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

Date: 13 August, 2024

To

Corporate Relationship Department
BSE Limited,
1st Floor, Rotunda Building,
P.J. Towers, Dalal Street,
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,

Scrip Code: BSE - 530549/ Stock Symbol: NSE – SHILPAMED

Sub: Transcript of the Q1/FY 24-25 Conference call

In furtherance to our intimation dated 2 August, 2024 with regard to the Q1/FY24 -25 Conference call held on Friday, 9 August, 2024 at 11.00 AM IST, please find the enclosed transcript of the call.

Thanking you

Yours faithfully,

For Shilpa Medicare Limited,

RITU TIWARY
Digitally signed by RITU TIWARY
Date: 2024.08.13 15:20:36 +05'30'

Ritu Tiwary
Company Secretary & Compliance Officer

“Shilpa Medicare Limited Q1 FY25 Earnings Conference Call”

August 09, 2024

MANAGEMENT: **MR. KESHAV BHUTADA – EXECUTIVE DIRECTOR, SHILPA PHARMA LIFESCIENCES LIMITED**
MR. ALPESH DALAL – CHIEF FINANCIAL OFFICER, SHILPA MEDICARE LIMITED

Moderator: Ladies and gentlemen, good day and welcome to Shilpa Medicare Earnings Call for Q1 FY25.

As a reminder, all participant lines will be in the listen only mode and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing "*" then "0" on your touchtone phone. Please note that this conference is being recorded.

I now hand the conference over to Ms. Runjhun Jain from E&Y IR. Thank you and over to you, Ms. Jain.

Runjhun Jain: Thank you, Raj. A warm welcome to all the participants to the Q1 FY25 Earnings Call of Shilpa Medicare Limited. The "Financial Results" and the "Presentation" has been uploaded on the Company's website and on the exchanges. Please note that this conference is being recorded and the transcript along with audio of the same will be made available on the website of the Company, as well as the exchanges.

I would like to remind you that today's discussion might include forward-looking statements based on the current expectations and assumptions. These statements are subject to risks and uncertainties that could cause actual results to differ materially. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Now to take you through the Results and to answer your questions today, we have the management team from the Company represented by Mr. Keshav Bhutada – Executive Director of Shilpa Pharma Life Sciences Limited and Mr. Alpesh Dalal – Chief Financial Officer.

Now, I request Mr. Keshav to provide you with a "Brief Update" of the Quarter. Over to you, sir.

Keshav Bhutada: Thank you, Runjhun. A Very Good Morning, Everyone. Thank you for joining us today to discuss our Q1 FY25 results. I am Keshav Bhutada, and I will share with you various business segments brief overview before handing over to Mr. Alpesh Dalal, our CFO, who will provide the financial highlights post that, we can open the floor for any Questions that you may have.

Overall, I will give you major growth drivers in each segment and my briefing will be divided into four main verticals of Shilpa Group – API, Formulations, Transdermal Patch, ODF and Biologics.

So, let me start with the briefing of API business vertical. In the oncology segment, the major updates are that there were two NDA molecules which we were developing for our clients for many years in which NDA molecule #1 which we were developing for our US client, the client has received a breakthrough designation for the same product and for the same product NDA is

planned to be filed by our client in Q4 FY25. We have already secured a pre-launch order in this quarter for which the supplies will be done over the current quarter and subsequent quarters.

For the NDA molecule-II, currently the client project is under Phase-III supply. For the Phase-III clinical study we have successfully received order, for the same the delivery is already finished in the same quarter, and for this product, currently, the client is doing Phase-III three clinical studies.

Apart from that, two new oncology molecules, which is Abiretarone and Methotrexate, for which US DMF and European CEP is planned to be filed in Q3 FY25. And two new molecules plant scale up and validations in the oncology segments are already initiated and expected to complete in Q3 FY25. And for all four products, we are also developing our own formulation so that we are not dependent on only external sales, also we will have our internal captive formulation consumption. The major focus in oncology is with the existing portfolio, build a differentiated long-term complex pipeline which can give us sustainable growth in years to come.

Now, I move forward to non-oncology business, in which the most important update for the Company in this quarter was Ursodeoxycholic Acid, which is a very complex and niche API which we have in our grid, for which the European CEP was received in this quarter. With the approval of CEP, it opens a big opportunity for Shilpa Medicare in export markets, and in the quarters to come, we are confident that this molecule is expected to grow in export market in a large volume.

Apart from that, UDCA, which is again an NDA molecule for which Shilpa is already developing the formulation. For the same molecule the DMF is completed, and the initial launch quantity orders manufacturing has already started.

In the non-oncology segment, we have always kept our focus on import substitute molecules and complex molecule. So, we have successfully completed two new non-oncology molecule's lab validation. For the same product, the plant scale up is currently initiated and we are planning to finish the plant validation and subsequently DMF filing for two new molecules, which are complex and import substitutes, which can give us a sustainable revenue in the years to come.

Now, I move forward to new verticals which is CDMO peptide and polymers, which is again very important focus for Company. In the CDMO space, the major updates are - for the US client the preclinical supplies were successfully done. Now, the program has advanced to Phase-I/Phase-II clinical studies for which we have successfully received order and for which the supplies are expected to complete in Q2/Q3 FY25.

For the second client, which is from Taiwan, the program has moved to the Phase-III study and currently client has given us order for finishing the client scale up and validation batches and making drug master file ready which again gives us assurance that we will be one of the major

suppliers for the same client. For this product also, we are expecting to complete the plant validation in this financial year.

Apart from that, two to three new CDMO projects were signed in this quarter, for which initial large-scale development is commenced.

Now, moving forward to polymers in which our major focus has always been on developing specialty complex polymers. In Q1, we are happy to share that we could crack one more US MNC client, for which the initial sample order was successfully completed in Q1, and for which the order is already received for the pilot quantity, for which the supplies are expected to complete in Q2/Q3. Apart from that, there are many other specialty polymer projects which are currently in the development phase.

Now, moving forward to peptides, our major focus has been a mix of GLP-I portfolio and some complex products. I am happy to share our first GLP-I product, which is Liraglutide, for which the plant validation was successfully completed, which is a very complex API and the DMF for the same is expected to be filed in Q3.

And the second update in peptides is, for one of the European clients which is the NCE molecule for a new indication, we have successfully finished the initial development phase of the contract, and the initial supplies were finished in Q1. Now going forward, we are expecting the supply for Phase-I, for which the Company is geared up.

Apart from that, Semaglutide, which is again a second molecule in the peptide space, the large-scale development is finished and now our target is to finish the plant validation and make drug master file ready in this financial year.

The last important update is on the regulatory front. In Q1, we could finish the ANVISA Brazil GMP audit for almost 29 products in Unit-II and the audit was successfully completed. I am sure in years to come; this will give us a good opportunity in Brazil market also to sell our API.

Now, I move forward to the formulation business, in which the major updates are, our first NDA molecule for which we had received approval Pemetrexed for which the J Code was already granted. J Code is for premium pricing. Now, our partner has applied for the same product for K Code which will help them in insurance reimbursement for which they are expecting to get approval this quarter. So, going forward for Pemetrexed in the US, we are confident that in the quarters to come we are likely to gain good market share.

Apart from that, the second most important NDA molecule which Company had filed in the last financial year, we are likely to get approval for the same product in Q2/Q3 of FY25.

Now, the third update is, there is one more NDA molecule which is the oncology oral liquid, for which our partner had filed this product in the US, which is in the oncology space specially in

the oral liquid it is the first-of-its-kind US NDA which is filed and for which the approval is expected in Q4. With this, we are confident that for the US market, the pipeline is very well built up and the same will give us growth in years to come.

Apart from that, in European market, now I move forward to our upcoming big launch, which is for Nilotinib where I am happy to share that our regulatory review for the same product is completed and the launch for the same product is expected in Q3 and for this product Company has partnered with the #1 Company in the generic space in oncology selling in Europe. So, we are confident that this product also will give us good sales in the European market.

The second update in European market is on the Transdermal Patch portfolio where our first product will be filed in September of this financial year, for which the complex clinical studies are completed and is successfully passing, and the product is expected to be filed in Europe in Q2 FY25.

Two new Transdermal Patch products deals were signed in this quarter, again with various partners, for which the development is already started, which will give us the confidence that on the Transdermal Patch portfolio, we have a sequential pipeline, and the partner is ready to sell our product.

Apart from that, when I speak specific on the pipeline, we have two NDA molecules which is SMLNUD07 which currently Company has developed for NAFLD indication for India and emerging markets. Currently, the Phase-III studies are expected to complete in Q2 FY25 and we are expecting to file this product in Q3 FY25 in India and we will start partnering in various emerging markets.

The second product, SMLTOP09, which is for Androgenic Alopecia, for the same product the Phase-II studies were completed, and for the Phase-III studies we have applied in DCGI, and we are expecting to start the Phase-III study in Q3 FY25.

Overall, our focus in formulation has always been to build a differentiated and complex portfolio which will give us sustainable growth and Company is very focused on cost spending, and we are only investing on programs where we have a partner and where we are confident of selling those products.

Now, on the regulatory update which is on the USFDA audit of our formulation facility. So, we have finished the meeting with the USFDA, and they have suggested us to appoint some subject experts for which the appointment is completed, and the review has started, and we are expecting to complete the review in Q3 FY25. Subsequently post which we will be again applying to US FDA for further course of action.

Now, I move forward to Biologics business, which has always been our interest and where we have seen a good traction in the last two quarters and the same you will observe in the current quarter also.

So, in the biologics, our first product Adalimumab was approved in Morocco market, which was our first biologics approved in the export market and the same product is filed in many of the emerging markets currently we have filed, and we have started discussing on partnering also for the same products with other clients.

Now, the second product, the major update is on Aflibercept where currently our client scales up batches are ongoing, and we are expecting to start the Phase-III human studies for the same product in Q3 FY25.

The second major update on Aflibercept is we have finished the European scientific advice for the same product. We submit our study, our development data, our RLD data and we ask the EMA agency permission to start the Phase-III study. So, the initial advice has been positive and now going forward we will be submitting the permission for Phase-III study. And then for Europe also, we are starting to discuss with various partners in the European market.

Now, on the CDMO space in the biologics, the Korean client for which the complex project was well executed at our end, the various orders for the preclinical and Phase-I supplies have already started, and for the same, there was a GMP audit also with the same client which was very important for us to pass successfully. So, the Company could successfully finish the audit and now we are confirmed as a primary supplier currently for the client for the Phase-I and Phase-II supplies.

And apart from that, we have two new CDMO projects which are likely to be signed in second quarter FY25. And we are seeing very good traction in the biologics business where there is a lot of opportunity in the development space, in the manufacturing space, and we are confident that in quarters to come, biologics will be a very strong portfolio for Shilpa group.

Now, the last and most important update is on Albumin, where I am happy to share that Phase-I human study for the same product is completed and now we are rushing towards getting the permission for Phase-III study and we are expecting to start the Phase-III human study in Q4 FY25 and the study duration is for one year and the Phase-I study what we have completed was against the European reference product. So, the same Phase-I data will also be submitted to European regulatory authorities for asking them the Phase-III permission.

Apart from that, the US DMF filing for Albumin for the excipient grade was successfully filed which gives us more confidence on the quality of our product with not only manufacturing but also with the dossier quality.

Apart from that, the new facility for large scale Microbial Fermentation, the project is going well on track, and we are expecting to complete the project in Q3 FY25.

Last but not the least, we are delighted to announce a key CDMO signed during the quarter with Unicycive Therapeutics for Oxylanthanum Carbonate. We will be supplying to them the finished formulation along with our own API. We will be receiving US$ 10 million milestones for this deal. As informed earlier, we will build a dedicated facility for them which will be funded by the customer. Initial launch quantity orders are received from the client for which the manufacturing with the current facility will be starting in the quarters to come. Considering all the developments and expected growth in biologics, we have been building our teams further.

In conclusion, we are confident in our ability to continue delivering strong performance, driven by our robust R&D pipeline, operational excellence and strategic focus on licensing and CDMO. And Company's major focus has been on monetizing the existing assets and will continue to do so. We are committed to creating long-term value for our shareholders through consistent execution and innovation.

I will now hand over to Mr. Alpesh Dalal, who will Provide a Detailed Financial Overview.

Alpesh Dalal: Thank you very much, Keshav. Good morning, everyone.

Let me briefly take you through the Financial Performance for the 1st Quarter of the current Financial Year:

Our top line stood at Rs.302 crores, registering a growth of 15% YoY and this was driven mainly by our formulations business which witnessed healthy growth in the emerging markets as well as in the licensing segment that we are operating in. The gross profit for Q1 was at Rs. 200 crores with a margin of 68% as compared to 66% in the comparable quarter last year. The EBITDA for the quarter was at Rs. 83 crores compared to Rs. 50 crores in Q1, again, a strong growth of 66% YoY and EBITDA margins were also up at 28% from 19% during the same quarter last year.

I am also pleased to inform that this is the seventh consecutive quarter wherein we we re able to improve our EBITDA and EBITDA margins. And as we continue to optimize our cost and enhance our operational efficiency and rationalize our R&D investment, we expect to continue this momentum. Also, PAT for the quarter stood at 14%, registering a margin of 5%.

Now, just a Quick Update on the Segmental Performance:

Our API business clocked a revenue of Rs. 173 crores, up 4% compared to the same quarter last year. Typically for our API business, Q1 ends up becoming a seasonally soft quarter, which is generally visible historically as well. But however, we expect that robust growth should come in going forward in this business as well. Formulations business for the quarter was at Rs.104

crores, registering a growth of 13% YoY. Biosimilar revenue is Rs. 16 crores, which obviously is a new business that we have entered into. So, has a healthy 81% growth right over there.

Now let me take you through our balance sheet details. Our net debt as on 30th June 2024 stood at Rs. 514 crores as compared to Rs. 912 crores at the end of March '24. And our CAPEX for the 1st Quarter was Rs. 58 crores, which was again mainly driven by our investment in our Albumin facility that we are setting up.

With this brief introduction, I would like to now open the Q&A.

Moderator: We will now begin the question-and-answer session. The first question is from the line of Jigar Valia from OHM. Please go ahead.

Jigar Valia: One question if you can help with regards to Phase-II for Albumin, there is Phase-I and then all the updates are for Phase-III, so?

Keshav Bhutada: To give you a clear picture, currently in Albumin, we have finished a Phase-I study in which we have finished the evaluation of safety, immunogenicity as well as efficacy. Usually Phase-II is needed for compounds if the safety studies are not established in Phase-I. So, currently we have done a Phase-I/Phase-II study you can just tell that where we have also evaluated the safety of the product.

Moderator: The next question is from the line of Harsh from Bandhan, AMC. Please go-ahead Sir.

Harsh: Sir, two questions. One is on Albumin again. The Phase-I human trials are done and the excipient grade DMF is filed. Once you are done with the Phase-III trials, let's say at the end of fourth quarter of FY26, should we assume that these are global trials or these will be selective market launch, let's say, Europe and emerging markets, how should one think about the human launch in the end of the FY26 or early FY27 as well as the excipient grade launch?

Keshav Bhutada: I will first update you on the clinical study. What strategy we have planned currently is that there will be two studies which will be running in parallel. One study will be for India and emerging markets and there will be a separate study which will be running for European market, so the studies will run in parallel. In Europe, the procedure is once your Phase-I study is complete, you have to submit to EMA and take their advice, after that only you are allowed to start the Phase-III studies. For Europe, it will be a more elaborated studies, instead of 12 months, it will be maybe for 15 months. So, the strategy what we have built is, we will be doing two studies in parallel, one for India and emerging markets, and second one will be for Europe market. And on the second question on the excipient grade, the drug master file is filed. So, now various people will start using our Albumin as excipient in their formulation and then further they will be triggering it in their formulation and then we will be having a commercial high value sales for that application. But apart from that, there are many other applications which are non-GMP application, cell culture grade and multiple grades in Albumin. So, currently our focus is to build

a team which will promote this Albumin for excipient grade. So, for this, I will be able to give you more clarity on quarters to come as to how much sales we can do, and our focus is on getting good clients which can give us sustainable growth in excipient grade also.

Harsh: So, for the Phase-I that you have completed right now successfully, this data will then be submitted to EMA for their advice, which will help us to go into Phase-III for European studies?

Keshav Bhutada: Correct. So, even in Phase-I study before starting the study, we had done an EMA scientific advice and we had taken alignment with EMA for our Phase-I study protocol. After that only we had started the Phase-I study. So, the study what we have completed is very well applicable for EMA submission and for asking them for Phase-III permission.

Harsh: So, your Phase-I, which you have reported is very much in collaboration and the metrics which are required by the European authorities. If everything is successful then you will straight away move to the Phase-III part for both India, emerging as well as Europe.

Keshav Bhutada: Exactly. You are right.

Harsh: Just on this earlier comment of the two NDA molecules, one, the breakthrough designation part where you have secured the pre-launch orders and the second molecule with the molecules and the Phase-III studies. Could you help us give a little bit more color on the breakthrough designation candidate of what could be the overall commercialization timeline? Since it is a breakthrough designation, I am assuming that it will be a decent size market, but it may not be a billion dollar plus market to that extent. So, anything for us to understand, particularly for the breakthrough designation product molecule?

Keshav Bhutada: Currently for the first molecule which is in breakthrough designation, our partner studies have been successful, and they are planning to file NDA by end of this year. Currently, that is what they have given us as a plan and post which they will be having approval if everything goes well in the next financial year. So, I will be able to give you a right picture in the quarters to come because as and when the program advances, that is when usually there are more chances of having a long-term arrangement which you would have seen in case of Unicycive Therapeutics. So, there will be more advancements which will be happening in both the molecules in the quarters to come. So, currently. I will not be able to give you a clear picture on how big it will be, or how many billions, but I can tell you that having a breakthrough designation with such a niche opportunity, it is surely a good opportunity for Shilpa as a group.

Harsh: And the timeline for the second molecule will obviously succeed the timelines for the first molecule which is under breakthrough designation?

Keshav Bhutada: Yes, for the second molecule, it will all depend on the Phase-III study outcome for our partner, for which we are surely expecting some results for that in the next financial year. So, we will be able to give you more updates on that later.

Harsh: On Liraglutide, you mentioned that the plant validation is complete. And for Semaglutide, you mentioned the large-scale development is finished. If you could give us a little bit more color on the general timeline, what could come next for both these products, and when does the conversation with the client happen, like in which financial year would that supply start, assuming everything else falls in place?

Keshav Bhutada: With respect to the first molecule, Liraglutide, we have now finished the plant validation. So, now we will be promoting this molecule to various customers, and we will have some customers seeded in this financial year. So, for that molecule, I feel in the quarters to come there are chances that we will have initial sales happening. And also, we have developed our own formulation for this product, the formulation development is completed, and we are planning to scale up our formulation in Q3 FY25 and further it will be filed in various rest of the world markets. So, surely for this Liraglutide, we will see in quarters to come a lot of traction in API as well as formulation. And on the second molecule, Semaglutide, currently, the large-scale development is completed. And once we finish the plant validation with drug master file, that is when the commercial feature will start coming in. So, maybe for that you can assume in next financial year, we will have more picture on the commercial sales.

Harsh: Let's say if Liraglutide is more near to medium term, without getting into semaglutide, is that a better opportunity for you in the initial, let's say, next 2-3 years would be more of an emerging market and India market opportunity rather than the US, Europe market opportunity, would that be the right way to look at, because this is a fairly complex product, so there are very few players they'll be able to develop their own API, there are many formulation players, but API players are very far and few in between, would that be the right picture?

Keshav Bhutada: No, that is wrong because the API is developed for global market and our facility is already US FDA approved, EU approved, Japan approved, Brazil approved. So, we have global accreditations. So, I think many people will use our API in their formulations launch for US and Europe market in quarters to come if we are promoting it properly.

Harsh: And the competitive environment of Liraglutide is that the API players are far and few because the API complexity is very complex to that extent. And again, formulation players will be very high because they can buy the API from suppliers or the dual suppliers?

Keshav Bhutada: Exactly. Yes, you are right.

Moderator: The next question is from the line of Rahil Dasani from MAPL. Please go ahead sir.

Rahil Dasani: In the last call, we said we would update on the Pemetrexed injection post one quarter of commercialization. So, post-launch, what has been our sales to Amneal and what offtake have they seen for this product if you can provide some numbers?

Keshav Bhutada: Post launch currently Amneal has already sold more than 1,000 vials currently in US market and they are waiting for K Code which is again very important for insurance reimbursement which is expected to come in this quarter. So, post which I feel there will be more sales happening in the quarters to come.

Rahil Dasani: For Albumin, another player by the name of Albumedix, which was acquired by Sartorius, is also into recombinant albumin and has been selling the product commercially for a long time and that too in all the grades, while we use Pichia pastoris they use the Saccharomyces. So, what is the difference in terms of yield and efficiency?

Keshav Bhutada: I cannot comment on their yield and their process because that is confidential and not known to me. But what I can tell you is our process is highly competitive and Albumedix or Sartorius is currently selling this product only as excipient grade. They have been getting themselves qualified for many years. So, that is why currently they have had a good market share in the excipient grade itself. So, what we are doing is we will be offering a combo which will be excipient grade as well as therapeutic use. So, for us, the market will be much wider than Albumedix.

Rahil Dasani: And are we planning to undersell them or go for a premium?

Keshav Bhutada: I think that is too early for me to comment currently because as you know Shilpa is more a B2B partner, so once we are entering into some arrangements in upcoming quarters or years to come, I think we will be able to give you much clear picture.

Rahil Dasani: For the excipient grade, now that we have got the DMF, what sort of interest are we seeing for our product, how many potential customers are conducting stability tests with our grade, something around that?

Keshav Bhutada: Yes, I think currently it is at a very early stage. So, I would prefer to answer this question maybe in upcoming quarters if it is okay.

Rahil Dasani: Okay. And for the licensing part of the business, this quarter's licensing revenue growth, was it led by increased partnering contracts and thus the initial fees or more of the older contracts doing better milestones?

Keshav Bhutada: Yes, it's a mix of both. As I have informed you in the previous quarterly calls also, we are a pure B2B Company, and our focus has always been on developing complex portfolio. So, if you see every quarter we have signed existing deals, we have upcoming milestones also and we have also had a new contract signed. So, from last four quarters, we have successfully signed in every quarter deal with new clients, which shows that our existing contracts are also giving us revenue as well as new contracts. So, currently in this quarter, it's a mix of both; it's a ratio of maybe around 50:50.

Rahil Dasani: And just to quickly understand a few products in the pipeline, Dr. Clot seems to be a very innovative product and according to our last quarter's presentation, we launched it in India. So, what is the update for this product?

Keshav Bhutada: Currently in Dr. Clot because it is a product which is currently under prescription, we are trying to get approval under OTC, then the market will expand drastically which is a very time-consuming process which we are trying. So, currently I feel our focus is on getting that OTC, after that only we can have a good commercial market share. So, currently, I feel with the mix of so much of portfolio and all, Dr. Clot until we get a OTC permission, we will not have a big commercial business.

Rahil Dasani: Any timelines around that when we expect the approval?

Keshav Bhutada: No, I think so it is purely government-driven, and they have committee approval procedures which we are also doing for the first time. So, I will surely give you a right picture whenever we have some update on that.

Rahil Dasani: And according to this quarter's investor presentation, I saw a new product by the name of SML ODA010. We haven't talked about this before. So, what is this exactly and what is the early launch advantage?

Keshav Bhutada: Yes, that is the product which we have developed in our ODF division, where it is one very unique opportunity majorly in U.S. market where against the current formulation, which is of tablets and capsule, we have developed the ODF product. It is confidential. So, what I can tell you currently is it is a good opportunity where our human clinical studies we have successfully completed, and we are planning to file this product in US sometime in Q3/Q4 FY25.

Rahil Dasani: And for polymers, the supplies to two big customers were to start this year. Do we still stand on that?

Keshav Bhutada: Yes, in polymer majorly, as you know, in the previous quarters, we have already briefed, we are working with one US customer where we have supplied them initial pilot quantities and now, we are expecting big launch orders in the upcoming quarters. So, that is the update with first US client. And in the Q1 FY25 we could successfully secure one good order from a US MNC client which was the initial pilot order, but this is a complex polymer and if we are successfully delivering them, then this will be again a good long-term opportunity for us. So, we will be able to give you more picture on the upcoming quarters once the successful delivery is done.

Rahil Dasani: We were previously guiding for 15 to 100 crores of target. So, how much of that do we see from these two customers that we have talked about?

Keshav Bhutada: No. What we have mentioned is in a mix of CDMO-Peptide-Polymer, together it will give us a decent top line and bottom line. That is what we have given as indication. So, I will not be able

to disclose on client-specific details as to what will be the order value and how much it will be. But I can tell you as a mix of these three combo segments, there is good potential for us not only from top line, but also a very good bottom line.

Rahil Dasani: I guess, but you are confusing it because in the previous con calls we have said to get 100 crores of target in the next two to three years from Polymer segment alone?

Keshav Bhutada: Yes, in two to three years, that is what we have kept it as a target, and we are on it for sure.

Rahil Dasani: So, that's what I am just trying to understand, are these two customers enough for that or will we need more customers to achieve that target?

Alpesh Dalal: Rahil, I think as Keshav had mentioned earlier, these are early days to comment on some of these aspects. So, we are talking about a two to three years' timeline. We will need to wait and watch how it develops.

Moderator: The next question is from the line of Tushar from MK Ventures. Please go ahead, sir.

Tushar: First, a quick understanding on Albumin. In the Albumin clinical trial, there is no efficacy data point, right, for us. So, Phase-III is essentially just an extension of Phase-I trial with more participants, right, or are there any specific efficacy data points also that we are going to observe?

Keshav Bhutada: No, Phase-I is more like a pilot study where we have also evaluated efficacy. So, Phase-III will be more extrapolation on a greater number of subjects and Phase-III is more done on a patient-based study with specific indications. So, that is the difference.

Tushar: And in terms of the excipient grade, now that we filed the DMF, what is the process in terms of when we approach clients, can they already include the product in their dossier or do we need to wait for the excipient grade approval before they can start to include it in their plans, how does this work?

Keshav Bhutada: So, initially what clients do is because we have drug master file ready, right, so it's more like API selling where they will start taking the initial quantities and dial up their formulation and then they also register our product with their product with our API like Albumin API.

Tushar: And for the therapeutic grade, can you highlight if we are already in any kind of conversations with any of the global players, because now that we have a visibility over the near-term, are there any kind of conversations we are already engaging in or expect to engage shortly for business development?

Keshav Bhutada: I think it's too early for me to comment, Tushar. So, I will maybe update in the future quarters.

Tushar: Second, this quarter, the other income is on the higher side. In the past, management has highlighted that some of this other income is essentially operating income for us, but we route it

through other income. Maybe if you can just clarify again how much of this Rs 9 CR or Rs 10 CR other income is actually the operating income of business-related income and how much of it is maybe interest income or otherwise?

Alpesh Dalal: So, Tushar, half of this income is interest related income, which is purely based on some FDs that we had created out of the QIP proceeds and the other half is more in the nature of other kind of incomes including some write-backs that we may have in the business and all, because ideally when the expense hits you, it is part of operating expenses, but if there is some write-back that happens, that goes and sits in other income.

Tushar: And the licensing income that we have booked for this quarter, does it include a component from Unicycive already?

Keshav Bhutada: Yes, there is a very initial milestone of Unicycive currently.

Tushar: So, this licensing income that we have booked, right, so we did about Rs 150 crores licensing income last year. And is it fair to expect that as some of our programs start to come towards commercialization or late stage that we should be able to maintain or better the overall licensing component, independent of whatever else we do in formulations, within the licensing income is sustainable and can further be strengthened this part of the business?

Keshav Bhutada: Yes, Tushar, it is very sustainable, and you will observe that in quarters to come.

Moderator: The next question is from the line of Dheeresh from WhiteOak. Please go ahead Sir.

Dheeresh: Alpesh, in the presentation, in the revenue breakup, we have given API and formulation. So, API is about Rs 173 cr, formulation is another Rs 104 cr and then there is excluding other income total revenues are Rs 293 cr. So, what we add up, there is still a gap of about Rs 17 crores. So, what explains between Rs 293 cr and what we add up Rs 104 cr and Rs 172 cr, Rs 276 cr. So, that extra balancing Rs 17 cr is what revenue?

Alpesh Dalal: Dheeresh, if you see, there is also biologicals piece that we have mentioned here, which is about Rs 15.5 crores, if you refer to Slide #4 that will explain you the entire pie.

Dheeresh: . And this Unicycive, when we are going to supply both API and formulation, right, in API there is a CDMO segment, so we will show that in CDMO API in the revenue classification that you have and when we supply formulation, we will show it in the geography breakup, how are you going to bifurcate, or you just put everything in CDMO which is in API?

Alpesh Dalal: So, first and foremost that here the API will be supplied by our API unit to our formulation unit and formulation unit will be supplying the final product to Unicycive. Now, currently we have the licensing fee coming into it, but as we go along, the way it shapes up, the sales from API to formulation as in standalone API business would feature as a CDMO revenue and likewise it will come up in the geography in our formulation business.

Dheeresh: That will show up in the US revenue in the formulation, right?

Alpesh Dalal: Right.

Dheeresh: How much is the CAPEX requirement this year, next year?

Alpesh Dalal: I think we have mentioned that for the year we have about Rs 125 crores kind of CAPEX requirements in toto, about Rs 50 crores for our Albumin project, about Rs 50-odd crores for our maintenance CAPEX and all and around Rs 25-odd crores for our Tranexamic Acid expansion, that's the full year number.

Dheeresh: And how much R&D is capitalized?

Alpesh Dalal: So, in this Q1 from a cash flow perspective, we have done Rs 58 crores, because that also includes certain advances that we would have paid and all.

Dheeresh: Rs 58 cr total. How much expense and how much through the balance sheet?

Alpesh Dalal: No, there's no expense in this. No, these are all balance sheet items. Only thing is some of them are part of CAPEX and some of them are sitting there as advances for CAPEX.

Moderator: The next question is from the line of Ranvir Singh from Nuvama Wealth. Please go ahead, sir.

Ranvir Singh: Sir, my question is related to the UDCA. So, just wanted to understand how big this UDCA opportunity could be? And what I understand the raw material has been very scarce. I wanted to understand the whole business of the UDCA because of the sourcing of raw material and plus earlier we used to have a joint venture where this was a key product. So, after launching this, is there any conflict with the erstwhile joint venture for this product?

Keshav Bhutada: No, I think, see, UDCA has the opportunity. We are very bullish on the opportunity only because the market and the application for this product is very big and there is a worldwide very big consumption and the major players in this product has been over the years mainly Europe and China. So, in the export market, we are hoping very positive. Having a CEP grade API with complete drug master file support, we will be growing in this product very well. And answering your second question on the joint venture. Joint venture what we had is already concluded I think maybe 2-3 years back. So, there are no implications of that.

Ranvir Singh: I think the erstwhile joint venture is still into this business. So, is there any we are competing?

Keshav Bhutada: It's not in the joint venture, so that is not there currently, it's already completely ended the European supply with our JV client.

Alpesh Dalal: I think your question around, see, we have developed our own independent process, independent of the process which was there in the joint venture. So, there is no conflict with them on that front at all.

Ranvir Singh: Secondly, in CDMO business, I think that two molecules what we are talking about currently where the pre-launch orders are received, so just how big this could be, I think it would be difficult right now but still if you could give some number to understand that whether that is going to be very significant for overall financial perspective?

Keshav Bhutada: No, I think see what we are mainly focusing in our API business is to build more complex and long gestating business. So, that once we are securing and once we are entering with the clients in their Phase-III supplies, then it's a long-term business for us. So, in the years to come, maybe with the announcement of Unicycive Therapeutics, which already you would have read, which is the first CDMO supplies where we have made a long-term agreement with the client. So, I can tell you we are planning to do similar such arrangements in the quarters to come so that will give us more assurance on the long-term business.

Ranvir Singh: And last one is on taxes in front, what tax rate we are expecting for whole year for FY25?

Alpesh Dalal: Typically, our tax rates are in the region of about 35%-odd. For the quarter it has been on a bit higher side mainly on account of intercompany interest which has been there where the income is getting accrued in a higher tax Company as compared to the expenditure getting booked in a lower tax Company. Some of that we are correcting right now where certain loans have been already converted into equity, which you would have read in one of our notes as well. And in certain cases what also happens is that because some loans are given for pre-capitalization stage, the interest over there does not get hit to P&L. So, there the income is getting charged to P&L but there is no expense-related benefit coming into for that interest payment. These have resulted into higher tax rate for the current quarter, but generally we should be able to maintain it in the region of about 35%.

Moderator: The next question is from the line of Yash Mehta from Art Ventures. Please go ahead Sir.

Yash Mehta: Can you throw some light on the EBITDA margins? They have expanded considerably this time? And can you guide on what kind of EBITDA margins do you aim to maintain in this financial year?

Alpesh Dalal: See, the main reason for the EBITDA margin improvement is the mix that we've had. Some of this licensing income also helps in that because compared to that licensing income, the related costs are lower. Also, we see decent growth has happened in the formulation business, which is a better margin business as compared to API. So, some of these businesses mix related aspects have contributed to improved margin and obviously as we have been mentioning it since the past few quarters that we are very actively looking at more efficiency in our operations and also keeping our costs under check. So, this is a combination of all these efforts which you are seeing

in the improvement in the EBITDA, and we expect that the EBITDA should remain in similar kind of range.

Yash Mehta: Any guidance on the revenue for FY25?

Alpesh Dalal: I don't think we would be in a position to provide any guidance first. That's something that is a policy we do not do.

Moderator: The next question is from the line of Prisha from Molecule Ventures PMS. Please go ahead.

Prisha: My first question is on the formulation side. So, if we look at the breakup, the US formulation segment has come down from Rs 30 crores to Rs 10 crores if we compare it on a quarterly basis. So, could you please explain the reason behind this because as far as the data goes, the contribution from Pemetrexed injection was supposed to come from this quarter. So, what caused this kind of performance in that segment and then how much of that was contributed by Pemetrexed?

Keshav Bhutada: See, there are two aspects here. In Pemetrexed for U.S. business, we are having an arrangement with our partner where we supply them at a floor price and then we have a profit sharing. So, whatever sales revenue you will see in the last quarter in the US, which was for one-time supply for the US market, which we have done at a floor price, and for which we will be expecting in quarters to come, a profit share also which you will see it will be in the US sales income which you will see in the upcoming quarters to come. So, as I already mentioned in Pemetrexed case, there are two code J Code and K Code. So, J Code for the premium pricing already secured. So, once K Code which is the reimbursement code approval which we are expecting in this quarter, once we receive that, then you will see a jump in the sales in the upcoming quarters.

Prisha: Because let's say last quarter Rs 30 crores and this quarter Rs 10 crores, so how much was contributed by the Pemetrexed if you can give the break-up?

Keshav Bhutada: In the last quarter, Pemetrexed contributed as a total revenue of Rs 20 crores.

Prisha: And in this quarter?

Keshav Bhutada: This quarter it has not given any contribution because the supplies were one-time which was done in the fourth quarter.

Alpesh Dalal: They were all launched earlier.

Prisha: So, you are seeing the profit-sharing sales income will start coming from next quarter?

Alpesh Dalal: So, partially it has started coming in, but it takes time for things to come in. So, I think these are early days for a product launch and we will have to wait for it to take shape and develop.

Prisha: Sir, my next question is on debt. So, in the previous con call you had mentioned that the prepayment option will get active in August. So, has the timeline changed or are we on track to repay or sort of prepay our debt in this month and what amount will be prepaid in August and if I am not wrong, the entire amount will be long term debt, correct?

Alpesh Dalal: We are on track to prepay as we had mentioned earlier. We have earmarked Rs 300 crores out of the QIP raise that we had done and that is something that we would prepay during this particular month. We are on track for it. And this prepayment is happening towards NCD which is a long-term debt.

Prisha: My next question is on the third biosimilar which you have mentioned in this PPT, which is Pembrolizumab. The market size that we have mentioned is huge, around $28 billion. Can you provide us with more details with respect to let's say the development of the biosimilar or the milestones that we are looking at in future regarding this product or when do we plan to launch it and other details like that?

Keshav Bhutada: See, on Pembrolizumab, as it is very important development in our pipeline, so in quarters to come what you should observe is how the product is moving from large scale development to validation stage and then the clinical studies. So, what is important for us is as a pipeline we have taken that molecule already increased, and we have finished initial lab scale development already. So, in quarters to come we will be moving the product from lab to clinical studies.

Moderator: The next question is from the line of Neha Karodia from Abakkus. Please go ahead.

Neha Karodia: Sir, first question was regarding the Albumin. So, please correct my understanding if it's wrong. So, for excipient grade can we expect a launch in FY26? I understand that therapeutic grade launch can be a little later maybe in FY27 once we complete the clinical studies on that.

Keshav Bhutada: See, in albumin, in excipient grade, there is nothing like a launch because once we have drug master file, right, we will start feeding our samples or we will start selling initial small quantities in various markets in the quarters to come. So, important is in the quarters to come, we will see how the traction is, how the market is taking volumes. So, I will be able to give you a right picture in the upcoming quarters. So, currently I am not in a position to give you a right picture.

Neha Karodia: And also, other question was about this line item of loss from JV and associates which has increased in this quarter versus YoY as well as QoQ. So, if you can maybe help us understand more details about that?

Alpesh Dalal: With one of our associate companies, we had a certain balance. Now, in that case there were certain losses that were reported in the earlier period when we received the financials, we had to take those into account and that has been corrected during this particular quarter.

Neha Karodia: On the tax rate, as you explain that it will be 35% overall broadly in that range for FY25, but FY26 onwards, can we expect some moderation there or more normalization or it can remain in that same range only?

Alpesh Dalal: Neha, let's take one thing at a time, right. We will talk about that in the coming periods.

Moderator: The next question is from the line of Sanjay Kumar from iThought PMS. Please go ahead Sir.

Sanjay Kumar: First is on albumin. Do we plan to out-licensed before Phase-III itself or will it happen after Phase-III? I just want to understand our strategy given both efficacy and safety are established.

Alpesh Dalal: See, some of these are strategical things which are fairly confidential from a corporate perspective and as Keshav had explained that we are initiating our Phase-III studies. So, this is probably not the right time to have these kinds of discussions from a corporate perspective.

Sanjay Kumar: Do we plan to start US specific trials for this?

Keshav Bhutada: Yes.

Sanjay Kumar: Any timelines for that?

Keshav Bhutada: Now, since our Phase-I study is completed, so same as Europe and US also we will be submitting this data and once we have response from the agency, accordingly the timelines will come in picture. So, I think we will have a more picture in maybe by Q3 FY25.

Sanjay Kumar: Second is on Liraglutide. When can we start the commercial sales, do we have any firm orders because one Indian Company is launching this financial year, two more in FY26, but all three have existing partners I am told. So, our launch cannot be or will not be before FY26, is this a right understanding?

Keshav Bhutada: No. See, because we were waiting for the drug master file to be ready because that is very important for anyone to use our API, which has been made ready just in 1st Quarter. So, you will see in quarters to come, there will be sales for this product which will slowly start ramping up also. And about the source qualification, see, because no one will wait for the launch and then start adding source, everyone in the development, once their filing is done, they will start adding additional sources for launch so that they are more competitive in the market. So, there are possibilities where we will be starting to get qualified in the formulation source of some of the clients.

Sanjay Kumar: And finally, is on biologics, 8 KL Mamillian facility is yet to be utilized, so we've added one US client, we've added two more CDMO customers. Are these expected to add two more in Q2 FY25, are these for mammalian facility, can you talk about the therapy, are there indication for these three customers?

Keshav Bhutada: Since we are under confidential agreement with this customer, so I will not be able to tell you about these things, but what I can tell you is we have a mix of mammalian microbial projects.

Sanjay Kumar: The South Korean CDMO, the peptide molecule, once we start the GMP supplies, can we utilize our 2 KL microbial facility at Dharwad just from this or we need more such molecules?

Keshav Bhutada: No, we can utilize it.

Moderator: I would now like to hand the conference over to Mr. Alpesh Dalal for closing comments.

Alpesh Dalal: Thank you, all. Thanks for your continued interest in Shilpa Medicare. We continue to remain available to you for any further questions or queries that you may have, and we will speak to you soon again. Thanks a lot for joining our call.

Moderator: On behalf of Shilpa Medicare that concludes this conference. Thank you for joining us and you may now disconnect your lines.

(This document is edited for readability purpose)