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: 30 May 2025

To
Corporate Relationship Department
BSE Limited,
1st Floor, Rotunda Building,
P.J. Towers, Dalal Street,
Mumbai – 400 001.

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

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

Dear Sir/Ma'am,

Sub: Transcript of the Q4 FY '25 Conference call

In furtherance to our intimation dated 19 May 2025 with regard to the Q4 FY '25 Conference Call held on Monday, 26 May, 2025 at 17:00 hrs., please find the enclosed transcript of the call.

Thanking you,

Yours faithfully

For **SHILPA MEDICARE LIMITED**

Ritu Tiwary
Digitally signed by Ritu Tiwary
Date: 2025.05.30 11:08:26 +05'30'

Ritu Tiwary
Company Secretary and Compliance Officer

“Shilpa Medicare Limited

Q4 FY '25 Earnings Conference Call”

May 26, 2025

MANAGEMENT: **MR. KESHAV BHUTADA – EXECUTIVE DIRECTOR AND CEO – SHILPA PHARMA LIFE SCIENCES LIMITED**
MR. ALPESH DALAL – CHIEF FINANCIAL OFFICER – SHILPA MEDICARE LIMITED
MR. MONISH SHAH – HEAD, STRATEGY AND INVESTOR RELATIONS – SHILPA MEDICARE LIMITED

Moderator: Ladies and gentlemen, good day, and welcome to the Shilpa Medicare Limited Q4 FY '25 Earnings Conference Call. 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 this conference, please signal an operator by pressing star and then zero on your touchtone phone. Please note that this conference is being recorded.

I now hand the conference over to Mr. Monish Shah from Shilpa Medicare Limited. He is the Head of Strategy and Investor Relations. Thank you, and over to you, sir.

Monish Shah: Thank you, Dorwin. Good evening, and warm welcome to everyone to our fourth quarter results conference call. Today on the call, we are joined by Mr. Keshav Bhutada, Executive Director and CEO of Shilpa Pharma Life Sciences Limited; and Mr. Alpesh Dalal, our CFO.

Before we begin the call, please note that the financial results and the presentation have been uploaded on the Exchange. Note that this call is being recorded and the transcript along with the audio of the same will be made available on the website of the company and the Exchange as well.

I would like to remind you that today's discussion might include certain 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, further events or otherwise.

I would like to hand the call over to Mr. Keshav for his opening remarks. Thank you, and over to you.

Keshav Bhutada: Thank you, Monish. Good evening, everyone. FY '25 as a year has been very exciting year, and a year full of opportunities for us. And our focus on monetization of assets has helped us to bring in a good performance.

Now I will start briefing you about our fourth quarter performance as well as on the full year results. So first, let me start with the briefing on various business divisions. So overall, my briefing will be divided into API, Formulations, Biologics. These are the 3 main divisions in which I'll be giving you a firm update.

So, when it comes to API, my overall briefing will be in oncology, non-oncology, CDMO peptide and polymers. Starting with oncology, for the current quarter, our first molecule, which is the NCE molecule for the Innovator customer, we have completed Phase III clinical study. And we understand from the customer that the results are very promising. And now subsequently, after that, they will be planning the DMF and finished product filing. The customer has also received the breakthrough designation for bladder cancer and the filing is expected in FY '26.

The second molecule, for which we are supplying, is an oncology API, the Phase III clinical studies are ongoing.

Apart from that, the molecules like Methotrexate for which CEP is already filed. The CEP review is going on track, and we are expected to have approval in current financial year FY '26.

Nilotinib, which was a non-infringing API developed by Shilpa and for which even the formulation was non-infringing, the product is successfully launched by our Formulation division for which API supplies were successfully done by our API division. And in the next financial year, we expect to launch Axitinib in Q1FY26 for which, the API supplies are ongoing. With this, we are confident that in the current financial year, the oncology overall revenues are likely to grow on year-on-year basis.

The second update is on non-oncology division, for Tranexamic acid we have completed capacity expansion and commercial production has started. Apart from that, our second molecule, UDCA for which CEP was already granted, we have started to ship export samples and we expect to start commercial orders.

Third molecule is Nor-UDCA, for which we have developed the Novel API and for the first time the formulation for NAFLD in India and our approval of formulation is expected in the first half of FY '26. And subsequently, launch is also planned in first half of FY '26. The API manufacturing for Nor-UDCA has also started for Formulation division and is expected to complete in first half of FY '26.

The new molecule, which is Mycophenolate Mofetil where the PV campaign is ongoing, and we expect to complete PV and file the product in FY '26.

CDMO peptide and polymers are very important divisions in which Shilpa has invested a lot. In this, the major updates will be on Unicycive where we are constructing a dedicated block for the customer and the construction is happening as planned, this is expected to be completed in first half of FY '26. Subsequent to that, the PV batches and the filing from this new block will be planned into FY '26.

The second project in CDMO is a Phase II molecule where we have developed both API and Formulation for our NCE customer, and the customer has received clearance from agency for starting the Phase II clinical studies, for which the material is supplied from our end and Phase II clinical studies will be started in first quarter of FY '26 by our partner.

Apart from that, in the Q4 FY '25, we have successfully signed two new CDMO contracts in which one molecule is a commercial product where we are doing a site transfer to our facility, where the project is awarded to us. The second project, which is an NCE molecule for development for a different indication for one of our Australian clients, for which, again, the program is awarded, and initial development work has started.

In peptide division, for Liraglutide our PV campaign was completed and our DMF is expected to be filed for this product in first quarter of FY '26. Semaglutide where, Shilpa has invested a

lot of resources on development of this product, and out process development in R&D is completed. Our PV campaign is planned in first half of FY '26 for the API.

Polymer division, as earlier updated in the previous call, we have received one order from one of the U.S. customers for $4 million, for which the commercial supplies have started, and the revenue is expected to be realized in FY '26. The second polymer project, which is a very complex polymer, we have developed for one of the U.S. companies. The material is supplied to our partner and their trials are ongoing.

Apart from that, I'm happy to tell you that in the current quarter, our API business, both Unit 1 and Unit 2 have successfully finished USFDA inspection. And for the Unit 1 we have received EIR with VAI status.

Now let me start briefing about our Formulation division. In Formulation, as on date with the company, we have 3 NDA approvals in place, which is Pemetrexed, Bortezomib, and the third product is an oral liquid product in U.S. All the 3 product commercial launches have completed, and revenues will be realized in FY '26.

Apart from that, for the Europe market, our Nilotinib launch is doing well. And as on date, there is no competition in the market, and we have a good market share via our partner. Second molecule, which is Axitinib, having launch planned in Q1 FY '26. We have the supply orders in hand and we are expecting the deliveries to start from 1QFY '26.

Nor-UDCA, which is again an NCE molecule, which Shilpa has done a clinical study in India for NAFLD. The product approval is expected in first half of FY '26 and even the launch is planned in first half of FY '26. And company has already partnered with various companies in India for this product.

Apart from that, the transdermal patches, our specialty division, we expect to get approval for Rotigotine transdermal patch, in FY26. This will be our first TD product for which the review is ongoing with the agency.

The second transdermal project, which is again a very complex transdermal patch, here we are developing against a tablet for which the pilot bio is successfully completed, and now the PV batches and clinical studies are expected to start in FY '26.

SMLINJ011, which is a long-acting injectable, a very unique product, where we have our own IP, for which the Phase III study is expected to completed in Q3 FY '26. And subsequently, we'll be filing this product in India. And parallelly, for the said product, European scientific advice is already submitted, so for this molecule, we will be going ahead with the U.S. and Europe studies also in FY '26. Our major focus for the formulations will be on advancing 2 to 3 new such specialty pipeline products to the advanced stages.

And on the regulatory side, I'm happy to tell you that for our transdermal patch and ODF facility, we have received our EUGMP certificate in the current quarter. Apart from that, on the USFDA

issue for our formulation manufacturing facility, the USFDA remediation is completed from our end, and we are waiting for the response from agency.

Now I'll start briefing you about Biologics division. Biosimilar Adalimumab, which is our first commercial molecule launched in India, the sales are doing well. And for the current year with the approved additional indications, we are expecting to double the sales in the current financial year FY '26.

Aflibercept, which is our second biosimilar, the clinical studies are ongoing, and we are expecting to file this product in FY '26 in India market. Nivolumab and pembrolizumab, which are 2 blockbuster molecules by revenue, the product development in R&D scale is completed, and our preclinical studies are ongoing, and we expect to start human studies in FY '26.

Coming to CDMO Biologics we have 2 projects, for which a sizeable amount of work was done in FY25. These molecules are expected to generate decent revenue in FY '26, where the Phase 1 supplies are expected to start, or preclinical, will be ongoing.

For the current quarter, we have signed one more large-scale microbial long-term contract for more than 5 years, for which we will be developing both DS and DP, for which we have a binding contract. Apart from that, there is a second project which is a mammalian project, which we have signed with one of the U.S. based customer and for which we will be starting the development work. We are seeing very good traction on the CDMO Biologics side, and we expect to add more products in FY '26.

On our deal with MAbTree Biologics, where it's an NDA asset for which Shilpa will be exclusively developing for our partners. The cell line delivery is expected in first half of FY '26. And our customer is expecting to start their investigational trial in FY '26.

I'm happy to tell you that on Biologics side that our facility has received EUGMP approval, which gives additional regulatory certification to our customers that the facility is very well capable of supplying to Europe and the global market.

Next, I will start briefing about Albumin. As most of you are aware, the manufacturing facility, which Shilpa is building, the facility is expected to commission in this year, and we are planning to start the product batches in current financial year. And apart from that, in Europe, we have already submitted our scientific advice, and we are expecting the response closure in first quarter of FY '26. Subsequent to that, in FY '26, we will be starting the clinical studies. In India market, we have received the permission for starting Phase III clinical studies, and we are planning to start supplies for the India clinical Phase III studies in FY '26.

I'm happy to announce that we have strategic partnership with Orion Corporation for exclusive commercialization in Europe region. And Orion will be our exclusive partner for distribution, marketing and sales of recombinant Albumin, and this partnership is purely for the Europe market, and this is for only therapeutic use.

Apart from that, the applications, which are in excipient grade and other applications that is not in the scope of current agreement, and we are allowed to sell our product for these users. Also note that this deal is mainly for Europe market, and we are still open for U.S., RoW and India markets. This underscores the commitment we have had to this project over the past eight years. We have made significant strides over the years, and we are confident of commercially launching this product in years to come.

With this, I would end my briefing on business. And at the end, I would want to tell all our investors that as a company, we are very focused on monetizing the assets and whatever assets which Shilpa has invested over years, we will ensure that we get revenues from each one of them.

With that, thank you, and I hand over to Mr. Alpesh Dalal.

Alpesh Dalal: Thanks, Keshav, and good evening, everyone. Let me briefly take you through the financial performance for the fourth quarter and the full year ended FY '25. Our total revenue for the quarter stood at INR338 crores, recording a growth of 15% year-on-year and growing 13% for the full year to INR1,310 crores. The growth for the year was largely driven by finished dosage form and biologics verticals. On the gross margin front, our gross margin for the quarter improved by 200 basis points at 69% compared to the same quarter last year. And this improvement came despite lower contribution from licensing income and CDMO revenues, which also underscores the profitability of our business model. The EBITDA for the quarter was at INR84 crore as compared to INR73 crore in the fourth quarter last year, showcasing a growth of 15% year-on-year. Whereas EBITDA for the whole year was at INR340 crore as against INR253 crore last year. The EBITDA margin for the quarter were at 25%, whereas for the full year, the margins were at 26%. With the improving business mix and higher utilization of assets, we could expect some further improvement in the EBITDA in the future quarters.

I'm also happy to share that our interest burden has started coming down with the interest cost declining by 38% year-on-year for the quarter. Going forward as well, I believe that there are savings expected out of lower interest costs. During the year, we repaid high-cost NCD loans of INR300 crore out of the proceeds of QIP and replaced another INR75 crore NCD with a significant lower cost. We expect to repay the balance NCD of INR75 crore by mid of August '25 to enable further reduction in our interest burden.

On the tax front, our effective tax rate for the year has reduced to 36% compared to 41% last year on the back of conversion of loans given to subsidiaries into equity, resulting in lower tax expense. During the year, we also had a onetime exceptional item pertaining to settlement of our pending litigation with Celltrion amounting to INR29 crores but adjusted for exceptional items for the quarter stood at INR33 crores versus INR20 crores on year-on-year basis, whereas adjusted PAT for FY '25 was INR97 crore, growing by more than 2.5x compared to previous year.

On the segmental performance for the quarter, our API business clocked a revenue of INR188 crores, growing 3% year-on-year. In this business, we have done portfolio rationalization and also improved offtake of key products from our newly expanded capacities.

Formulation business revenues for the quarter were at INR 133 crores, growing 38% year-on-year. And the growth in the Formulation business was driven by our new geography where we continue to have limited competition for Nilotinib. And significant ramp-up in our RoW market that witnessed a growth of over 3x compared to the same quarter last year.

Our Biosimilar business recorded a revenue of INR10 crore during the quarter.

Let me now give you an overview of our balance sheet and cash flow items, where our net debt was at INR558 crores as on 31st March'25 compared to INR905 crores for 31st March '24. And the reduction in debt, coupled with improved performance has resulted in our net debt-to-EBITDA improving to 1.6x from 5.8x last year.

On the capex front, our net capex for FY '25 was INR216 crore, and it was majorly for our large fermentation facility that we are building. Additionally, I'm also happy to inform all of you that the Board at today's concluded meeting has decided to declare a 100% dividend on the back of improved performance of the company.

I would now like to open the floor for Q&A.

Moderator: We have our first question from the line of Krisha Kansara from Molecule Ventures.

Krisha Kansara: My first question is related to the Biologics segment. So you mentioned that the sales from Adalimumab will double in FY '26? Now if we see in FY '25, segment reported close to INR75 crore of top line. So if you can give us the breakup of this INR75 crore number, how much was from the CDMO segment and how much was contributed by Adalimumab?

Keshav Bhutada: So if we see on overall Biologics segment in Adalimumab, we have clocked a revenue of INR15 crores to INR20 crores, in the last financial year, which is expected to double in FY '26. And rest of the revenue, is split between CDMO and licensing revenue.

Krisha Kansara: My second question is on the Formulation segment. So first of all, congratulations on the official launch of Bortezomib in U.S. market and also for the J-code approval. Our ramp-up in case of Pemetrexed has been slightly slow and gradual, and it has been more than a year now.

And now we are expecting to see a pickup in Pemetrexed sales from, let's say, FY '26 onwards. So can we expect the same gradual ramp-up in case of Bortezomib because this is the same market and the same distribution partner for us, the ramp-up in sales could be much faster?

Keshav Bhutada: What I can tell you is with Pemetrexed, first, we had the approval, the sales pickup took time because there was also eagle pharma another competitor in the market. But when we talk about Bortezomib, there is not much competition in the market. We are the only company having the subcutaneous approval right for the RTU. I think that will really open up market quickly. But how it will evolve in the financial year, we have to observe because for us also, this is a new kind of opportunity which we are exploring. However, we are confident that the partner should do good numbers in FY26 on both Pemetrexed and Bortezomib.

Krisha Kansara: So you are observing a pickup in sales in Pemetrexed for FY '26?

Keshav Bhutada: Yes.

Krisha Kansara: My third question is on the Albumin side. So first of all, congratulations on your partnership with Orion with respect to Albumin. I have 2 sub-questions related to this. First is, what kind of milestone fee can we expect from such kind of an out-licensing agreement for a new biological entity?

And usually, what is the timeline for that? Can we expect some fee to be received once we conclude the Phase III trials, let's say, 9 to 12 months down the line? And my second question is, we were supposed to start the Phase III trials in first quarter of FY '26, and we are almost 2 months into the first quarter. So I just wanted an update on the fee.

Keshav Bhutada: Coming to financials, we will not be able to disclose that because of our confidentiality with our partner. But I can tell you it's a very good deal, mainly because Shilpa has invested a lot of time on this product, from so many years. And yes, there will be milestones, which will be spread across signing, filing, approval, launch. So that way, the various milestones will be divided.

And yes, coming to the second question on the clinical studies. We were expecting to start in first quarter, you are right. But I think we may have some delay, maybe it may move to 1 or 2 quarters because we are trying to give our Phase III clinical study supply from our new facility, so that the new facilities are in our part of our dossier from day 1.

Krisha Kansara: So what is the delay that we can expect for Phase III?

Keshav Bhutada: It may move by 1 to 2 quarter.

Krisha Kansara: On the import alert side. So we have completed all the remediation initiatives and all. Now my question is, have we received any final inspection date from USFDA then? Why I'm asking this is because once we are through with this issue, we might see some kind of improvement in our margins because the cut that we basically pay to the CMO players as of now for our U.S. Formulations will no longer be paid. So any update on the final inspection date? And also, is my understanding on the margin improvement, correct?

Keshav Bhutada: No, there are 2 things. See, first thing on the FDA import alert, we have completed all the remediation activities. And lately, what we have seen is FDA is more doing surprise inspection. So I think we will surely have, or we are likely to have in the current financial year a surprise inspection. So this is something which we know currently. And apart from that, the second question on the margin improvement. Margin improvement will not happen because we are currently paying to the CMO. However, that cost is not significant. Only improvement, what will happen once the U.S. approval of the facility happens is we may see a good increase in the CDMO revenue. And apart from that, our existing products, where the final approval is not received, there all approval will get started.

Moderator: Our next question comes from the line of Rupesh Tatiya from Shree Rama Managers PMS.

Rupesh Tatiya: My first question, is on this Formulation slide, slide number 17. The licensing revenue, it was INR34 crore in Q4 FY '24. It's gone down to INR24 crore in Q4 FY '25. And my understanding was with new product launches, I mean, we have launched Nilotinib, Pemetrexed, Bortezomib.

So my understanding was this revenue should have gone up. So can you explain why it didn't go up? And then overall on FY '25, we have this INR181 crore revenue. So can you give some idea about how much of it is onetime milestone payments? And how much of it is linked with the sales or the production of the Formulation?

Keshav Bhutada: First thing is when the product is commercialized in any of the market, the revenue line item where we will be reporting the numbers, that will not be in licensing, those numbers will be in the sales revenue. So if you see the numbers, what we have shared, the Europe revenues have increased. So whatever sales revenue, which we have generated from Nilotinib or any profit share, that all will come in the Europe business sales, not in licensing.

And apart from that, on your question on decrease of revenue from fourth quarters FY '24 to fourth quarter FY '25, right, or even from third quarter to fourth quarter, licensing revenue is such a way, as I mentioned in previous call also, that is a product once we out-license, there will be various milestones, which will be there for the product. So sometimes in some quarter, you will see it will be more. Some quarter; it will be less. So the variation will be there, but only the kind of product mix, which we have out licensed in that quarter, that will define my licensing income.

And of the last year, there was no onetime income as such, as I have mentioned before, we have a strong pipeline of molecules. So once one molecule in first quarter have out licensed, second quarter, there will be one more molecule. Third quarter, there will be one more molecule. And every year, we will add new pipeline. At the same time, existing pipeline I will advance and out-license. So that is how the licensing revenue will be a continuous revenue. It is more like if you have a company which is doing purely CDMO business, they will have a fixed CDMO revenue. Sometimes it may be more, sometimes it may be less, based on the product deliverables.

Rupesh Tatiya: The reason to ask that question, it is almost 50% of our EBITDA. And at least as an analyst, I have no way of predicting it that this will grow 15% every year, right? It is quite lumpy. So that is why I was asking you that question.

The second question, is, what is the significance of this EUGMP approval that we have received for Biosimilar plant? Is that like a major approval where now we can see Biosimilar revenue going from, let's say, INR75 crore to INR150 crore, INR200 crore? Does that approval enable us to do that? That is one. And then another one, if you can give some update on Lenvatinib settlement?

Keshav Bhutada: I think on the first point of EUGMP approval for the facility, yes, it's a significant update for our Biologics facility because if you see in India, the number of Biologics facilities and in that, how many are EUGMP or USFDA approved? I think as analysts, you will understand that there are not many. So if you have a facility with regulatory accreditation, especially from Europe, I think that opens a lot of doors for CDMO services.

And yes, the revenue is expected to increase. How much it will be in this year, how much it will be in next year, it will all be decided mainly on the CDMO revenues. So we have to observe that with time. But yes, we are confident as a company that this approval will give us good uptake for CDMO revenues.

Keshav Bhutada: And on Lenvatinib settlement we are currently not disclosing anything right now as its confidential.

Rupesh Tatiya: My final question, is when are we expected to recruit all the patients for Albumin Phase III? And when can we see some results of that?

Keshav Bhutada: For Albumin, once we start our clinical study, our clinical study duration is between 12 to 15 months, including the study, dosing, the analysis and report.

Rupesh Tatiya: The first patient has been recruited?

Keshav Bhutada: No. See, for patient recruitment, first, we have to supply the material. And supply of material from the facility which we have commissioned, the large-scale microbial facility. From there, if we are supplying and with that only if the clinical study will start, then once I file my product from the same facility, I can commercialize also.

So our current plan from the new facility is, the large-scale batches are ongoing. And once that is completed in this current year, maybe sometime in Q2 or Q3, we are expecting to start our Phase III clinical studies for India. That is the plan. And in next year, we will be completing our Phase III study.

Rupesh Tatiya: And where are we on the nontherapeutic usage?

Keshav Bhutada: See, on nontherapeutic, as I explained in the previous calls also, I will be able to give you more clear picture in the next financial year once I see how the uptick is. But yes, we have started feeding our samples to various customers and they are testing our product.

Moderator: Our next question comes from the line of from Meet Katrodiya from Niveshaay.

Meet Katrodiya: Sir, my question was on the part of CDMO business. Beyond the commitment of 20 million tablets, is there any visibility for further scale up in FY '27 or FY '28? Also could you help us to understand the expected annual revenue from this engagement?

Keshav Bhutada: I think I will not be able to give you how much will be the expected revenue. But for sure, I can tell you that we have a good visibility. And the kind of indication where this molecule is targeted, we are expecting it to do better. But once the product is launched and it is in market, then only we can give you more clear picture.

Meet Katrodiya: So second question is on part of intangible assets. So there is also a good rise in intangible assets. So how we plan to impair or amortize the intangible assets? Could you throw some light on it?

Alpesh Dalal: Yes. We follow a very structured policy for amortizing the intangibles. At a point in time when we start commercial usage of that particular intangible asset, we end up amortizing it over its useful life. We have generally come to a conclusion that broadly that useful life should be on an average at about 10 years. So we amortize it over a period of 10 years.

Moderator: Our next question is from the line of Kumar Saurabh from Scientific Investing.

Kumar Saurabh: So my question is on the recombinant Albumin, from the overall market, this share is only 5%, and it is dominated by 3 global players. So first question is, are we targeting more than this 5% market? And how we plan to compete against the bigger players? And given I think it's the cost which will kind of bring this in favour, if you want to take a bigger share. So how do you plan to fight on the cost side to have a bigger market share?

Keshav Bhutada: Yes. I think, first thing, currently with recombinant Albumin, where specifically, the application, which we are targeting is a therapeutic use, where currently recombinant Albumin globally, there is no approved product for therapeutic use. That is first part which I want to clarify. So recombinant Albumin, whatever you will see some market where people are selling it as an excipient grade. So that is a completely different market, which is for nontherapeutic applications.

Apart from that, how do we see to ramp-up? See, our partnership with Orion, I think that itself will give you a clear picture that the molecule has very good potential of selling. And obviously, if we are cost competitive, then only any partner will come and sign with you for the product. So we are confident that we are cost competitive and manufacturing-wise as well as clinically and getting the product to market.

Kumar Saurabh: My second question is around some of the new products like Rotigotine or Bortezomib. So these are expected to be launched in FY '26 and I heard in your commentary also. If you can talk something about the addressable market size of these opportunities and what is the kind of market share, we want to take in some of these molecules/ products?

Keshav Bhutada: See, mainly in transdermal patches globally, there are not many companies who are working on it. And especially for products like Rotigotine where we already know that many companies have taken this product in R&D, but have failed either in clinical or at manufacturing level. So totally, the end market for Rotigotine as on date is, I think, more than EUR 200 million as per IQVIA data.

And we have already partnered for this product with one of the very good European companies, who is very strong in selling Parkinson's disease products. So this is an add-on to their already existing sales force where they have experience of selling such products. So yes, there is a good sizable opportunity for us, and we just need to see how it will evolve based on numbers.

Kumar Saurabh: Last question because I have started studying the company only for the last 2, 3 months. The CDMO and the Biologics business, I think a lot of effort and a lot of investment has gone, but the numbers doesn't reflect the actual potential. So one question is, what is like if the business

performs up to its potential, maybe in next 3, 4 years, what is the expected asset turn out of this business? And what do you feel is going to be a sustainable return on capital on this investment?

Keshav Bhutada: Yes. I think, your question is very long. But what I can tell you in short words is once you will study more about our company and if you come on every quarterly call, I'm sure you will get a very clear insight. But as a company, if you see in India, there are very few companies who are having both development and manufacturing platform like Shilpa because we can do small molecules, we can do peptides, we can do polymers, we can do biologics, we can do ADCs, we can do injectables, we can do oral solid, we can do PFS.

When you have a company which is a one-stop solution for any partner when it comes to development and manufacturing, where I feel the opportunity what we are talking is significant. And in years to come with more focus on CDMO, we are confident that each of these assets will start giving us returns. As on date, if I understand correctly, our ROCE is around 9%.

Moderator: Our next question is from the line of Ajay Surya from Niveshaay.

Ajay Surya: Sir, my question is on Albumin. So with the Orion partnership in place, can you please provide more clarity on the regulatory filing timeline, the expected launch here? And more on our readiness in terms of our fermentation capacity?

Keshav Bhutada: As I already mentioned, our manufacturing facility for supplying this recombinant Albumin is almost ready, and we are starting our scale-up batches in this facility. So manufacturing-wise, we are confident, and we are ready with the product. The scale-up and the registration batches will be completed in this year and including supplies to clinical trials, that's the only milestone which we are targeting for the current financial year. Once we do that, it's a 12 to 15 months' timeline for completion of the clinical study and subsequently filing and approval.

Ajay Surya: My next question is, how do we compare the recombinant Albumin in terms of cost? Like where would Shilpa be placed versus other players like the larger players like Albumedix? And how much of the total capacity, which we plan to put there? And so how much of that capacity do we plan to target for the therapeutic grade and the excipient grade? Can you give any breakup on that?

Keshav Bhutada: No, I think giving breakup on capacity-wise, will be not at all possible for us currently. But what I can tell you is our major market focus will be on therapeutic use because that's a very large and sizable market, for which we have built this facility. Apart from that, nontherapeutic is surely something where once we get customers, we will supply. But I think majority of our capacity will be utilized for our therapeutic applications.

Ajay Surya: And on the costing side, if you can help?

Keshav Bhutada: The costing, I can only tell you, we are competitive.

Ajay Surya: One last question. If we look at the human grade Albumin market, which is quite large, maybe to the extent of $7 billion, $8 billion, but wanted to understand how much extent can the

recombinant Albumin replace this market? Because to our understanding, this cannot be replaced completely. So I just wanted to understand to how much extent can this replace?

And we also mentioned that as of now, there is no other company which is doing apart from the excipient grade, they are not targeting. So I wanted to understand why are other companies not targeting for the therapeutic grade? Is it because of the lower addressable market? Or is there any lack of my understanding? If you can help on that.

Keshav Bhutada: No, I cannot tell why other companies are not doing, what is their strategy. And even if someone is doing, we are not aware as on date currently. So let me be clear on that. So what we have done as a product we have invested in Albumin almost 7, 8 years before, where we acquired a company, we built this asset. We've completely scaled up the development of fermentation process, and we even did preclinical studies, even did Phase I clinical studies. So this is a long journey, so every company has a different strategy.

Ajay Surya: How much of the extent can this RHA replace the human grade Albumin market?

Keshav Bhutada: That we cannot tell it today. I think we have to observe that with time.

Ajay Surya: Over the last 3 years, if I look at our service income and license fees, it has grown nearly 3x from like INR94 crore in FY '23 to almost INR310 crore in FY '25. And one of the previous participants also mentioned that there was a noticeable dip in the current quarter.

So just wanted to know the thoughts on the sustainability of this growth. How much of this growth is driven by recurring royalty income versus milestone based? Or is it a onetime payment? And going forward with the Unicycive and this Orion partnership, should we expect a more predictable revenue stream? Or will this line item continue to be lump in nature?

Alpesh Dalal: As explained a little earlier in the call, the licensing revenues that we receive are towards the initial signing as well as certain milestones related to a few project developments that happens or the filing that happens or the approval that comes through or the launch that happens. Once the product is launched and commercial supplies start, they do not form part of the licensing income bit. That is part one. Part two, our company has remained a B2B company, where we do develop products and out-license to various potential partners. So as with any pharma company, we do have a developmental pipeline. And as and when we keep developing more and more products, we keep out-licensing them. So that out-licensing the molecules or the products is part of our normal strategy and business revenue stream.

Having said that, yes, because different molecules can have different potential in different geographies and even the timelines for some of these milestones when they accrue could differ. So there could be lumpiness in a few quarters. But by and large, because we have a larger or broader portfolio of this, we should be in a position to generate this revenue fairly regularly.

Moderator: Our next question comes from the line of Tushar from MK Ventures.

Tushar: So the CDMO revenue that we typically generate, we have multiple heads under which we are booking revenues. So we have API CDMO, we have some Formulation CDMO projects. We also have Biologics CDMO.

Can you help aggregate the revenue which is being booked under different heads? What would be the component of revenue generated for us, which is basically where we are working with innovators or large pharma or biotech? And which can be sort of classified in the nature of a CDMO project, even if it is right now being bucketed in different heads?

I'm just trying to understand what is the total component of work that we're doing, or which is by other firms classified as CDMO, which we may be putting under different heads? And also, how many projects, some more qualitative details around the CDMO part of business?

Keshav Bhutada: I think if you see overall details what we have given on the investor presentation also, our CDMO revenue for FY '25 is around INR158 crores. And number of programs is 20-plus, which we have currently in our CDMO segment. And what we are trying to do, is that in the years to come or in the next financial year, segregate CDMO revenues. We are even considering that and showing it separately. Overall, yes, there is a lot of opportunity of CDMO work, which already company has done, we are clocking a revenue of INR158 crores for FY '25.

Tushar: But let's say, at the beginning of this call, there was this commentary on a couple of oncology projects in the API business, what I could figure out on the call is more in the nature of developmental work being done for the Innovator. But if your commentary puts it under the oncology API business, has that been counted in the CDMO or would that be separate from the INR158 crores?

Keshav Bhutada: No, it's already included in INR158 crore currently as part of oncology. And going forward, we are trying to segregate and make investors understand more clearly all these revenues because initially, we were not segregating separately as the CDMO revenue. So our dedicated CDMO reporting numbers, we have just started from last few years. So that is the clarity.

Tushar: Also, given that both Biologics as well as the number of projects on the CDMO side and developmental projects, a lot of projects, there is a pivotal outcome expected in FY '26 and maybe FY '27. Would it be fair to assume that from this year onwards, we should see an accelerated improvement in the overall earnings profile and the return on capital generated, given that a lot of the projects for which costs have already been incurred, or do we see a sharp operating leverage at the business this year in short?

Keshav Bhutada: I think only what I can tell you is we are expected to do good during the upcoming financial year also.

Tushar: Can you highlight some more about the new CDMO projects in Biologics that you have picked up?

Keshav Bhutada: Yes. The major opportunities, which I mentioned to you in Biologics, where one of the projects is a long-term collaboration, which we have done with one of the partners, is a long-term contract

where we are developing both drug substance and drug product. And post that, we also have commercial supplies for minimum 3 to 5 years. And apart from that, there are several NBE programs, which already we are under development for our partners. Some are under preclinical, some are in Phase I.

Tushar: Last question on Unicycive. I think we are expecting the approval for Unicycive product in this financial year, right? I think it was the first half of the financial year. Does that remains on track? Would you have an idea of that?

Keshav Bhutada: No, that approval doesn't remain on track. However, we are expecting approval in this financial year. But we have to observe this with time how it will evolve. But overall, from a revenue perspective for the company, there is no major change because the revenue numbers, which we have considered for Unicycive, post commercial launch and the scale up in revenues were considered in FY '27. So I think still we remain on track for that. I will be able to give you more clear picture in maybe Q2 FY '26.

Moderator: The next question is from the line of Gaurav T. from Antique.

Gaurav T.: Sir, the presentation still talks about a PDUFA date for OLC on June 28, 2025. So has the partner got some queries from the filing, and that's why we're expecting a delay now?

Keshav Bhutada: Yes. I think, what happens is PDUFA date still remains same. But majorly, the issue is the facility where the batches were done, the facility had some issues with the USFDA, where the company is working on remediation.

In the meantime, what we have done is, we have also successfully completed manufacturing of registration batches from the new facility, with a new partner and planning to put this new facility in the application. So PDUFA date still remains same. Once we apply with the new facility, then we have to see how the negotiation happens with agency on the approval and launch.

Gaurav T. Which facility was this expected to be supplied from?

Keshav Bhutada: That's confidential. We cannot disclose.

Gaurav T. So we are not expecting launches. So the major growth driver this year will then come from the Formulation division, right? Is that understanding, correct?

Keshav Bhutada: No, because the major growth will come not only from Formulation division, but also from Biologics and API division. So if you see all of our divisions, each one has their own pipeline, their own products, which are growing at their respective pace.

Gaurav T. Any guidance on what was the R&D spend for FY '25 and what we're expecting in FY '26?

Alpesh Dalal: Yes. See, basically, we have an R&D spend that depends on the programs that are being conducted. But for the current year, we have had a run rate of about INR30 crore to INR35 crore per quarter. And we expect that this thing would be in a similar range.

Gaurav T. This INR30 crore, INR35 crore is what is seen in the P&L, right?

Alpesh Dalal: Right. That's what is charged in P&L.

Gaurav T. So gross margins for FY '25 is improved. EBITDA margin, you expect some improvement. But on the gross margin front, do we continue to see improvement in FY '26? Or are we expecting them to be more stable at the current 70% level?

Alpesh Dalal: See, as far as gross margins are concerned, as you would know that in pharmaceutical business, typically, all the generic products are under constant pricing pressure. Having said that, there are incremental benefits that you try and get from your new product launches. So it balances out more or less, it remains in similar region. But with new launches and good launches coming in, it can improve with improved business mix.

Gaurav T. What would be the capex spend for FY '26?

Keshav Bhutada: Yes. For the FY '26, we have to still see, there are some capex which we are trying not to do. But what we can tell you is it is not significant capex, when we compare to last year.

Moderator: Our next question is from the line of Shubham Sehgal from Skill Ventures.

Shubham Sehgal: My question was on the Formulation business. So in this quarter, Q4, what drove such high growth in EU region? Like was it just Nilotinib? Or did we see other molecules also ramp up? And likewise, if you could provide the reasons for higher growth in RoW and lower growth in U.S.?

Keshav Bhutada: Yes, mainly in the Formulation side, for the current quarter, the major revenues are from Nilotinib, you're right. Apart from that, there are some small launches also, which we have done in Q4.

Shubham Sehgal: So with the higher growth in RoW region and lower growth in U.S. So what was this driven by?

Keshav Bhutada: Yes, majorly higher growth in RoW is only because of various tenders where we had participated, we have got approval. And also, there are a lot of registrations which Shilpa has done from last 2 to 3 years, where the approvals have started coming in and also the commercial sales have already started. That is majorly bringing us this increase in the RoW sales.

And when it comes to U.S. sales, U.S., as you know, our facility is under import alert. There is a decrease in U.S. sales only because of uptake of difference between azacitidine and other products like NDAs, which we are supplying from the CMOs.

Shubham Sehgal: And so I wanted to ask like we have incurred higher OpEx costs. So in the previous quarter, I think we had mentioned that, that we increased our R&D spend and there was also FX loss. So the quarterly OpEx spend, which are there, like will this be sustainable, which will continue? And like is there any one-offs this time?

Alpesh Dalal: So see, there are times that some small portion of OpEx could have certain one-offs like some write-offs that happen or at times some fluctuations that happen in OpEx. But more or less, our OpEx for the quarter remains in the region of INR70 crore to INR75 crore, and we should be continuing with that.

Shubham Sehgal: My last question was on our API business. If you see over the years, either our API business has been flattish or declining. I mean I know that we had an issue with our bigger customer. But going forward now, with the upcoming launches and the work we are doing in our API division, do we see API division to grow further? Or do we think for the next 1, 2 years, it will still stay the same?

Keshav Bhutada: Yes, it will grow You will see growth in FY '26.

Shubham Sehgal: And like what would you base that on? Like what would be the major drivers according to you?

Keshav Bhutada: See, majorly, all our captive products for which we are making APIs, starting from Nilotinib to Nor-UDCA, that all will start adding in revenues. Apart from that, even UDCA for which we have CEP will add revenue. Tranexamic acid, where the additional capacity is added, that will add revenue. So we are positive that for FY '26, the revenue will grow against FY '25.

Moderator: The next question is from the line of Vishal from Systematix.

Vishal: On the generic API business, would you be able to put the growth number for FY '26, say, mid-teens or higher?

Keshav Bhutada: Yes, possible.

Vishal: And on Nilotinib, do we continue to be the sole player in the European market? And what market share we would have achieved? And any sense on whether we expect competition to be there?

Keshav Bhutada: Yes. I think last call also I mentioned. On the Nilotinib, yes, currently, as on date, we are the only generic in the market. But in quarters to come, we can expect some players to come in the market. A lot of supplies are done and then distribution and then getting those numbers back in IQVIA, it takes time. So I think as on date, we are not clear how much market share they have taken.

Vishal: So would the entry of competition be staggered or we can expect all of the generic players to come together?

Keshav Bhutada: See, I think we will not expect like generic where there are suddenly more than10 players entering the market. How many players will come that only time can tell.

Vishal: And sir, do we have follow-on products to kind of substitute for the dip in Nilotinib revenues post entry of competition?

Keshav Bhutada: Yes. We have a lot of such products, which are very differentiated also. So yes, there is a continuous pipeline in place which will add on revenues.

Vishal: And on the transdermal patch, any sense on when we can expect the launch in the Europe markets?

Keshav Bhutada: In Europe, we should have launch sometime in Q4 FY '26, tentatively or it can be Q1 FY '27.

Vishal: And just on Biosimilar Aflibercept, should that approval come through this year? And would we be the first one?

Keshav Bhutada: No, approval for this should come in Q1 FY '27 because this year, we will finish clinical trials and file the product. Competition-wise, we may have 1 or 2 players with us, but not many. It's a very complex product.

Vishal: And on Nor-UDCA, would this product compete with Saroglitazar, or it would compete with UDCA?

Keshav Bhutada: Nor-UDCA, the way it works, the therapy-wise, the molecule efficacy-wise, it is very different than both Saroglitazar and UDCA.

Vishal: So you mean it would be even better than Saroglitazar?

Keshav Bhutada: Yes.

Moderator: The next question is from the line of Deepak Sharma, an Individual Investor.

Deepak Sharma: My question is for the Albumin side. What is the average realization figure per gram basis and the average cost from therapeutic and excipient side?

Keshav Bhutada: I think that is confidential, so we will not be able to disclose currently.

Moderator: Ladies and gentlemen, due to paucity of time, we will take that as our last question for today. I would now like to hand the conference over to the management for closing comments.

Alpesh Dalal: Thank you, everybody. Thanks for your continued interest in Shilpa. We hope we have been able to satisfy your questions. And we hope to continue to interact with you in the future as well. Thanks a lot.

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

(This document was edited for readability purpose)