Innovating for affordable healthcare

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Date: 14 February, 2025

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 Q3 FY '25 Conference call

In furtherance to our intimation dated 4 February, 2025 with regard to the Q3 FY'25 Conference call held on Tuesday, 11 February, 2025 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: 2025.02.14 15:44:06 +05'30'

Ritu Tiwary
Company Secretary & Compliance Officer

“Shilpa Medicare Limited

Q3 FY '25 Earnings Conference Call”

February 11, 2025

MANAGEMENT: **MR. KESHAV BHUTADA – EXECUTIVE DIRECTOR – 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: **MS. RUNJHUN JAIN – EY INVESTOR RELATIONS**

Moderator: Ladies and gentlemen, good day, and welcome to the Shilpa Medicare Limited Q3 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 the conference call, please signal an operator by pressing star, then zero on your touch-tone phone. Please note that this conference is being recorded.

I now hand the conference over to Ms. Runjhun Jain from EY. Thank you, and over to you.

Runjhun Jain: Thank you, Yashashri. Good morning, and a warm welcome to everyone. To take you through the results and 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; Mr. Alpesh Dalal, Chief Financial Officer; and Mr. Monish Shah, Head Strategy and Investor Relations.

Please note that the financial results and the presentation have been uploaded on the company's website and on the exchanges. Note that this conference call 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.

I would now like to request Mr. Keshav to provide you with a brief update on the quarter. Over to you, Keshav.

Keshav Bhutada: Thank you, Runjhun. Good morning, everyone. Thank you for joining us today to discuss on our Q3 and 9M FY '25 results. It was a very exciting quarter for the company with multiple opportunities shaping up well for supporting us in growing for years and quarters to come. I'll start briefing about the various business segments in which Shilpa is currently invested, mainly into API, Formulations, Biologics and CDMO. So I'll start briefing with API business segment.

In API, let me start with the oncology segment, for the current year in the oncology segment, our main focus was on building products which are more complex and where there are not many manufacturers or either it's an import substitute. So many of our existing production blocks where we were manufacturing some old products, we have replaced that with new products and validated them so that for the upcoming financial year, we will have a good growth opportunity in the oncology segment.

So let me start with molecule 1, which is an NCE molecule, which we are supplying to one of the US big pharma client, where they have already received breakthrough designation therapy

for one of the cancer treatment. For the current year, all the supplies for the clinical trials have been completed, and there is already a forecast which is given by them for next financial year. And the current clinical trial Phase III is going as planned by our partner. That is the update what we have from our partner.

Now I'll start updating on molecule 2, which is also an NCE molecule, we are supplying to one of the US big pharma company, which is currently under Phase III, where we have a pending order for Phase III supplies, which we are planning to complete in Q4 FY '25. Apart from that, for Methotrexate, which was an important product in our oncology pipeline, we have validated in the current financial year and the CEP and DMF is filed in Q3 FY '25. And for next year, we are hopeful that we will start having commercial revenues from it.

Apart from that, abiraterone acetate we have developed this molecule with in-house API, and also we have developed a differentiated formulation. For API, the process validation batches are completed and DMF will be ready in Q4 FY '25. Two new molecules in oncology, mainly Olaparib and Palbociclib, the plant validations are ongoing, and we are expecting to complete in Q4 FY '25. With this, we will have a total of 4 new oncology product launches planned for next financial year, where we will have a growth having supplies to our internal formulation and also supplies to external formulation players.

Now let me start briefing about non-oncology segment. In non-oncology, mainly on Tranexamic Acid, where we had earlier invested on capacity expansion. In the current quarter, the capacity expansion was completed, and commercial production has started. And we will start seeing a delta of revenue increase in this product from next financial year.

On second molecule, UDCA, a molecule for India, where very few companies are manufacturing, we have received CEP in previous quarters, and we have started feeding samples to various customers in export market. And we are hoping positive that we will have a likely good traction in export market with multiple commercial orders in UDCA for exports.

Third molecule, which is NorUDCA, where company has developed their own API and formulation, which is NCE in India developed for non-alcoholic fatty liver disease. The molecule is expected to have approval in Q4 or Q1 FY '25 for which the API supplies will start from Q4 for our internal formulation, where we will be the only supplier for our formulation.

With this for the next year, we will have an increase in revenue mainly from NorUDCA and our additional orders from ursodeoxycholic acid in export market and also Tranexamic acid where the capacity expansion is completed. So with this, we are positive that in the next financial year, both our oncology and non-oncology segments are likely to perform well.

Now I'll start briefing about new segments, mainly CDMO, Polymer and Peptide, where we have had very good traction in current quarter also. So let me start with CDMO- lanthanum dioxycarbonate, which we have developed and where we are manufacturing both drug substance and drug product for our US partner, the launch order execution has started. And the API supplies for that is expected to be completed in Q4 FY '25 or Q1 FY '26. And with this, the product commercial API sales will start coming in from Q4 FY '25.

The second molecule where we are the only supplier for our US partner, where we are manufacturing both API and formulation. The molecule is being studied for multiple indications and our partner has received Fast Track Designation and the molecule is being studied for more than 5 indications, where we are the only API and formulation supplier. In the current quarter, we have finished the API supplies for our partner for their Phase II clinical studies. And the formulation supplies are expected to complete in Q4 FY '25. And with our partner the Phase I/II studies are ongoing.

The next update is on Polymer, where I'm happy to share in the current quarter, we have received a ~$4 million worth of single purchase order for one of our partners, where we are the only supplier for them from India for the specialty non-pharma application, which is a very complex specialty Polymer. And once the supplies which are likely to be finished in first quarter of FY '26, we expect a repetitive order from them.

The next update is on Peptides where the GLP-1 portfolio in which we are seriously focusing. Liraglutide is the first molecule in which our drug master file is ready now and our formulation registration batches are planned in Q1 FY '26. And once the formulation batches are done with 6 months stability, the molecule will be filed globally in Europe, US and all the rest of the world markets. The second update is on Semaglutide, where our API development is complete and our API process validation batches are planned in Q1 FY '26.

The next update is on regulatory where in the current quarter, we had an audit from Mexican authority and the audit was successfully completed for multiple products. So with mix of oncology, non-oncology and CDMO, Polymer, Peptide, we are having a positive outlook in FY '26 for our API business.

Now I'll start briefing on formulation business. In formulation, totally, we have now 3 NDA approvals with us currently, in which the first molecule, Pemetrexed, for which already the NDA approval is received. The molecule is already launched in US with our US partner. And the molecule is having good traction quarter-on-quarter, and we are hopeful of doing well for the next financial year also with being only generic player to have a RTU room temperature stable product.

The second molecule, Bortezomib, for which the NDA approval is already received, and we had applied for various codes which are required for selling this molecule for insurance reimbursement and premium pricing. The codes are received recently, and our partner is planning to launch this product in April 2025.

Now the third molecule which is Imatinib oral liquid, which is again an NCE molecule where we are the only company to have this oral liquid oncology product approval in US for Imatinib. The molecule is launched by our partner in Q4, and we look forward to have a positive outlook for this also in next financial year.

Apart from that, now let me start briefing about Europe business where Nilotinib, which was our first generic launch in Europe with non-infringing strategy. We were the only player to launch with a number 1 partner in Europe in generic space, and the molecule is expected to really do

well in quarters to come. And with being only generic player in the market and with non-infringing API, company is well positioned to do well in quarters to come.

Apart from that, the second molecule, which is Axitinib, where the formulation approval is already received. And this is again a molecule with non-infringing API strategy. And upon patent expiry, we are planning to do day 1 launch, which is planned in Q1 FY '26. Third project, which is SMLNUD07, which is a molecule which we have the NorUDCA, which we have developed for non-alcoholic fatty liver disease.

Our filing in India is completed, and we are hopeful of getting approval in Q4 FY '25/Q1 FY '26. With this, we will be the only company to launch this NCE molecule in non-alcoholic fatty liver disease. And there is a serious interest from multiple partners, and we are under final negotiation with multiple partners for launching this product in next financial year.

The next molecule, which is Rotigotine, we have already filed this product in Europe, which is a very complex transdermal patch product. And we are not expecting many generics in this product and expecting to launch this product in next financial year. We will be one of the very few generics to have this product. And already, we have partnered with the very strong player in Europe who is very strong in Parkinson's disease for which this molecule is being treated.

Two new transdermal patch products, which are already signed with our European partners. For the 2 molecules, currently our product development is already completed, and our pilot clinical studies are starting in Q4 FY '25. We also have multiple other 4 to 5 new differentiated products for which we have given a brief in our investor presentation. And we are really hopeful that each of this molecule will progress very well in quarters to come. And upon launch, it will give us a sustainable growth in quarters to come.

We have a very strong order book in formulations with not only Europe market and US, also from rest of the world market, where the multiple registrations, which were done in previous years, we have approvals for these products and we have multiple launches in multiple markets. On regulatory front, our US FDA remediation, I'm happy to share that we have successfully completed all the remediation actions, and we have submitted to US FDA requesting for audit.

Now next, I'll start updating you on biologics front. In biologics, our second molecule, which is Aflibercept, which is again a very complex ophthalmic product. The clinical trial batch is completed and our Phase III clinical study is already initiated. We are expecting to complete this study and file this product in India and rest of the world market in next financial year.

And it will be one of the very few generic molecules with very limited competition in India and ROW markets. We have also added two new molecules in our pipeline in current financial year, which are progressing very well. These products being Nivolumab and Pembrolizumab, are major blockbuster molecules being top 10 biologics in world. We plan to initiate preclinical trials in Q4, and we are hopeful to start human clinical studies in next financial year.

And there were 3 new blockbuster biologics, which we have added already in our pipeline, and we are planning to start preclinical studies for these products in next financial year. In total,

company will have almost 6 biologics products with each molecule having a market size of more than $1 billion, at a global level. Now mainly, I'll start updating on the CDMO business for biologics. In the current quarter, we have had very good traction on multiple RFPs, and there is a serious interest from multiple CDMO partners to partner with us for our CDMO business in biologics.

As on date, company has more than 5 CDMO projects, which are in various stages of development, some molecule being where we have already submitted the material for preclinical studies and even Phase I studies. And as mentioned in previous quarter, every quarter, we have a target of signing at least one new CDMO project, as and when the program will ramp up, we will have a likely increase in the revenues.

Now I'll start updating on albumin, which is recombinant human albumin, which is a New Biological Entity being a first synthetic albumin being studied for the therapeutic use. Our molecule Phase I study data was reviewed well by Indian SEC authority, and we have successfully received permission to start the Phase III clinical study, for which the material generation is currently in progress, and we are planning to start the Phase III human study for India and rest of the world markets in Q1 FY '26.

Apart from that, for the global market, for Europe market, our Phase III clinical study protocol is submitted to EMA, and we are expecting response from European authority in Q4 FY '25. Once the response is received from the European authority, we'll be submitting the same clinical study protocol for US, and we will be taking the alignment with US FDA also in Q1/Q2 FY '26. And with that, we will be planning to start a global Phase III study for US and Europe market in next financial year.

Now lastly, I'll update on the Unicycive project, where company has partnered with Unicycive Therapeutics for drug substance and drug product supply. For the molecule, the launch order for 5 million tablets is under execution for which API manufacturing is ongoing, and we are planning to finish formulation supplies of initial 5 million tablets in Q1/Q2 FY '26.

Once these supplies are done, there will be repetitive orders from our customer. At last, we are very positive on company's outlook for FY '26 with multiple assets getting very close to monetization, and we are very positive of having a growth.

I will now hand over to Alpesh Dalal, who will provide a detailed financial overview.

Alpesh Dalal: Thanks, Keshav, and good morning, everyone. Let me briefly take you through the financial performance for the third quarter and nine months ended December '24. Our total revenues for the quarter were INR320 crores, recording a growth of 11% year-on-year and 12 for the 9 months period.,

The growth was largely driven by improved performance in our Formulations and Biologics business, and that was partially offset by the muted performance in our API business. Given the improved business mix, the gross margin for the quarter improved to 72%, which was higher by 5% year-on-year and 7% quarter-on-quarter. And then the resultant EBITDA was at about

INR82 crores as compared to INR68 crores in Q3 of FY '24, showing a growth of 20% year-on-year.

And EBITDA for 9 months FY '25 stood at INR256 crores, which I'm happy to report that it was higher than the entire EBITDA reported during the previous financial year. So we have done significant improvement on the operating side. And EBITDA margins for the quarter and nine months were at about 26%.

We believe that going forward with further improvement in operating leverage and better asset utilization of newer initiatives that we have taken and also the improvement in the business mix that we have been witnessing, we could witness further improvement in the margins.

I'm also happy to share that on back of repayment of a substantial part of our NCD and other loans post our QIP issue, the interest burden has started coming down with the interest cost declining 55% year-on-year during this quarter. Going forward as well, we are working on measures to reduce this interest burden.

Now on the profitability side, profit after tax for the quarter stood at INR32 crores versus INR5 crores last year, whereas for nine months ended December '24, the PAT was INR64 crores, which has almost doubled the entire PAT of FY '24. On the segmental performance, our API business clocked a revenue of INR182 crores during the quarter. That was down 10% year-on-year, largely on account of lumpiness in purchase pattern from our key customers.

Formulation revenues for the quarter were at INR118 crores, which grew by 64% year-on-year, and the growth was mainly driven by our EU business, where we launched a limited competition product as Keshav had explained about Nilotinib. Similarly, the biosimilars business recorded a revenue of INR18 crores, which was a growth of 43% year-on-year.

Now a quick update on a couple of balance sheet items. Our net debt was INR532 crores as at 31st December 2024. And our capex for the nine months period ending December '24 was INR173 crores. And this was mainly on account of our albumin facility, which is coming up.

And with that brief update, I would now like to open the Q&A.

Moderator: Thank you very much. We will now begin the question-and-answer session. First question from the line of Kiran B from Table Tree Capital.

Kiran B: Fantastic update of all the molecules. I have a broader question than any specific question. Are there any particular molecules that can give us a delta of INR100 crores, INR150 crores, INR200 crores in FY '26? Because apart from Pemetrexed scaling, all the other molecules are relatively smaller is my understanding, but I'm happy to be corrected.

So the answer that I'm trying to look for is, are there any molecules which can give us a delta over FY '25 about 100, 150, 200 crs more apart from Pemetrexed scaling up? Because OLC goal date is 28th June, then J-code and it will take time to scale. That's probably FY '27. So that's roughly what I'm trying to understand.

Keshav Bhutada: I will not be able to tell it will be INR100 crores, INR150 crores or INR200 crores delta. But what I can tell you is the molecules what we have mentioned, mainly the NCE opportunities and our Nilotinib launch, Axitinib launch, Rotigotine launch, I think the delta in the revenue is surely possible.

How much it will be that we have to see because as you can also understand, these are mainly NCE molecules, and being a 505(b)(2) product, more complex product. So I feel that giving the number for us currently is difficult. But I can tell you with mix of each of the opportunity, there is really a good opportunity for the company.

Kiran B: Got it. Then sir, the other question that I have is Pemetrexed, we launched maybe in Q4 FY '24, but let's say, Q1 FY '25. So we have taken about a year for Pemetrexed to really start scaling. Is that going to be a similar case for all the other molecules as well? So for example, bortezomib we're going to launch in Q1 FY '26.

Is it going to take 1 more year because even Pemetrexed, we had J-code, we had everything. Is it how the market dynamic usually works that it takes offer all the 505(b)(2) products because of the payer and insurance and everything else. Does it take a year to scale? I mean, just like Pemex is taking, will bortezomib and the other launches in the US take similar amount of time?

Keshav Bhutada: No, Kiran, I'll try to help you understand. Pemetrexed was the first 505(b)(2) injectable launch for our partner also. So, there were some codes which we had to apply for this product, which were applied post approval. But what we have done is in bortezomib case, we have done differently. So, once we had approval, we immediately applied for codes.

It take more time for J-code approval. So in case of bortezomib, that is already available now for us, which we have recently received. And with that only, our partner is planning to launch in April. So I'm very sure that for bortezomib, the case will be better, and we should have a revenue ramp-up as we will be the only RTU player with subcutaneous use, which is a big indication in bortezomib. It will be a better opportunity for us for sure.

Kiran B: Got it, sir. And my final question on the OLC, Oxylanthanum Carbonate. So OLC, 5 million tablets by June 2025, additional 10 million by December 2025. So I'm just trying to understand the dynamics here. OLC goal date is 28th June. Hopefully, we get the approval within 28th June. And then the J-code application and all those things are going to happen, right? So this 15 million tablets that we are pushing in the market, we can't really push in the market. Is that a fair understanding? And therefore, the real growth in OLC will happen only in FY '27?

Keshav Bhutada: No!. One is the launch, but this being an NCE molecule. Our partner is not planning a direct launch. There is a different strategy, which they are adopting, which I'll not be able to disclose. But what I can tell you is for OLC, for next year, already 10 million tablets order is confirmed for us. And the supplies are planned accordingly.

Moderator: We'll take our next question from the line of Nikhil Upadhyay from SIMPL.

Nikhil Upadhyay: Thanks for a detailed input on each of the assets. It's really helpful. So as these products now get launched into the market, so would we see that the license fee income, which we received this year would drop off and it would move more towards formulation sales, how should we understand the dynamics between the license fees and the actual formulation sales? So would there be a drop-off?

Keshav Bhutada: There are 2 things which you should understand. One is the existing products, once the approval comes, that will move to the sales revenue, you are very right. But for the company every year, we add at least 4 to 5 new complex pipelines, which we have already been doing for last 4, 5 years. So there is already a pipeline. If you go through our investor presentation, there are already 5 differentiated products which are already in Phase II, some are in Phase III, some are in preclinical or some are close to filing and approval.

So those molecules will also get out-licensed. So there will be a licensing income, which will start coming in from these new molecules, which are already under execution. So, dynamics will be the existing molecules once the approval comes, we will move to the sales revenue and the new molecules for which already we have been investing from last 3, 4 years. their licensing income will start coming in.

Nikhil Upadhyay: Okay. Secondly, on the API side. So just at a broader level, some of the companies did mention that the pricing pressure in the API has again come back. And if we look at our onco sales and the non-onco sales, year-on-year or over the last 3 quarters, we have seen a drop off. Is it more pricing driven? Or is it just a difference in terms of when the molecules will start getting the supplies? Is it a timing difference? Or is it actually a pricing pressure also you are witnessing?

Keshav Bhutada: Very good question, Nikhil. So I think for us because as you understand that at Shilpa API, mainly we are manufacturing more of a complex APIs and not a me-too generics. So, we have not had so much of pricing pressure, but the major decline what we have experienced in our oncology business this year against last year was because of our major customers who has received some regulatory issues in last financial year. So, they have worked on remediation and after that, slowly quarter-on-quarter, the revenues started kicking up. But what we have done is for this year, we have taken this as an opportunity.

And all the new molecules which were in our pipeline, which we couldn't execute for validation and DMF filing and for future growth, that execution we have done in current financial year, which has resulted in revenue decline. But because, again, these are complex APIs and not many players have it, and we will supply to our own formulation and to the external customers, with classic example being Nilotinib, where we have a non-infringing API. So we are mainly focusing on building such pipeline in our existing production blocks, which will improve the efficiency of the block as well as it will give us increase in revenue.

Nikhil Upadhyay: Okay. So to some extent, we are prepared for the future, and we've used this opportunity to put our capacities and be ready on the back end. So whenever demands come, we are ready with the supply.

Keshav Bhutada: Yes, we already have some visibility that there will be a demand for some products where we have selected and worked on these products. So that is the pipeline on which we are mainly focusing.

Nikhil Upadhyay: Okay. In the Europe, On formulations, we've seen this jump from current run rate of INR12 -16 crores to INR35 crores. And if I understand our commentary of previous quarters, it's only one product which we have launched this quarter and the rest 2 would be launched in Q4 and Q1. Is that understanding correct?

Alpesh Dalal: Yes, its largely due to Nilotinib launch and this is likely to continue for quarters to come. Apart from that, Axitinib, which is a second molecule, will be launched in Q1 FY '26. And then there are a series of launches in upcoming quarters. So yes, you are right that our existing Nilotinib will continue to have revenues, which is already launched, and then there is a pipeline of upcoming launches.

Nikhil Upadhyay: And this Nilotinib opportunity, how long do you see can remain a limited competition kind of opportunity? Because earlier in last call, you had mentioned we would be the first generic player. But when do you see competition can come in or any sense if you can give there?

Keshav Bhutada: Currently, it is difficult for us to give any thought there. But we feel at least for a couple of quarters, we'll not have any competition.

Moderator: We'll take the next question from the line of Krisha Kansara from Molecule Ventures.

Krisha Kansara: So sir, my first question is on our API division. So in the last Concall, you had indicated that the European API segment is now set for a good growth in the coming quarters. And in the last 6 months or so, we have received close to 4 or 5 API approvals for Europe market, including Desmopressin, UDCA and many other approvals. So how do you see Europe as a market shaping up for us? If you could give us the context as to how much of our API sales in, let's say, in this quarter or 9 months were contributed by Europe market? And what is your view on European API segment in the upcoming quarters?

Keshav Bhutada: In API when we are selling to our formulation, for many of the partners, they don't take molecule by saying that we are taking only for Europe. It will be for a global market because we make single quality for all the grades. So for me, it will be difficult to give you exact percentage as to how much of our API is going to Europe because many of the partners are using our API for US, Europe, ROW and many multiple markets.

But Europe business and rest of the world market is again a very big opportunity. And since we have a pipeline of products like UDCA, Tranexamic Acid or some complex molecules in Peptides like Desmopressin, Octreotide, Liraglutide for which now our DMF is ready. So, what will happen is in quarters for years to come, these all will start giving us a delta of revenue.

So, I'll not be able to give you an exact percentage of how much it will be, but we are positive that all these new molecules, what we have in pipeline will start adding revenues. And since you

can understand that for many of the formulations which are launched and to be launched, we are backward integrated, which will be a source of revenue for us from Europe market.

Krisha Kansara: So, for us going forward, Europe will be a key market is what we can assume, right?

Keshav Bhutada: Not only Europe, but it will be a mix, like when we are doing CDMO for multiple partners, they are mainly targeting US market. So I will say it's a mix of US, Europe and rest of the world market.

Krisha Kansara: In our biosimilar segment, so we reported close to INR18 crores of top line in this quarter. Now correct me if I'm wrong, but our entire biosimilar revenue as of now is coming from Adalimumab and CDMO projects that we have. And previous quarter, we did INR31 crores in sales in this segment. So it has come down from INR31 crores to INR18 crores. So is it fair to assume that this is because of the CDMO project lumpiness nature? Or are we seeing some kind of a slowdown in the Adalimumab segment?

Keshav Bhutada: I think we are not seeing any lumpiness in our biologics business. It's mainly because of seasonality of our customers, especially in CDMO. Like in last quarter, we had given one big supply to one of our Korean partner for their Phase I and preclinical supply, which actually gave us a big growth. But apart from that, you are right that our current major revenues are coming from CDMO and Adalimumab sales. But going forward, you will start seeing more of the revenues from multiple licensing opportunities in multiple markets.

Krisha Kansara: Okay. So will you be able to give a breakup of, let's say, how much was from Adalimumab then from CDMO.

Alpesh Dalal: At this juncture, we wouldn't be providing those details. But as Keshav was mentioning, Adalimumab is having consistent sales currently. So we are not seeing any challenges over there. CDMO business remains lumpy depending on the development stage. So to that extent, yes, there will be lumpiness.

Krisha Kansara: Okay. And if we observe our gross profit margin has improved significantly. If we compare on a sequential basis, it is up from 65% to 72%. But the same has not been translated into EBITDA because of an increase in other expense. So I wanted to understand as in what drove our other expenses. Was there any onetime expense that we took in this quarter? Were there some remediation expenses that we took in this quarter? Or what was the composition?

Alpesh Dalal: Yes. So there are a couple of items over there. I think one of the things is that because of the developmental cycle that we have, some of our R&D spends during the quarter have been on a higher side as compared to what it has been in the past. Also, due to euro exchange rate going against the exporters, there has been an exchange loss as well. These 2 have been the main contributors for the other expenses going up during this quarter. But I think going forward, it should come back into the normal region.

Krisha Kansara: Okay. So what was the remediation expense in this quarter?

Alpesh Dalal: Remediation expense was not significant, maybe roughly about INR2-odd crores, not much.

Moderator: We'll take our next question from the line of Rupesh Tatiya from Intelsense Capital.

Rupesh Tatiya: There are so many segments, CDMO, non-CDMO, biologics, FDF. I am very new to the business, and it's very complicated. So can you maybe just give some sort of a 2-, 3-year revenue and EBITDA guidance?

Alpesh Dalal: Sorry, as a policy we do not provide any guidance.

Rupesh Tatiya: Coming to specifics. First question now is on the biologics. So, we have these 5, 6 assets in biologics and then also, I think recombinant albumin, some commercialization, which is expected towards the end of FY '26. So, can we expect, biologic to become, let's say, INR300 crores business for us in FY '27? I mean is that like a reasonable estimate? Can business have that kind of trajectory? Or do you think it will take longer?

Alpesh Dalal: So first, as I mentioned, as a policy, we don't provide any guidance. I think what we can tell you is that the way our business is building up with development happening for our pipeline products as well as the CDMO contract pipeline that is building up for us. I think we see a very good traction happening in our biologics business, and we should be able to generate sizable revenues going forward.

Rupesh Tatiya: Okay. What is our total CDMO revenue? Because I am confused. In API segment, you say some CDMO revenue of INR25 crores in 3Q and INR62 crores for nine months. And then there is this licensing services revenue in formulation. So maybe can you help me with the 9 months numbers, what is our total CDMO revenue, all development plus commercialization combined?

Alpesh Dalal: So again, this CDMO revenue that we have got in API business is north of INR60 crores during the nine months period.

Rupesh Tatiya: Okay. And then there is no CDMO revenue booked in FDF?

Alpesh Dalal: No.

Rupesh Tatiya: Okay. And then so what is this licensing services component? Maybe can you just explain that a little bit? And I think earlier participant also asked how will this move in, FY '26, FY '27? Can this component decline?

Keshav Bhutada: Since you are new to the business, I'll give you some understanding. See, Shilpa Medicare as a company, we are mainly into B2B. In all the markets, except India for a few of the molecules. So what happens is for all our pipeline molecules, we partner with some of our partners like we have relations in Europe, US and multiple markets.

So for each of these molecules, we partner with some company to sell the molecule. So when we partner with them, there will be upfront licensing fee and then there will be various milestones on approval on launch, post-launch sales achievement milestones. So these are all revenues which are called as licensing income. Is it clear?

Rupesh Tatiya: Yes. So, it is not CDMO though, it is kind of like out-licensing for our products we have developed in generics.

Alpesh Dalal: Yes. Fundamental difference in licensing and CDMO would be that in licensing, the IP belongs to us. We own the IP. We have developed it on our own account. After developing that IP, we have given the license for the IP to somebody else. In CDMO, we do the development for our partners.

Rupesh Tatiya: Okay. And then, sir, maybe another question is, this OLC that we are developing for Unicycive. Can you give some sense of the market opportunity? How large a product can this be? I mean, however you want to explain it by number of patients or therapy or application, but how large can this product be?

Keshav Bhutada: Just to tell in simple words, this molecule going forward, it's for our end customer, it's likely to be more than $1 billion opportunity.

Rupesh Tatiya: Okay. And we are a single source supplier, for API and formulation?

Keshav Bhutada: Yes.

Moderator: We'll take our next question from the line of Neha Kharodia from Abakkus.

Neha Kharodia: So, my first question was regarding the API business. So, in case of oncology business, we were expecting the supplies to Intas to improve in the coming quarters as per our commentary in the Q2. So just wanted to understand the reason behind the decline in the current quarter for the same and why there was lumpiness in the client business?

Alpesh Dalal: The Intas business against the last year in Q3 once they had the remediation issues. From there, it has significantly improved in current financial year. But it is still ramping up. So as per our end customer, they are hoping to do better for next financial year with respect to our API supplies also. So that is the understanding we have with Intas. Still, it is ramping up, it is not fully ramped currently. That is why you will see this. It's slowly increasing.

And since in the last financial year, these were very big revenues, from Intas. So, you will always see that degrowth. But what we are also doing is, the blocks where we were manufacturing for Intas, in those blocks we have currently changed our production plan, and we are manufacturing some more high-value complex good gross margin products, for which currently we will have some pain for some quarters. But for next financial year, they will again contribute to the commercial revenues.

Neha Kharodia: Okay. Sir, but even sequentially, we have seen a decline in the oncology business. So, like the supplies have further reduced to Intas or was it led by some other reason?

Keshav Bhutada: Yes. Sequentially, it has decreased mainly because of Intas and for some of our products where we have orders, but we have taken production of Nilotinib because that's an important launch for our formulation. So, because of that, you will see a decline in the current quarter because in those blocks now we are manufacturing mainly Nilotinib for our formulation.

Neha Kharodia: Okay. So the situation for oncology business, if my understanding is correct, is likely to improve from Q1 and probably in Q4 as well, we can see some pressure on the oncology business?

Keshav Bhutada: Yes. I think from Q1, there will be improvement.

Neha Kharodia: Understood. And also on the non-oncology business, so with the Tranexamic Acid expansion, we expect the commercial supplies from Q4. So how should one look at the non-oncology business because there also we have seen sequential as well as year-on-year decline?

Keshav Bhutada: Yes. In non-oncology, what we have done is for some of our molecules, which we were manufacturing for many years like Ambroxol, Phenylephrine, there we have reduced our production and for those production blocks, we have now replaced with high-value products like UDCA, which will also go in the export markets and followed by NorUDCA, which is for a formulation for NAFLD. So going forward, in FY '26, the old molecules, which were not giving a significant revenue jump, those molecules we have replaced with some better molecules with better margins. So, you will see a good increase in the non-oncology business also starting from Q1.

Neha Kharodia: Understood. And also, regarding the tax rate. So as of last quarter, it was at 51%, and we had guided that it is likely to come down to 35%. So just wanted to understand the reasons for improvement in the current quarter? And how should one look at the tax rate going forward? Will the 24% level of the current quarter be sustainable or how to look at it?

Alpesh Dalal: The current quarter numbers that have come up, there are certain MAT credits and all that have come in, which may not necessarily continue. But as we had guided that we were taking certain measures to arrest the tax leakage happening on account of intercompany loans and all. So, a large chunk of that we have done that has helped us from an overall perspective. And as I had guided last time also that overall, we are likely to remain in the region of 35% tax rate.

Neha Kharodia: For FY '26?

Alpesh Dalal: Yes. We should reach nearer to that. We are currently at about 39%, 40% for the 9 months. So, we might be slightly a couple of percentage points higher during this year. But next year onwards, we should reach 35% our tax rate.

Moderator: We'll take our next question from the line of Deepak Sharma, an Individual Investor.

Deepak Sharma: How will the Trump policy impact the export revenue of the company? If yes, then how much there will be impact on which segment?

Keshav Bhutada: I think on the Trump recent announcement on tariff, whatever they have given. still, I think multiple things they have not clarified how much will be the tax rate and for which therapy of drugs, etcetera. But what I can tell you is if you have gone through our numbers also majorly, in our formulations, still the US revenues are not significant. And the molecules which we are manufacturing are more of a life-saving drugs. We think this should not have significant impact, but we should observe in quarters to come.

Deepak Sharma: Okay. Will you sustain the EBITDA margin of 26% to 27% in the coming quarters?

Keshav Bhutada: Yes, that should be sustainable, as I was mentioning in my commentary as well that we do believe that there are opportunities to improve it further. But certainly, 26%, 27% is maintainable.

Moderator: We'll take our next question from the line of Vishal from Systematix.

Vishal: One clarification on Nilotinib and Axitinib. So, since you have launched this ahead of others on the market through a non-infringing route, so basically, have you been able to kind of circumvent the patents around this and launch it earlier? Is that the case here?

Keshav Bhutada: Yes.

Vishal: Okay. So, how long this window will last for you?

Keshav Bhutada: That depends on how the litigation goes for other partners for which we don't have clear information. But as I mentioned, at least for a couple of quarters, we will be the only generic, what we feel.

Vishal: And post that, do you still expect this to be limited competition? Or you would expect kind of markets getting flooded with several generics?

Keshav Bhutada: No, this is a very complex product. So, I will not say that there will be like 10, 20 generics like that. But how many will come, how the market will shape up, I think we have to observe.

Vishal: Okay. And are you also kind of trying to build on this opportunity for the US markets through the non-infringing route?

Keshav Bhutada: No. US has a different strategy, and we think at the moment there is no opportunity for this molecule in US for us.

Vishal: Okay. And with respect to the Rotigotine transdermal patch, you would be a generic, a substitutable generic, right?

Keshav Bhutada: Correct. You're right.

Vishal: Okay. So, it would be easier to garner market share.

Keshav Bhutada: Yes, you're right.

Vishal: Okay. And just on this licensing income, if you can kind of talk about the events that trigger a licensing income for you? And, some guidance on a broad range, like if you can set a floor for the licensing income that you would expect probably a basic level of licensing income that you can generate every year with whatever assets you have currently?

Alpesh Dalal: So, I think as far as the various milestones related to licensing income is concerned, Keshav already explained those, that each contract is different. And depending on various milestones

that you reach within the contract, which could be either submission of a dossier or completion of certain studies or filing of the dossier receipt or marketing authorization approval, launch of product, there could be several such milestones for which licensing revenues can be generated or triggered. But it differs from contract to contract.

As far as setting any expectations or floor for the licensing fee and all, I think what we have been mentioning is, see, we are a B2B company. So, this is part of our regular business that we would develop products, and we would generate licensing income out of it. How much is the quantum and all will be dependent on each opportunity that comes up, the kind of product, which is there, the kind of market potential that the product has. So, it is very difficult to quantify or provide any guidance on that.

Vishal: Okay. So just if you could share whether there was a onetime lumpy licensing contribution from a single product this year? And so, if you could share that? We have different opportunities that we have worked on, right?

Alpesh Dalal: We have had different opportunities that we had worked on and we can't disclose specifics about any contract because of the confidential nature of the agreements that we have.

Vishal: Maybe whether there was a single product contributing to a large part of the licensing income, Not the name of the product.

Alpesh Dalal: As I mentioned, we have a number of such opportunities, which we have worked on.

Keshav Bhutada: So, just to clarify, for the current year, we did not have a licensing fee only for 1 product or 2, 3 products. It was a mix of more than, I can tell you, at least 15, 20 products in different customers in different territory with multiple products, multiple strengths. So, it is very difficult to quantify exactly that. But I can tell you it's from a multiple pipeline product.

Vishal: Okay. And on the biosimilar Aflibercept opportunity. Do we have the block manufacturing Aflibercept capitalized or once it is commercialized, you will capitalize the asset then?

Alpesh Dalal: Yes. The capitalization will happen once everything is completed, and the product is ready and all. So, capitalization has not yet happened fully over there.

Moderator: We'll take our next question from the line of Tushar Bohra from MK Ventures.

Tushar Bohra: Just to carry over from the previous participant on licensing. Is it just fair to assume that given you have highlighted so many new products that you are working on and a lot of opportunities are closer to commercialization or in advanced stages, that licensing income should continue to be a major driver of both revenue and profitability for us going forward over the next maybe couple of years? Not looking beyond that, but in the foreseeable future, do you think that it will continue to be a major driver?

Alpesh Dalal: Yes, it's right. I'll not say it will be only a major driver, but it will be one of the major drivers.

Vishal: Got it. So, we should continue to model for licensing as one of the important revenue drivers for the firm.

Keshav Bhutada: Yes. We are a B2B company, And yes this will be an income which will continue for us every quarter. It can be sometimes very high, sometimes it can be down against previous quarters, but it will be there every quarter.

Tushar Bohra: Second, on CDMO, so when the contract with Unicycive came up, I think it caught a lot of people by surprise who are not aware that Shilpa is in advanced stages of development in any CDMO project. Maybe you would like to highlight overall strategy behind building our CDMO business across API as well as biologics. And if there are any other products that may be similarly placed, which could come up over the next couple of years in terms of commercialization possibility?

Keshav Bhutada: So, there are a lot of molecules already in pipeline, and the main focus is on CDMO because these are surely a good gross margin business. And also, once if you have a good customer where you are supplying API and if you get even formulation, you will be one of the only suppliers for them or at least there will be a second source or third source opportunity. So, it will be a sizable opportunity as and when there are milestones which our partner will achieve.

Tushar Bohra: Maybe, if you can qualitatively highlight what kind of efforts the company is doing to build up the revenues of the business development of CDMO specifically?

Keshav Bhutada: Yes. Like company has a good talent pool in various markets, starting from US, Europe and some high-quality rest of the world markets. And since one good thing with us, many people ask us that we are into so many segments, but that is the main strength what Shilpa has. Because we are into API, we are into formulations, we do Peptides, we do Polymers, we do Biologics, we do fermentation, so when we go to any customer, we have multiple offerings. And if we enter with them in any of this one vertical, that's a hit for us. So that is the kind of advantage which company has.

Tushar Bohra: If you can highlight on albumin besides the therapeutic grade, if any efforts are being taken to develop it for excipients and cell culture, etcetera?

Keshav Bhutada: Yes, on excipient grade, we are focusing on developing some clients, where we want to start feeding them samples. So, there is a business development team, which we have appointed, and they have joined. So slowly, there is an effort now getting started for selling this excipient grade, which we are doing for the first time. So, we have to observe how it will evolve now in the upcoming financial year.

Tushar Bohra: If you can highlight more on the ADC side, what are we doing exactly on antibody drug conjugate?

Keshav Bhutada: Yes. Because we manufacture biologics, we have small molecule capabilities also. So, we have now taken some ADC molecules in our pipeline. Similar to how things are today where in top 5 molecules globally, 2-3 are Biologics.

So same way for ADCs will get into picture in the coming years. This being more targeted than even biologics. So, we are well positioned because we have biologics, we have small molecules where we can manufacture payloads, linkers, etcetera. So together, we have very good manufacturing and development capability of ADCs now.

Moderator: We have a next question from the line of Bhawani Shankar Somani, an Individual Investor.

Bhawani Shankar Somani: We have big product being lined up for launch in next financial year. So, I wanted to know from the management perspective, which are the top 3 products, which according to you will be the biggest revenue generator next financial year.

Keshav Bhutada: Yes, the top 3 molecules will surely be Nilotinib, Axitinib and our CDMO products what we are doing broadly.

Bhawani Shankar Somani: Okay. I have a question slightly different from the business perspective. So, there are a few promoters. I think they have been with the company for like 6, 7 years, but now they are trying themselves to be reclassified to public category specific reason or?

Alpesh Dalal: I think some of the promoter family people who are not involved in the business, they have not been actively doing anything. They have not been participating in anything. And obviously, as promoter group, there are additional responsibilities cast on you. So, it was just more of a compliance-related requirement that was coming up, which they wanted to avoid, nothing more than that.

Bhawani Shankar Somani: Okay. Like you mentioned in biologics segment about one new project being signed up in food sector. So, I just wanted to know more about like what's the product and what the project basically is like.

Keshav Bhutada: It's one of the projects, which is developed by fermentation. I wont be able to disclose the molecule name, but it's a CDMO project where the client has regular commercial requirements. And now we will be the one more source for them where the development activity he has initiated with us.

Bhawani Shankar Somani: So, will that be launched in India and/or other foreign countries?

Keshav Bhutada: It's mainly for export market.

Moderator: Ladies and gentlemen, due to time constraints, we'll take that as the last question for today. I now hand over the call to management team for closing comments. Over to you, sir.

Alpesh Dalal: Thank you very much. Thanks, everybody, for your continued interest in Shilpa. We hope we were able to answer most of your queries. If you have any follow-on questions or queries, you can reach out to our IR team, and we will get back to you. Thanks a lot.

Moderator: Thank you, members of the management team. On behalf of Shilpa Medicare Limited, that concludes this conference. Thank you for joining us, and you may now disconnect your lines.

(This document has been edited for readability purpose)