pressure on our API business margins like yield improvement through the process changes, backward integration to the intermediates including reducing dependency on China, increasing the scale of operation by increasing the batch sizes and expanding the capabilities of the various manufacturing blocks.

And going forward, our API business, we would continue our existing focus on the established Onco segment while trying to reduce the dependency on it by adding niche high value Non-Onco products to our portfolio and the peptide business, the peptide, again, we are not doing the peptide as being a niche area and high entry barriers. We are working, we have put up the dedicated block for including the R&D and the production. Peptide we are working on that. Now this year, we will be able to complete. This financial year, we will be able to complete two products exhibit batches, and next year probably, we will be able to do another four products. So, next year by 2023-24, at least six peptides we will be completing in the exhibit batches.

On polymer, we are not working on the polymers which are normal polymers. We are working on a very specialized polymer where it is used as a drug carrier or high energy where there is an entire dependency on the import.

The second one is where we can give a drug carrier because the polymer is used majorly for making the non-infringing processes and the carrier where the drug delivery systems can be made very smooth. So, such type of polymers we are working, and we are happy to say that the various companies, last two years we are working on that, and we are getting the repeated orders from this company. Though it is a small initiation initially, but we feel that there is enough opportunity to grow into the polymer business. Peptide, of course, this is also the business where it will grow.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

The third segment we are seeing is the CDMO business. The CDMO, we were working CDMO since 2003 with the ICE S.P.A., which was the oldest CDMO we were working, but now it has been hived off. We restarted this CDMO business since last year and because of our credentials and the capabilities in Onco, Non-Onco, polymer, peptides, getting the CDMO business is much easy. All the people trust us, and we started getting the good inquiries, started working with the phase one, phase two, phase three. Some of the molecules we started working. We feel that in the coming year, the CDMO business also will grow to substantial level.

Coming back on the intermediates, the intermediates being the high trust area put by the Government of India as well as by the industry, China plus, the factor has come into the picture. So, what we are trying to do is the some of the intermediates where there is 100% dependency on the China, we are trying to manufacture that in-house using conventional chemistry or the flow chemistry. So, this is what we are trying to do and we are hoping that this business also will grow.

So, the Onco, Non-Onco, polymer, peptide, the CDMO, and intermediate. So, in this, particularly, if you see in our API segment, currently what we are doing it, currently the matured business is the API on Onco and some part of this one is a Non-Onco, and there is enough potential to grow in the polymer, peptide, CDMO, and the intermediates. Of course, the Onco and Non-Onco also will grow, but there are enough growth engines into the API.

Now on a formulation, the formulation is, again, we have a formulation which is the current facility what we have it in SEZ, there we have an import alert currently, which last 1.5 year we are working with the various consultants on this, and we have given the remediation measures; it has been almost completed.

We are regularly submitting to the FDA on this and the third party, those who have done this audit with respect to the import alert, we have made the significant progress in our remediation efforts with the submission of our CAPA to the USFDA. As on date, none of the consultants based on the retrospective review of all our ANDAs has suggested. None of ANDA has been suggested for recalling; indicating no challenges in relation to the data integrity. As we move forward to resolve the issues surrounding the import alert, we are pursuing an initiative to de-risk against single site operations. So, we are already working on shifting some of critical products to various USFDA approved CMO sites for both oral and injectables. Of course, Non-Onco anyhow we are working with the outside CMO business and that on Non-Onco, Derma or the other segment which we don't have in-house capabilities, we are already working with the other CMOs.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

So, in a formulation, this is a vertically integrated business, drawing significant synergies with our API segment and dedicated in-house research. Our range of products covers liquid and lyophilized injectables, sterile dry powder injections and oral solids in Oncology and adjuvant therapies. The segment is focused on sales of the complex products in key regulated and RoW markets.

The focus on the segment is on niche and value-added products together with a pursuit of strong strategic partnership model in order to give a better reach in key world markets. As on June 30th, we have 170 AMA, AMD and the other products approved in various markets along with 237 pending approvals that this covers the entire globe. So, including the US, Europe, Canada, Australia and entire Russia, The LATAM, CIS countries this includes. This is what current status.

Two broad aspects that differentiate Shilpa Medicare are our emphasis on the continuous research that gives the innovative products and manufacture the high-quality drugs at an affordable manner.

We have a robust research establishment backing our entire product range today and engaged in creating the product mix for the future. This includes product development and pathway engineering

Our focused R&D efforts have led us to create a portfolio of 505B2s and complex generics including working on solution for taking care of the nitrosamine impurities which is in certain products which is subject now currently which is going on in the US and other part of the world. The development of these complex products would allow us monetize the opportunities by licensing it out to the strategic partners and creating the value. Currently, we are working on various 505B2s and the complex generics development in Onco and the Non-Onco segments.

In the Dermatological segment, we have already launched one product in the woman hygiene segment, and we are registering our products in various countries.

Another product which currently we completed the Phase-3 study of Tranexamic Acid's spray, which is developed first time in the world by us. It is used as an anticoagulant in any sort of the accidents or in the injuries or in war or anywhere where we feel that the enormous use can be done with the Tranexamic Acid spray which was first time developed in the world by Shilpa. And the Phase-3 also we completed.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Now we have submitted to the SEC meeting for the approval. Once we will get the approval from the SEC, we will be able to launch.

The third product what we are doing in Derma is again on the hair growth which is Phase-1 study we completed. It is also a 505B2 or the hybrid application in the Europe and very high demand probably. So, we have successfully completed the Phase-1 study and now we will be taking once we take this approval from the various government authorities, we will be going to the Phase-3 level.

For the Ophthalmic segment, we have developed 2 505B2s and we ended two complex products. We are looking for the partners with the appropriate manufacturing set-up to license these products.

Ophthalmic products we have currently developed this portfolio, but we are not doing further investment in this. We are trying to see that once we partner this, then probably, we will be able to do, more complex products have been already identified, and if we get some good partner, we have enough capabilities in-house where we can develop this niche segment.

We are, again, in an oral dissolving film and a transdermal film. So, in a transdermal and the oral, we have a combi line, which is a first line in India where we have established the film and the transdermal both in a Bengaluru facility. Now this facility has been recently audited by the UK MHRA, and without any major and minor, we have recently got the clearance also from UK MHRA. Now with this approval, we will be able to launch the various products in the Europe and the other market.

In India also we are seeing where we will be able to launch this, the film formulation. Now, currently, we have developed almost seven products in the film formulation, and two or three products currently we are completing for the transdermal. Again, in this also, we are trying to see that there is a high unmet need in the patient ease of taking this formulation is important, and we are trying to do this in a film formulation.

We are trying to do the nutraceutical also where because of the COVID and other things, there is a high demand for the nutraceutical products in a film. Currently, we are trying to develop the 505B2 for the US also in a film formulation and a complex ANDA for the transdermal patch. So, this is what currently we are working on and with this EU and US submissions, hopefully, we should be able to get a good revenue generation in '23-'24, '24-'25.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

So, coming back on this formulation, then we have one more vertical which is a biologic. This segment is pursuing development of difficult products at a world-class research and manufacturing platform. We have currently 1 NBE (new biological entity) and 6 biosimilars in a limited competition space with significant cost advantage.

In past, we also selectively pursued vaccine production opportunities at our Dharwad site. Unfortunately, because of the COVID, which is subsidized, the vaccine has not gone the way in which we thought that this should go. But the capacity and this all has been created. Initial revenue generation commence at this stage through the CDMO agreement during Q4 '22 and to strengthen the CDMO segment, we are looking at a various further strategic tie-ups.

Coming to our own product portfolio, we have received approval from the RCGM for CT of the Aflibercept. We would be initiating the trials in the next month. I am happy to announce that we were the first company to get the Aflibercept RCGM clearance, and we are starting with the Phase-3 study. Aflibercept being a very complex molecule, around $9 billion molecule, no generics are currently available in India.

The second molecule which recently Phase-3 study we completed and announced also, the high concentration Adalimumab. The high concentration Adalimumab also where the originator has converted 80% of the market in the US and other part of the region, that high concentration Adalimumab nobody has launched in India. With this Phase-3 successful completion of using the European R&D, we completed this study, and this study we have submitted to the authority. Once we get the approval from them, we will be the first company to launch the high concentration Adalimumab into the India and because we use the European R&D for our Phase-3 study in India, we will be able to use this study for the RoW market also.

To sum up, we are our research-oriented company, pursuing differentiated strategy with the niche segments in key regulated and RoW markets. We have various strategies at the final stage of implementation and expect that coming years will see a superior business mix, backed by our own research and manufacturing capabilities that can deliver the robust growth and improved profitability profile.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

So, Shilpa currently has this where the API business is currently giving the revenue. Formulation has enough potential. API-formulation has enough potential to grow in various segments. Of course, biological is not giving any substantial revenue. With this, probably, we should be able to once now the facility is completed, we will be able to generate the revenue from this. Then the film formulation and the transdermal patches still we have not generated any revenue in this. So, these are the areas, and we are focusing now currently on an India launch also because in India also, we have an innovative product and the research oriented products where the high unmet need from the patients is still there, especially in oncology so that all formulations which we have currently filed in the US and Europe.

So, now I would like to ask our CFO, Alpesh Dalal to share the highlights of our financial performance.

Alpesh Dalal

Thank you very much, sir. So, welcome everybody. I will just quickly take you through the financial performance that our company has during the first quarter. In Q1 of this year, we basically clocked a growth of 13% on a consolidated basis with overall revenues of Rs. 269 crore. However, our gross margins, you know, took a bit of dip and gross margins are at 61% as compared to 68% during corresponding quarter in the previous year.

And the main reasons, you know, why we witnessed these erosions was on account of pricing pressure on some of our key products both in the API and formulation segment as well as, you know, where we also witnessed some cost hikes in some of our major products. So, both these things put together, you know, resulted in a slightly higher erosion in our margins.

However, the management team or the company as a proactive measure took certain cost rationalization measures and as well as, you know, we were also able to reduce some of our remedial costs for our Jadhchelra site, and all those approximations resulted into negating some of these effect of gross margin erosion that we have, and overall the EBITDA margins were at 11% as compared to 14% in the corresponding quarter previous year. So, our EBITDA for Q1 of this year was at Rs. 29 crore as compared to Rs. 34 crore during Q1 of '22. Whole at the PAT level on a consolidation basis, we had the small Rs. 2 crore profit as compared to a Rs. 3 crore profit in the previous year. So, there was slight dip there as well.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

From this particular quarter, I would also like to explain, clarify a bit on the standalone results that we had reported, because for our standalone results, we are required to report our results after segregating the performance of our API business because API business was supposed to be transferred on a slump sale business to another subsidiary. So, it gets classified as a discontinued business and hence, you know, we have to segregate the performance and show it slightly differently as per IND AS requirements. And on account of this slump sale that we had done in our standalone financials, we had recorded a gain of Rs. 63 crore on sale of our API business to our wholly owned subsidiary.

Now this gain of Rs. 63 crore along with, you know, reversal of certain deferred tax liabilities in relation to the API business resulted in showing the profit of Rs. 104 crore from our discontinued operations and the profit from our continued operations was at about Rs. 5 crore. So, that resulted in an overall PAT of Rs. 109 crore.

So, those were, you know, broadly the results. And just to give you a quick update on the kind of Capex that we incurred during the first quarter as manufacturing focus company, we end up incurring regular Capex and all. So, we incurred the Capex of about Rs. 53 crore overall at Group level, of which around Rs. 15 crore was invested in API business and a small investment of more of maintenance kind of Capex in our formulation business, again, a small investment of about Rs. 6 crore in our biological business, and we have invested about Rs. 29 crore in our Albumin business.

So, that's the kind of investment that we did in the first quarter on the Capex side. And going forward, we believe that, you know, the majority of our Capex would be focused on setting up our Albumin facility, and we are not planning to incur any further Capex on our biological Dharwad facility, and there would be some regular Capex that would come up for capacity expansion in our API business, and no significant Capex in the formulation business that we plan. So, broadly, that's how we are planning to allocate our resources in the near future.

And with that, you know, I would like to open up the forum for question-and-answer, and we will be happy to take any questions that we would have from the participants. Thanks a lot.

Moderator Thank you very much. Ladies and gentlemen, we will now begin the question-and-answer session. First question is from the line of Vineet Gala from Monarch Networth Capital. Please go ahead.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Vineet Gala I would like to thank the management for hosting this. I feel it's an excellent platform to understand more on the company and look forward to good engagement from the Shilpa management. So, my first question is on the recombinant albumin part. So, can you help us understand in terms of the timelines on the clinical trial, the size of the market that's targeting, and the monetization part for both the recombinant albumin as an excipient as well as other drugs? So, what are the timeline and the monetization that we are looking at?

Vishnukant Bhutada So, on albumin, we have received the already Phase-1 clearance to carry out this Phase-1 study from the Government of India. So, now what we are trying to do… we have to manufacture the batches, and we have to start the CT for this Phase-1. So, we will start by this year end hopefully, we should be able to start this by the albumin trials now, and excipient grade once we have now where, as you know, that we have one Shilpa Biocare also. We have started one separate unit where we are doing the 150,000 liter scale capacity for fermentation, where we are going to take this, the huge manufacturing of recombinant albumin near Raichur where we are putting up the plant. So, while putting up this plant, we are trying to complete this Phase-1 study and the Phase-3 study if government needs it. So, Phase-1 study will start by this yearend, and we should be able to complete in a nine-month Phase-1 study.

Vineet Gala So, sir, have we stabilized the product at a certain quantity? Like as you mentioned, we have started doing it side by side. So, have we stabilized our product at certain levels?

Vishnukant Bhutada Yes. Around 1k L we were able to 200 liter to 1k L, we have shifted this product. And we are able to scale the recombinant albumin.

Vineet Gala So, going by your timelines, so next year will we be able to sell the excipient? Is that a fair assumption and I believe more so in 2024 or '25?

Vishnukant Bhutada Yes. Definitely, we should be able to sell this, because by the time our DMF and all will be completed. Hopefully, we should be able to do that. Not only excipient grade. It is the excipient in the various drugs it is used. Excipient plus another two, three areas where still there is a huge demand for the recombinant albumin other than the drug also.

Vineet Gala So, sir, where do we see monetizing this? Like, I mean, are we going to, you know, some kind of an out-licensing agreement with the US partner? Like how do we go about monetizing? What is the kind of revenue that you look at from this albumin project?

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Vishnukant Bhutada See, we have to see all options which are the markets because albumin being the always shortage product in all over the world, and there is a high demand for even in an excipient grade also because of the unpredictability in whatever they are getting the current albumin, and there is impurity levels are very high. So, consistency of giving the drug where the excipient albumin has been used, so that difficulty is everybody's testing it with using this, the recombinant albumin, which is a 99.9% pure material, definitely, everybody needs it. So, in various geographies, still we are not discussing with anyone on this, but once we start Phase-1 study, probably, all options are open with us, and then if we do that, definitely, it will be informed to all.

Vineet Gala Last question on albumin would be like, is there any ballpark number that you have estimated given the kind of size that you have created on albumin? Like, I think, the capacities that we have on metric ton basis is around 80 metric tons. So, what are the revenues that we can do out of this particular plant?

Vishnukant Bhutada Once we are putting now almost 400 crore of the investment in this particular plant.

Alpesh Dalal Sir, if I can come in here, Vineet, you know, this should be a little premature to start giving some guidance about the revenue numbers growing in from there. You know, there will be a gradual build up as you rightly mentioned that, you know, first we will start getting our revenues from excipient grade, which is a smaller market and smaller size. But it can then keep expanding once we get the drug quality product out and our approvals are in place. Then you can start scaling up and building up fairly quickly. So, you know, at this juncture, I would suggest that, you know, based on the kind of capacity that we are creating which we have indicated, you can try and determine from the available market rates and levels that what potential revenues should be generated. But it would be a little premature for us to provide any guidance on the revenue side.

Vineet Gala Sir, my second question will be on this API IPO. So, in the Q4 call, what we mentioned is that we are looking to conclude the transaction by FY23. So, what is the status of the transaction now?

Alpesh Dalal So, Vineet, you know, as far as the API business is concerned, we have just concluded our slump sale of that particular business, and we have put it into a separate subsidiary, right? I think, we would allow some time for the operations to settle down as a separate entity, and also generate its own independent revenue, and its own independent performance to be visible and available.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

And it's right pointing them, I think, we should be able to take a call if we require to monetize some of these assets, which we are creating through our IPO subsidiary, sorry, API subsidiary, right? So, whether, like, obviously, our Board has given us a go ahead to explore an IPO if it is the most appropriate option, but we are still evaluating that and, you know, at a right point in time we will come out with our further updates and announcements on the same if and when we are going ahead with any of monetization of our APIs.

Vineet Gala Sir, my last question will be on biologics. So, sir, we have already invested around Rs. 100 crore in this Dharwad facility. And I mean, given the kind of projects that we take you mentioned it would take lot of time to conceptualize. But these are long lead projects. So, what is your perspective in terms of, you know, when these assets should start sweating and contribute to the revenue? And also, sir, given our debt position and the fact that some in biologics, they have not monetized to their full potential, I just wanted to understand your perspective as to why we are spending on further Capex as far as this Albumin asset is concerned? So, I just wanted to understand more on this part of the capital allocation.

Vishnukant Bhutada See, the most important is the, first of all, the mab manufacturing facility is separate and this albumin where the microbial facility is separate. So, these are the two separate areas where we are doing the investment. The mammalian manufacturing facility, which we currently from where the Adalimumab, Aflibercept and the other products has been there, this is a totally separate segment. Why we invested in the microbial facility where the albumin is there? Because as you know, that the albumin is always much shortage products all over the world. We have been able to successfully make this package, the 200 liters and submitted to the animal study completion in R&D Authority, and Authority has given us a Phase-1 trial permission that that has weighted what we have done, and we have a granted patent for the US and Europe. So, investment on this two separate, what we are doing is a separate area. I think you were mentioning some Rs. 100-crore investment, but we made in biologics around 600 crore investment, if I am correct. So, Alpesh, correct no?

Alpesh Dalal That's right, right. We have done Rs. 600 crore investment.

Vishnukant Bhutada So, around 600 crore has been invested in the mab facility currently, the mammalian facility. See, what has weighed in this particularly, what has not actually crystallized is the vaccine. So, vaccine has created the 1, 1.5 years a turbulence in everywhere.

What has happened? Our facility was, everything was ready, and suddenly the vaccine opportunity has come, and everybody was jumping on that. The DRL, Serum, everybody wants to manufacture including the Zydus.

They came in our facility, asked us to produce this, and they have signed the license agreement. Unfortunately, and with that R&D and our all resources has gone in that, developing that, taking it to the next level, and unfortunately, by the time we were ready, it was not able to, there was no demand, and we were not actual owner of that vaccine. So, ultimately, we were depending on someone else. So, they have backed out. Backed out in the sense they were also not having the order. So, that 1, 1.5 year property we lost in the focusing on our own mab. Of course, we have worked parallel. Phase-3 study was completed in that. The development was completed. Another three molecules are almost ready in the R&D.

We were the only company who has a cell line manufacturing. We manufacture our own cells also. So, cell line manufacturing department has been created. So, parallely, this work was going on, but we are not able to get this any substantial revenue from this. So, whatever the investment has been done, now we are trying to see that whether can we do the licensing of Adalimumab? Can we do the licensing of applications Aflibercept, including any other whatever the current development which is going on, which typically all company does it?

The co-development model was not done at our end. We wanted to establish and show to the company, other companies, saying that the most difficult product was first developed by us. It was not developed by the, you know, you name the company so called. Any, I don't want to name the company, but those who are known in the biologics, they were not able to develop and get this clearance on this high concentration Adalimumab including the Aflibercept also.

So, we wanted to establish first on our own and show to the world that we have enough capability, enough manufacturing capabilities including the R&D development strength. Now with this, the credentials, probably, now we will try to see that the co-development model or the manufacturing or CDMO, there are several opportunities in this, but being the biologic, it will go a little slow. That is what we feel.

Moderator Thank you. The next question is from the line of Manish Bhandari from Vallum Capital. Please go ahead.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Manish Bhandari Basically, I hear about the grand plans what we have on biologics as well as on albumin and the investment phase what we are into. But looks like there is a mismatch on the cash flow side because all these investments or the investment phase would require a lot of cash flows before the first drug comes out or gets licensed or whatever. So, what should be your strategy to bridge this cash flow deficit what we have in the next 18 months? And my second question is regarding the state of the formulations facility from the FDA?

Vishnukant Bhutada Yes, I agree that the overall cash flows and if all this, the investment which we have made into the biologic and the albumin currently, so Rs. 600 crore plus almost Rs. 100 plus crore we have invested already into the albumin. So, Rs. 700 crore plus cash has gone into these two plants or two segments rather I can say. So, now to see that the cash flow is again there into the system, what we have options. We are trying to explore the options including the Alpesh, the IPO, and the second one is licensing of all our formulations, whatever the OpEx we have it. Third one is the, again, working with the co-development model and the licensing note on the albumin or any other mabs which we have developed. So, there are various models concurrently, where we are working internally to see that, again, the cash flow is generated using our assets whatever currently we have it. Assets in the sense not the plant wise, but assets in the sense whatever the developments on the R&D spend which we have done.

Coming back on your second question on the formulation, you are asking on the remediation measures no?

Manish Bhandari Absolutely.

Vishnukant Bhutada Formulation as I already explained in my commentary saying that we are working on the remediation measures. We have completed almost all remediation measures what is expected by the FDA. Third party, all audits, everything has been completed. Fortunately, none of this, the FDA ex-inspector, nobody has consulted and asked or found out any data integrity or microbial or any sterility issue. That is why still we are supplying to the US suspension injectable product, and they are taking it currently, because there is in a shortage.

That shows that the quality was never compromised by the Shilpa, because this all reports also, the third party audits reports also to be simultaneously submitted to the FDA. So, they are continuously monitoring on the progress what we have done it. We had a call also with the FDA.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

So, we are waiting. We are continuously updating them on whatever the remediation measures, whatever we are doing it. Hopefully, we should be able to get the inspection maybe in this, we cannot predict, but we are waiting for the inspection.

Moderator Thank you. The next question is from the line of Rohan from ICICI. Please go ahead.

Rohan So, I have two questions. First of all, there is a sequential decline in the Onco API. So, is there any seasonality or some revenues which got deferred to Q2? This is the first question.

Vishnukant Bhutada Onco API, there is no such seasonality there. What we are feeling that overall not only in Onco, Non-Onco, the overall API industry, lot of people they are having because of the COVID and all, lot of people have taken the material in stock. So, they were feeling that these stocks can be utilized and because the supply chain was eased, so that is why now they are, you know, maybe utilizing this currently whatever the stocks they have it. This is what our gut feeling, and it will definitely from this quarter, next quarter onward, it will grow. And if you see Shilpa's Q1 of every year is normal it is off.

Alpesh Dalal So, Rohan, just to continue on that what Vishnuji just mentioned, you know, obviously, Q1 generally has been a bit soft for Shilpa historically. So, it's been slightly softer. Second thing is that we basically, you know, another part of your question was has any revenue got deferred to Q2? You are right. A part of our revenue because of the IND AS requirements and the revenue recognition requirements which are there, some of our revenues, which, you know, we actually made dispatches from our plant, could not be recorded as revenue because in income terms we could not recognize those revenues, you know, based on the IND AS requirements. So, a part of those revenues actually have got a bit deferred to Q2 as well. You are right on that front, Rohan.

Rohan And another question I had was, so what is the potential and opportunity for this biosimilar Adalimumab in India and RoW?

Vishnukant Bhutada Adalimumab, high concentration, still nobody is there. So, whatever we are comparing the data with whatever the 50 mg what they have, around Rs. 100 to 150 crore something with the reported figures are there. And of course, in the globally, other than the US, it's a total $20-24 billion product. So, globally, probably is such a highest selling product currently. But I think RoW we have not completed the study for the global.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

We have completed for the RoW and India market. We feel that there is enough potential being the first to come in this particular segment other than the originator. We'll have enough good market share in this.

Rohan And is there any capitalized expenses related to it, which will hit the P&L post the launch?

Vishnukant Bhutada No, I don't think capitalized expenses.

Alpesh Dalal There are certain expenses which have got capitalized, right? But it's not very substantial. So, it won't have any major impact on the P&L, but yes, there are certain capitalized expenses, intangibles that has been created for, you know, various studies that we have conducted and all. But it's not major.

Rohan Also on the RoW market which you had pertained to, so is there any RoW market specifically which you are targeting for this Adalimumab?

Vishnukant Bhutada Yes. The Russia or the Saudi. All the markets, probably, RoW has a huge including the Mexico, LATAM, all these countries are doing. Other than US, Europe, Canada, and Australia, probably, we should be able to get the partner in this area.

Alpesh Dalal So, Rohan, we would be open to partnership in various geographies apart from, you know, some of these developed markets that Vishnuji just mentioned. So, dependent on, you know, the kind of arrangement that we have or we are able to tie up for, we would be launching in various geographies based on that. This partnership, obviously, would then become, you know, in certain cases, it could become more of multi-country partnership. At times it could also be, you know, a specific country kind of partnership as well. So, that would depend on the kind of alliance that we end up having.

Rohan And the last question I had was, could you give an outlook on the CRAMS business? Is there any inventory on the books which is at the risk of write-off or anything on that?

Alpesh Dalal No, as far as CRAMS business is concerned, see, there is no inventory that we are holding on to on our books. Also, you know, this particular product is also common with one of our existing products as well. So, while our CRAMS business is continuing, but it is slowly coming down, and we are managing inventory based on the requirements. So, there isn't any risk of any inventory write off on the CRAMS business that we have been having.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Moderator Thank you. The next question is from the line of Jay Modi from EIML. Please go ahead.

Jay Modi So, in your earlier comments, you had mentioned that you see a delayed off take for biologics revenue. So, can you give us a broad time frame by when do you expect to utilize the gross block that you have invested in this plant? Will it be by FY25, '6? Just a broad guidance on that front?

Alpesh Dalal So, Jay, basically, whilst, you know, obviously, some of our products have got a bit delayed, and it may take some time, what we are trying to do in the interim is we are trying to look for more of CMO, CDMO kind of opportunities to utilize our facilities better, right? So, those are some of the low hanging fruits whilst we obviously, the kind of opportunity that we were looking for vaccine manufacturing has not fructified. But it has provided us a window to showcase our capabilities, you know, from a CMO and CDMO perspective. So, we expect that some of those revenues should start kicking in, which will help us in meeting the operational expenses, and that should start happening from current financial year, maybe the second half of current financial year onwards. And our own product portfolio as Vishnuji was mentioning, our first product Adalimumab probably should, could hit the market in Q3, and then that would be for the India market and all. And then we can start, you know, adding it, adding on more and more based on the kind of partnerships that we do in various markets. So, you know, it will be a gradual buildup, but till the time we are able to fully utilize our facilities, we will continue exploring more of CMO, CDMO or kind of opportunities as well.

Jay Modi So, by second half we expect to break even on this plant.

Alpesh Dalal See, this is again dependent on the kind of arrangement that we are able to garner for the CDMO, the CMO business, right? So, you know, if there are few things which are in pipeline, if things turn out well, then we could break even. But at the same time, you know, again, based on our historical experience, we wouldn't really want to start giving more of a finite kind of a comment on it.

Jay Modi My second question was that what is the investment, gross block investment that we would have made in the plant which is done by import alert currently?

Alpesh Dalal Gross block on this thing. It's around Rs. 350 crore but let me just reconfirm that number. So, gross block is about Rs. 350 crore.

Jay Modi So, is it fair to say that currently our total investment in biologics is Rs. 600, and this is around Rs. 300, so Rs. 900 crore of our gross block would be incurring, would have a negative profit contribution to our PMS?

Alpesh Dalal No, that wouldn't be correct, because by far Jadhchelra facility is under import alert. We still are allowed to export three products to the US market, right? So, we have been given exemption for three or five products that we can sell to US, and we are also selling to the European markets, you know, the products that we manufacture at our Jadhchelra facility. So, Jadhchelra actually is not a negative contributor to our bottom line, right? Our SEZ facility is not negative contributor. As far as the biological facility is concerned, it is obviously, you know, yet to start its real commercial operation. So, that has a negative contribution to the business.

Jay Modi And on the Capex front, so for next three years, what is our Capex plans? What is the amount that we intend on incurring every year?

Alpesh Dalal So, basically, you know, currently, the only major one that is required is on the albumin side as I had mentioned in my commentary. Apart from that, you know, broadly, for other investments and all, for our SEZ unit, which is our formulation business, we don't expect any major Capex to be done except for maintenance Capex that we have. And for API business, generally, we keep expanding our capacity based on the need and all. So, on an average, we end up doing anything between Rs. 40 to 50 crore kind of an investment in API business. And as far as biological business is concerned, we are not making many further investments into that facility of ours. So, I think we are done with our investment as far as the biological facility is concerned. So, predominantly, our investments will typically happen in our albumin manufacturing facility which Vishnuji had just mentioned in his commentary.

Jay Modi So, albumin needs more Rs. 400 crore, which will be invested over two years.

Alpesh Dalal Yes. So, not more Rs. 400. The total will be about Rs. 400. We already invested about 120 odd crore into it. So, it would require another Rs. 250 to 280 crore or 270 odd crore of investment in this.

Jay Modi My second question was around peptide. So, we had made a comment that we have around six exhibit batches which will be filed by FY24, correct?

Alpesh Dalal **FY** 23-24.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Jay Modi And how long does it take for these exhibit batches to get converted into commercial orders, and also, if you could broadly narrate the opportunity size that we have in these six products?

Vishnukant Bhutada Typically, if you know the API segment, once you complete the exhibit batches with the six month stability data, you can file the DMF. But meanwhile, while doing the exhibit batches, once you complete the exhibit batches, you can start giving the samples and everything. What here we are doing is, we ourselves are a buyer for this peptide. Actually, we are developing this complex in not only API, but complex formulations also where we are trying to see that this, the 505, either 505B2 or the complex generic is developed in-house. So, the portfolio is selected based on the first requirement from in-house only. And the second one is we are going to give it to the market. So, with this, typically, if you can say that the FY24-25 onward, we should be able to sell this product.

Jay Modi And broad opportunity size for these six products?

Vishnukant Bhutada These are a big opportunity I think. You know, the peptide is a biologic peptide and then something normal API. This is what. So, peptide is in between API and biologics.

Jay Modi And sir, lastly, internally, do you think that we have spread ourselves too thin in a lot of segments which is limiting our ability to scale up any one business in a meaningful manner, which would take up a lot of managerial bandwidth and which would have other restraints on the ability for us to scale up?

Vishnukant Bhutada Exactly, it is not correct. Yes, I agree that, partly, we are mid-sized. The company like ours is nobody has invested in such a segment like the Onco API first we have done it. The second one we have done the Onco injectable and the formulation, three on Onco injectable line, then biologics, albumin and the film formulation, and the transdermal film. But each of the area, the investment is already completed now. We have completed enough R&D expenditures also has been completed. Some of the products is already filed, and some of the products are licensed and going to be licensed. So, the capabilities on each of the segments has now started picking up.

So, I think, yes, I agree with you that the mid-sized company like ours, nobody has invested in a biological or the recombinant albumin or transdermal film and formulation so much. But yes, we are interested with the proper scientific justification in-house which we have made it. And I think we are able to do in each of the segments.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

If you see that in biologics, if you are able to develop this high concentration Adalimumab, Aflibercept, recombinant albumin, in a film formulation we were able to develop, it's difficult the transdermal patches, and the film formulations where the normal API is converted into the film, and then the 505B2s also can be filed in the US.

So, each of the segments we have done enough investment. Now this is the time to, you know, crystallize each of the segments. The bandwidth of the management is in each of the segments, we have the leaders who run that particular specialized business. Of course, management is looking after overall, but we have in-house the capable people including the R&D and the operations that take care of such a specialized business.

Jay Modi So, all the investments in R&D field, capacity building etc., since it is behind us, we do expect, internally, we do think that in next two, three years we will see some offshoots of the investment that we have made in past four, five years. Is that correct?

Vishnukant Bhutada Yes, of course, I think.

Jay Modi And this last question was, I missed your comment on this quarter's margin performance. So, could you just explain the reason for gross margin pressure in this quarter and if we will be able to reverse this in coming quarters?

Alpesh Dalal So, basically, you see what I had mentioned, Jay, was that during this quarter, we had a double impact where some of our key products were under pricing pressure. Also, cost of some of our other products had gone up. So, we basically got squeezed from both the sides. Now what we are doing is that, you know, to ease out some of these pressures, we are basically working on various optimization or process improvements and all, where we are able to get our costs down. We are able to then, you know, improve yield on some of our products, right? Also, when we do capacity expansion in our API business from existing block and all, so we are then able to utilize our, you know, existing, the same fixed costs get allocated to a larger base and all.

So, we are working on various measures of this nature to arrest the kind of pressure that we ended up getting on to our bottom line, right? At the same time, certain aspects, you know, some pricing pressure on the selling price that comes up probably may not go away immediately, but in certain cases, you know, the way a formulator when he feels pressure on the formulation in the markets, he tries and over a period of time passes it on to the API guys. API people also then try and, you know, do a **costing** effect onto these buyers and all.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

So, to an extent we are able to recover some of them over a period of time, but it doesn't happen immediately. So, we should be able to, you know, settle down at the current levels and then try and improve based on the operational efficiency plus some sort of, you know, rationalization that we take up with our suppliers and all.

Moderator Thank you. The next question is from the line of Vineet Gala from Monarch Networth Capital. Please go ahead.

Vineet Gala The licensing revenue that we get, what is the contribution of permit rights, the out-licensing that we did? So, if we could quantify that contribution on a quarterly basis? Sir, on a quarterly basis, we get around Rs. 17 odd crore in Q1. We got around 17 crore of license fees, right? So, what is the proportion of permit rights, the out-licensing that we did for the EU market, I guess?

Alpesh Dalal So, in Q1, you know, there wasn't any thing further in permit rights. See, what happens is in licensing deals, there are various milestones that come up. So, you know, actually, what Vishnuji was mentioning a while back, that we have done enough investment in our R&D, and now we are able to monetize some of these assets. So, various different assets are coming into play where we are able to get into licensing arrangements with, you know, our strategic partners, and different products and different molecules keep coming up. But these are all milestone based. So, what you get in one quarter, it doesn't mean that, you know, next quarter the same product and the same licensing revenues keep repeating. But it is, you know, opportunity based, based on the product that gets licensed and whenever the next milestone for this particular product is achieved, you get the next revenue out of that particular deal.

Vineet Gala So, how do we look at this particular line item? Because I mean, last two quarters we have recorded upwards of I think around Rs. 39 odd crore of this licensing fees. So, will this run rate continue over next couple of quarters or like it will taper down?

Alpesh Dalal No. So, see, basically, we have a very strong pipeline as we were mentioning. And you know, again, we do have a strong pipeline which we can capitalize on. It would really be dependent on the kind of deals that we keep striking at various points in time, right? So, in certain cases, you are able to get a decent upfront and then, you know, the later milestones could be slightly lower. In certain cases, the upfront might be slightly lower but then subsequent myself could be fairly heavy depending on the commercial situation.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

The kind of deals that we strike would determine the quantum that could come in. So, we cannot really say that there would be a specified run rate that we can talk about, but yes, we are targeting a particular level where, you know, on an ongoing basis, what you have seen in last quarters should at least continue.

Vineet Gala Sir, on the European formulation business, and so I was looking at the formulation business on a European under the US business perspective. So, US business is at around Rs. 12 crore run rate and Europe is around Rs. 37 odd crore run rate. So, given the potential, what is the run rate that we should be looking at given that in the US the products that we do are in sort of a demand because of the shortage situation that we have in the market as you mentioned? So, what is the kind of run rate, the base run rate that we can look at as far as these two segments are concerned?

Alpesh Dalal So, as far as, you know, Europe and US is concerned, see, currently, a large chunk of our business comes in from one particular product which has, you know, witnessed certain pricing pressure and all. So, that obviously has resulted into, you know, the revenues coming under, you know, settling down at a lower level and all. But again, as our pipeline keeps growing and we end up having more and more newer products coming in, which is where the growth of the US and European business for most Pharma companies come in from, we should start seeing an uptick in, you know, our revenues in both these territories, right? So, that is dependent on, you know, the timing of the approvals, various approvals that we get for our newer products.

As far as, you know, the settle down or existing business is concerned, well, you know, there could be some improvement that would happen because, you know, in certain one-off quarters, you could have a situation where, you know, because of inventory buildup, the one particular quarter might be weak and all. But Yes, the business has seen some pricing pressure and also newer, you know, players have come into the US market for this product. So, that has also resulted into added pressure on our revenue in the US market.

Vineet Gala Sir, my last question is on like Vishnu sir mentioned that we are looking to monetize a lot of these products and going in the domestic market. So, sir, like I just wanted to understand what is your assessment of our strength as far as marketing in the domestic market, the India market is concerned or are we looking at, you know, a marketing kind of a tie up or something of that sort? So, what will be the strategy going forward? And what is your assessment of the current strength?

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Vishnukant Bhutada As you know that we are launching this particular product in a various segment and because of the uniqueness of this product, lot of companies are approaching us for giving the in-license to them. Now we are, you know, making the assessment, should we give the exclusivity or should we give it parallelly to the other companies including our own launches? So, various options have been discussed on a product by product basis. We cannot decide that only we will launch all the products or we will not give to the any other companies; depends on the products and the opportunities. And of course, the revenue also need to look on balancing on that. This will take this, the decisions on the product basis, but I can tell you that we have enough potential and enough product pipeline in our portfolio which can generate good revenues in the future.

Vineet Gala Sir, like any product that we are looking to do for domestic formulation like we said? So, what kind of channel are you targeting? Are you targeting a b2c kind of a channel or you are targeting a direct to hospital kind of a marketing channel? So, what is the channel are we targeting as far as, you know, this segment is concerned? Because most of our products would be, you know, sort of complex in nature, but at the same time in thin films, and so we have an extremely different kind of a channel for, you know, the paracetamols and the other products that we have announced recently. So, I just wanted to understand like what is the channel that we are trying to build? And what are the products that we are trying to out-license?

Vishnukant Bhutada Channel I had mentioned already, that it will be a hybrid model, wherever the possibility, b2b, b2c, tendering, government entering, so hospital tendering. These are all options are there with us, and we will see every attempt to maximize the sales. This is what we are thinking that we will, of course, we will see what is the bottom line also we are getting it in that. So, to giving specifically answer on your question that we will see all options including the tendering's and all.

Moderator Thank you. Next question is from the line of Ritvik Seth from One-Off Financial. Please go ahead.

Ritvik Seth: Sir, just one question from my end. Sir, we have seen an addition of about Rs. 650 - 700 crore of gross block in last 2-2.5 years, you know, and you mentioned in a previous question that we will see launches of new products which will improve the revenue. So, you know, at peak utilization and with all product approvals coming in, is there any revenue that we can generate on the current capacity that we have added in the last 2 to 2.5 years and with all the investments that we have done in new products?

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Vishnukant Bhutada Yes, of course, you know, the biological facility, from there revenue can be generated. The second one is the film formulation and the transdermal patch where we have invested almost Rs. 150, 175 crore. From there, the current revenue is zero. That also is now because of the various approvals and completion of the exhibit batches. Definitely, the revenue from there also can be generated. The complex products which we have developed and filed already, some products we have filed already, where we can get a revenue generation by the licensing as well as the profit share model, that also can be done in the existing complex Onco, Non-Onco molecules. So, whatever the assets which were added in last two, three years, the Rs. 600, 700 or 800 crore, this is a time where things from this year onward, the revenue generation will start for sure.

Ritvik Seth: So, on this about say Rs. 1,500 crore of gross block, you know, what could be the peak asset turn that we could look at?

Vishnukant Bhutada See, currently telling will be difficult, but I think Alpesh, do you have any answer?

Alpesh Dalal So, see, typically, you know, Ritvik, it becomes a little difficult to quantify before and because see, it's a continuous process, right? You always keep investing a couple of two to three years in advance of the revenue generation that happens, right? If you were to see just as an example, today my, you know, gross block in my API business would be to the tune of roughly around say some over Rs 300 - 400 odd crore, which then we are able to turn two times, correct, which is a fairly stable and robust business. There also you keep adding on and you keep growing. So, typically, you know, that's the kind of, I think, and some of these businesses like formulation business or biological business, when they start peaking out, then they are able to actually turn the assets many more times than, you know, what API businesses can do.

Ritvik Seth: And one book-keeping question. What is the net debt as of June 2022?

Alpesh Dalal Net debt around Rs. 700 crore.

Ritvik Seth: 700? 700 crore, right?

Alpesh Dalal Net debt would be around Rs. 700 crore. That is correct.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Moderator Thank you. Next question is from the line of Rohan John from ICICI Securities. Please go ahead.

Rohan John: Thank you for the follow-up. So, I just had two questions. Why the other API revenue so high in Q1? Was there any one-offs in there?

Vishnukant Bhutada No, it is not one-off.

Rohan John: In the other API revenues, was there any one-off? It was quite high in Q1.

Alpesh Dalal So, you know, you are right, Rohan. There was some sort of trading revenue that got generated during Q1 in our API business, and we don't really indulge into more of trading kind of thing. So, that is not likely to, you know, continue in future.

Vishnukant Bhutada No, it was the one-time because of this or the 30th June our this one was expiring. So, we are moving to the next the Shilpa Pharma license that we (inaudible 01:16:54).

Alpesh Dalal So, you are right. A part of it was one-off, Rohan.

Rohan John: And another question, the last question I had was the Dharwad plant. Is it approved by any of the global regulators, let's say, USFDA, WHO?

Vishnukant Bhutada Which plant?

Rohan John: The Dharwad plant.

Vishnukant Bhutada Dharwad, no, it is not approved by any; because the authority will come once you file the product. So, you have to complete for that, you need to complete this study. So, if we take some CDMO project and all, now we are trying to complete this, the QP audit from the European authority which can be, you know, shown to the other companies for giving us this CDMO business, but currently, answering specifically on your question, no authority except Indian authority has completed. But yes, customer audit has been completed various including the DRL, the Serum, the Zydus. They have completed the audit, and then only the company had signed the agreement for the vaccine.

Moderator Thank you. We take the next question from the line of Srikant. That's an individual investor. Please go ahead.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Srikant: My question is how much of our R&D expenses are expensed? How much is the outright in the P&L? So, my question is how much of our R&D expenses are capitalized?

Vishnukant Bhutada Srikant, we can come back to you on that particular question a little later. You can send us a mail or something, and we will revert to that.

Srikant: And I have a second question. So, we have this film formulation technology, I think, from very long back, right? But we don't have a meaningful product in the US market with the film formulation. So, are there any specific challenges, you know, in getting the 505B2 products using the specific technology in US market?

Vishnukant Bhutada First of all, the film formulation was bought in India first time by Shilpa. So, getting the film formulation and accepting this as a delivery system was a challenging. So, what we have done is, we have done that India, our Hyderabad facility, where that was used for the Indian RoW market. There were no other companies were having this capability. So, we have completed all this work there. We have done enough expertise, but it can be a lot of pain to develop this product. It is not easy to develop such products in a film formulation.

Subsequently, what we have done in last 2-2.5 years, we have invested into the Bengaluru where the (Inaudible 01:20:21) machine has been bought from the Germany and there we have triggered the inspection from the UK MHRA, and that UK MHRA, we got the approval recently also from the UK MHRA. Because after getting the product strength, quality, stabilization from this all processed product, we are shifting these products to our Bengaluru facility. So, Bengaluru facility will have, once we have now the approval from the UK MHRA, and we filed some products in the Europe, probably we will get the again European approvals also. And in US, this year or the next year we will file the products in the US also. So, with this, we will complete all the global filings, and once we get the approval from this various authority, definitely, the traction will come on a sale.

Moderator Thank you. The next question is from the line of Sahil Chopra from KIFS Trade Capital. Please go ahead.

Sahil Chopra: By when we can expect the IPO of our API business.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Alpesh Dalal Sir, we had taken this question earlier where we had mentioned that, you know, we have just very recently done slump sell of our API business, and we would be, you know, allowing it to stabilize under the new entity for a while, also have its independent financial performance being witnessed and reported, and at the right point in time when we figure out, you know, what kind of monetization strategy we would want to adopt for our API business, right?

Sahil Chopra: And second question is related to the debt. What kind of debt figure we are looking for in next two years?

Alpesh Dalal See, depends on the monetization that we have for some of our assets that we have been talking about, right? We obviously are looking at gradually bringing it down and probably, you know, in the foreseeable future, we will try to see that we only end up retaining our working capital related loans on our book and then try and take everything out. But it will be, you know, in line with the monetization plans that we will have in place.

Sahil Chopra: So, I think that any revenue or margin guidance for next couple of years, if possible?

Alpesh Dalal No, Sahil, we wouldn't be able to avoid margin or revenue guidance.

Moderator Thank you. We will take the next question as a last question from the line of Jay Modi from EIML. Please go ahead.

Jay Modi I just had two questions. One was that, could you give us a broad understanding with respect to API business as to what percentage of your molecules would have some sort of backward integration like n minus 1, n minus 2 sort of backward integration in your API business?

Vishnukant Bhutada I think now answering this will be very difficult because we manufacture almost 40 odd API. So, this will be away, but we manufacture none of our DMF will be accepted without having the substantial manufacturing done at our facility. So, we are making some n minus three, n minus four, n minus seven. So, depends on the product and the KSM qualification divided by master file by the various authority who are taking this product. But none of the product like n minus one or n minus 2 we do it. We do it, you know, substantial backward integration. That much I can tell.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Jay Modi And secondly, with respect to the formulations, is that strategy around the, so do we file products wherein the API is solely manufactured by us or we are open to going for products wherein we may not have APIs with us, but we will still go with the ANDA filing? I'll repeat my question. So, for formulation business, do we go and file products only for which we have strong API manufacturing capabilities or that may not be our strategy?

Vishnukant Bhutada No, it is not so. Sometimes we use the external APIs and we do that formulation also. Also some of the APIs we don't manufacture, but we feel that there is a very good opportunity in the formulation. Some we do it as the second source for the additional qualification for the our formulation. So, two, three combinations we take it, but not necessarily that only we do with our only own API and then only we take the formulation. Yes, 70% probably so that once we have strong APIs, we do the formulation development also.

Jay Modi And my last question was around the site transfer. So, have all our products undergone site transfer which were filed from the facility wherein we had import alert?

Vishnukant Bhutada Yes, we have done already. Not all products. So, almost six products we are doing it now site transfer.

Alpesh Dalal So, Jay, we are looking at site transfer only of critical products because, you know, it may not make commercial sense to do site transfer of all of it, right? So, dependent on the size of the product and the commercial potential that it has got, you know, we look at the site transfer for those products.

Jay Modi Correct. So, those products which get categorized as critically important, all those products would have undergone site transfer or the process is still ongoing?

Alpesh Dalal No, still not completed. The process is ongoing.

Moderator Thank you. Ladies and gentlemen, that would be our last question for today. I now hand the conference back to the management for the closing remarks. Thank you and over to you.

Alpesh Dalal Thanks a lot. And I would like to thank all the participants for coming in and talking to us today. You know, it has been a great interaction that we have had. You know, we have just started this initiative recently, and we hope to continue this in future, and we look forward to your participation in future calls as well. Thanks a lot from all of us at Shilpa here. Thanks and I hand it over back to the moderator.

Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Moderator Thank you very much. Thank you, ladies and gentlemen. On behalf of Shilpa Meidcare Limited, that concludes today's call. Thank you all for joining us and you may now disconnect your lines. Thank you.