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Date: 19th November 2025

To,

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

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

Dear Sir/Madam,

Sub: Transcript of the Q2 - FY26 Conference call

In furtherance to our intimation dated 5 November, 2025 with regard to the Q2 -FY26 Conference call held on Monday, 17 November 2025, at 11.00 hrs., please find enclosed transcript of the call.

Thanking you

Yours faithfully,

For SHILPA MEDICARE LIMITED

RITU TIWARY Digitally signed by RITU TIWARY Date: 2025.11.19 15:42:21 +05'30'

Ritu Tiwary
Company Secretary & Compliance Officer

“Shilpa Medicare Limited

Q2 FY '26 Earnings Conference Call”

November 17, 2025

MANAGEMENT: **MR. KESHAV BHUTADA – EXECUTIVE DIRECTOR AND CHIEF EXECUTIVE OFFICER – SHILPA PHARMA LIFESCIENCES 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 Shilpa Medicare Limited Q2 FY '26 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 Mr. Monish Shah, Head of Strategy and Investor Relations. Thank you, and over to you, Mr. Shah.

Monish Shah: Thank you, and welcome to our quarter 2 FY '26 Results Conference Call. Today, we are joined by Mr. Keshav Bhutada, Executive Director and CEO of Shilpa Pharma Lifesciences; and Mr. Alpesh Dalal, our CFO.

Before we begin the call, please note that the financial results and the presentation has been uploaded on the stock exchanges. 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 stock exchanges as well.

I would like to remind you that today's discussion might include certain forward-looking statements based on current expectations and assumptions. These statements are subject to risks and uncertainties that could cause the actual results to differ materially. 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.

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

Keshav Bhutada: Thanks, Monish. Hi, everyone, very good morning to you all. The current quarter marks a very big breakthrough for us. We recorded highest quarterly EBITDA, and the excitement is not only to share another set of results, but to share the momentum, the confidence and the direction that the company is focusing on ensuring better asset utilization.

We are operating in some of the most advanced, complex and high entry barrier segments, namely API, Formulations, Biologics, as an integrated one-stop solution. So I'll start briefing about each of our business segment.

Let me start with the API business division. In API, mainly we are working in 4 key verticals: oncology, non-oncology, CDMO, peptides and polymers. In oncology and non-oncology segment, we are developing 2 NCE programs for a big pharma customer.

For the first product, our customer has got approval, and the commercial supplies are expected to start from Q4 FY '26. The second NCE program, where our partner is currently doing Phase III clinical studies, for which the filing is expected in FY27.

The third product, which is Nilotinib, where we are supplying our differentiated API to a formulation, the quarterly volumes are increasing, and we are gaining market share every quarter-on-quarter. In the current quarter, we have successfully completed 2 new products filing in U.S. and Europe. And we could also complete one new product, PV, in the current quarter.

Coming to non-oncology, Tranexamic Acid, the volume is growing every quarter-on-quarter, and we are expected to achieve our full capacity utilization in the current year. And we are also planning to build additional 100 metric tons capacity -- for which the capex investment has already started, and we are expected to commission this in next financial year.

The second product, Ursodeoxycholic Acid, we had received CEP approval in the previous financial year. Post the initial Business development activities we are expecting to start commercial supplies from Q3 FY '26.

Third product, which is NorUrsodeoxycholic Acid, which is a novel product, where our API commercial supplies will start from Q3 FY '26, and expect it to contribute meaningfully in next financial year. And there is one more new product, which is an import substitute, where the PV batches have started in current quarter.

Coming to CDMO, peptides and polymers, we are having good traction in the CDMO business, with several programs advancing in various stages of development. The Lanthanum Dioxycarbonate, a product which we have developed for Unicycive Therapeutics. We have built a dedicated facility, and we are planning to commission this block in Q3 FY '26. And the commercial launch for this product is expected in next financial year.

Coming to polymer, where we are doing commercial supplies to our U.S. customers and every quarter, the volumes are increasing. On the Peptide front, Semaglutide remains a very important product for us. We have finished all our development activities and our planned PV batches are initiated.

We are planning to complete our PV campaign in Q4 FY '26. And company is also investing a large dedicated peptide facility with fully advanced automation systems, and we are planning to commission this facility in next financial year. Overall, API business is expected to continue growth in double digit year-on-year.

Now coming to Formulation business division. Today, I'm happy to inform everyone that we have successfully launched our first NCE program in India, NorUrsodeoxycholic acid. Globally, to bring this product to market, Shilpa Medicare is the only company to launch this product in India.

The other 3 NDA products, which were approved in the last financial year, and the launches in U.S. have already begun. We continue to see encouraging response from our launches, especially in Pemetrexed injection where our market share is increasing quarter-on-quarter. And the other 2 products, slowly, we are seeing that there is a growing traction. And we are also planning to take NorUrsodeoxycholic acid to the global market.

Now coming to Europe market, where the Nilotinib, which was launched in Europe in last financial year. Every quarter, the market share is continuing to grow. And even today, we don't expect much generic competition for the current quarter. Coming to Rotigotine, transdermal patch, which is a very complex transdermal patch for Europe, we are expecting approval in Q4 FY '26.

And company has successfully completed U.S. clinical study, and we are planning submission in Q3 FY '26. The 2 new -- 2 other transdermal patches, which are already in the advanced stages of development, we are planning to file this product in next financial year.

Coming to Ondansetron long-acting injection, which is first of its kind long-acting injection for advanced patients with antiemetic diseases, where the Phase III clinical studies are completed, and we are planning to file this product in India in Q4 FY '26 and plan to launch in next financial year. Besides this we are having 5 more differentiated 505(b)(2) programs in different stages of development. NCE program, OLC of Unicycive Therapeutics is expected to have approval in FY '26.

Coming to Shilpa Biologics, we have 2 new NBE programs, one with mAbTree Biologics and second program with Alveolus, and both the programs are expected to enter Phase I human studies in FY '27. Our first ADC biosimilar, which our development work in lab is in the advanced stages, and we are planning to again enter this product in human studies in FY '27.

So now we have 8 biosimilar programs including our pipeline products, which are under various stages of development. Amongst these Aflibercept is the most advanced program, which is currently under Phase III studies, we expect to launch this product in FY '27 once the clinical studies are successful.

The second program is Nivolumab, which is a blockbuster product globally, the Phase I/III human clinical trial in India are likely to start in Q4 FY '26. And in our Biologics division, totally, we have 6 active CDMO programs, which are in various stages of development.

Now coming to Recombinant Human Albumin, we have permission to start India clinical studies, and we are also planning to submit our IMPD submission in Europe for starting European Phase III clinical study. And we are planning to start European Phase III clinical studies in Q4 FY '26. And product scale-up and filing in Europe for IMPD submission is on track.

Overall, company continues to position itself as one of the advanced integrated API peptide, polymer, differentiated formulation and biologics and CDMO services company. And overall, our financial results reflects discipline, innovation and resilience. And more importantly, it reflects the Shilpa of future, a stronger Shilpa, a more profitable Shilpa and a globally competitive Shilpa, which is defined by innovation, scientific depth and discipline to increase its asset utilization.

With this, I hand over the call to Alpesh Dalal. Thank you.

Alpesh Dalal: Thanks, Keshav. Good morning, everyone. Let me briefly take you through our financial performance for the second quarter and the first half of FY '26. We reported our highest ever quarterly revenues at INR372 crores, recording a growth of 7% year-on-year, whereas revenues for the half year were at INR700 crores, reflecting an 8% growth.

Our gross margin improved to 72% for the quarter and 74% for the first half. And this improvement in gross margin was seen despite lower contribution coming in from CDMO and licensing business as compared to previous year and thereby reflecting a strong margin in our base business, driven by scale-up in our share of complex product portfolio.

Now for the quarter, we recorded the highest ever quarterly EBITDA at INR110 crores. We have crossed INR100 crores landmark for the first time in our history. And that was as compared to INR 91crores in Q2 of FY '25, showcasing a 21% growth. And the EBITDA for the first half was INR208 crores, growing at 20% year-on-year.

Now with this strong top line growth, the company also reported a strong EBITDA margin at 30%, both during the quarter as well as for the first half, reflecting a 4% and 3% improvement in margins on year-on-year.

Now with the increased market share in our base business products, coupled with the introduction of novel products like NorUDCA, we believe that this change in business mix should help sustain our profitability in the current quarters. And besides this, we also have a very strong pipeline of complex FDF products, which would be launched across various markets in the globe.

We also continue to see a reduction in our interest outgo year-on-year basis, and we believe that we have now stabilized at the current level from a run rate perspective. And we also expect that most of our capex program would be funded through internal accruals. So, the interest outgo should be at the current levels.

The PAT for the quarter was INR44 crores. And for the half year, it was at INR91 crores. I'm happy to report that the PAT that we have achieved in the first half has surpassed our full year PAT in FY '25, which was at INR78 crores. I would also like to draw your attention to the fact that the ROCE profile of the company has been improving steadily.

Our adjusted ROCE, excluding investments made in our high-growth potential biological and NBE business has seen a significant improvement from 4% in FY '23, to approximately 17% in the first half of FY '26.And with Biologics business progressing well, we remain confident of improving our operating leverage driven by improved business mix and thus improving the overall ROCE in the coming years.

Now a very quick highlight on the segmental performance. Our non-captive API business clocked a turnover of INR205 crores, and the growth was on account of higher offtake of key products from our newly expanded capacities. The Formulation business for the quarter was INR109 crores, growing at 16% year-on-year.

And if we exclude the licensing income, the base business reported a robust growth of about 60% for the quarter compared to previous year and a 67% growth in the first half of current financial year. Thus, the base business growth is driving our growth in the Formulation business. And this growth was mainly driven by increasing the market share of our complex product portfolio in the U.S. and limited competition product in the EU market.

Likewise, our Biologics business has been growing well, recording revenue of INR25 crores in Q2 and INR61 crores in the first half of the current financial year. Moving on to the balance sheet items. The net debt at the end of September was INR569 crores with capex investments of INR153 crores during the first half of the financial year.

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

Moderator: Thank you. We will now begin the question-and-answer session. The first question comes from the line of Sucrit D. Patil with Eyesight Fintrade Private Limited.

Sucrit D. Patil: I have 2 forward-looking questions. My first question is, as pharma industry shifts towards more specialty drugs, oncology or global partnerships, looking beyond the quarter number, how are you planning to position Shilpa to build a lasting edge beyond just quarterly growth or licensing deal? Or is there any deeper plan of action that you are going to be putting into place that will keep the business strength strong? That's my first question. I'll ask my question after.

Keshav Bhutada: Yes. Thank you, Sucrit. As a company, if you see our historical performance and our historical investments, we have always done investments in something which is more complex and in specialty divisions. And Shilpa has done significant investments in Biologics, in our transdermal facility, in our fermentation facility for Albumin.

What we will be doing in next 3 to 5 years, we will try to monetize all these investments. I think that's a simple formula which we will follow because Shilpa has all the technical know-how, the complex pipeline in place, the R&D team is well positioned for such complex development. So only a focused strategic execution and monetization of asset is something which we will be focusing.

Sucrit D. Patil: My second question is to Mr. Dalal. Again, a forward-looking one because it has -- given the current guidance, I just want to understand how things go ahead. When costs rise, whether it is raw material, compliance or R&D investments, how do you make sure the margins stay steady without slowing down growth?

Is there any system you have built? Like smarter sourcing, pricing discipline or operational efficiencies that will help you keep the profits in line even when things sometimes get a bit out of control, or you don't have any -- certain crises may stand up in the coming days. Just want to hear your view on that.

Alpesh Dalal: Yes. The business is marked with uncertainties at all points in time. What we end up doing is that we end up having a very agile and efficient system in place where we keep monitoring the

changes happening in the marketplace and determining the actions required to offset some of those challenges that may come up.

What we try to do is we try to predict the market situation. Say, for example, if we expect a particular raw material is likely to come up in short supply, which would end up increasing the cost of the material in the coming days, we might end up stocking up that material.

We look at leveraging -- building on a lot of operating leverage of various businesses. As you know that we are present in various businesses across various segments and all. And we try to cross utilize a lot of our business intelligence from one to the other.

And even on the operational side, what we do is, some of our big cost items are constantly under our radar to ensure that we are looking at alternates which will allow us to reduce the cost and allow us to complete our ESG-related obligations simultaneously. So, the case in -- an example could be green energy related solutions, where we try to bring the cost down as well as building more sustainability. And that's a constant exercise that we keep doing all the time.

Moderator: Next question comes from the line of Krisha Kansara with Molecule Ventures.

Krisha Kansara: My first question is regarding NorUDCA. Now that we have launched this in Indian market, my question is with respect to the potential of this product. I'm aware that we have tied up with 3 marketing companies, and we are also going to launch our own brand. But I have 3 sub questions to this topic. One, can we assume that our own brand will take some time to scale up? And for at least next 2, 3 years, a substantial amount of top line will come from the profit-sharing arrangements which we have with our marketing partners. That is the first question.

Second, what is the kind of market potential that this drug has? What kind of an opportunity are we looking at in terms of, let's say, top line or profitability when it comes to our books in the next 1, 2 years? And also, if you can highlight -- if you can throw some light on the competitive landscape of this drug. I know Shilpa is the first company to treat NAFLD with this drug. But in terms of the other existing treatments of this disease, where are we placed?

And what do we bring on the table to compete with the other players? And the third part of the question is what kind of licensing income are we expecting from these 3 marketing arrangements that we have made? That is my question on NorUDCA.

Keshav Bhutada: Yes. Thanks, Krisha. On the first question, we don't have a profit-share arrangement. The arrangement is more with respect to supply price. So the revenues which will be coming in the upcoming quarters, it will be mainly with respect to supply price.

And second part, yes, we have a licensing income, we have received some portion of it and the remainder we will be getting it in the upcoming quarters. Mainly, we have some milestones which are year-on-year, which our marketing partners must achieve. Once it is achieved, then we will get those milestones.

But the most important part here is we are not expecting a big licensing income here. It will be more of a sales revenue, which we will be getting in the upcoming quarters. When it comes to NorUDCA -- and if you see the press release also, the NorUDCA as a product, it's a very differentiated opportunity because especially the NAFLD patients, the amount of patients which are available in India for this disease are significantly high.

And with respect to clinical adoption dynamics, we expect at least we will get ~10% of the treated NAFLD populations, that will get convert to NorUDCA. This is what is our estimate over the next 3 to 5 years.

Krisha Kansara: So you're saying that you'll be able to capture 10% to 20% of the market share of current NAFLD treatment, correct?

Keshav Bhutada: Yes. This is what is our estimate. But as I previously also mentioned in our previous calls, Shilpa is launching such innovative NCE, complete NCE first time in India. We have partnered with few of the best companies in India who have very strong marketing presence with various doctors, and with various specialty hospitals. Maybe in the current Q3 and Q4, it will be just supplies. But from the next financial year, we surely expect a sizable numbers from NorUDCA. This is our estimate.

Krisha Kansara: Okay. Understood. And sir, my second question is regarding the import alert. So we have been hearing from the market that USFDA is here for the final inspection at our Jadcherla plant. So would you like to provide any update on that?

Alpesh Dalal: As far as USFDA inspections are concerned, whenever we have any update to be provided to the markets, we will inform. As of now, we don't have any update to be provided.

Krisha Kansara: Okay. Sure. I understand. And one last bookkeeping question and then I can join back the queue. If you can provide the sales breakup of the API segment without including the captive consumption, just so that I can compare the numbers from previous quarters.

Alpesh Dalal: Yes. We can get in touch with Monish, and we'll provide you the breakup.

Moderator: Next question comes from the line of Shubham Sehgal with SIMPL.

Shubham Sehgal: Yes. My first question was, so what has been the effect of U.S. tariffs on our 505(b)(2) portfolio? And have we experienced any market share loss in these products, which we are supplying to the U.S.?

Keshav Bhutada: All the 505(b)(2) launches, which are critical for U.S. market, we are launching from our third-party partner CMOs. So especially all the 505(b)(2) products which are getting launched or to be launched, it will be all from a USFDA-approved third-party CMOs.

Shubham Sehgal: Okay. All right. Got it. But so for our existing products, like have we faced any challenges?

Keshav Bhutada: No.

Shubham Sehgal: Okay. Got it. My next question was, have we received a lower amount of licensing fees from Amneal compared year-on-year?

Keshav Bhutada: No, I think there is a confusion because there is no licensing income which we will be getting from Amneal currently because the product is already commercial. So currently, it is more a supply plus profit share what we get from Amneal.

Shubham Sehgal: Okay. But -- so is there any -- I was just trying to understand, is there any specific reason you'd like to mention that -- I'm aware that licensing fees is -- like it will vary from quarter-to-quarter and year-on-year. But is there any specific reason that we saw a little lower licensing fees compared to last year?

Keshav Bhutada: No, there is no specific reason. It is just that many of our products, which were in pipeline last year have moved to the commercial phase. So you will see whatever income we were getting in licensing have moved to the commercial supply revenues.

But more importantly, we have a similar strong pipeline, which we have mentioned in our investor deck also. and the licensing income will remain lumpy depending on the progress of various products to different phases.

Alpesh Dalal: In terms of quarter, as we have been mentioning in the past also, that the licensing income could be a bit lopsided depending on what stage the products are in. So that's not something which we keep comparing.

As Keshav was mentioning that we do have a strong pipeline wherein licensing income will continue to remain an important portion of our business going forward as well. But what we are seeing right now is that some of those initial licensing fees that we had received has started getting converted into a regular supply plus profit-share business now.

Shubham Sehgal: Okay. Understood. Got it. My next question was, so we had mentioned that we have partnered with around 3 companies for NorUDCA. Have we partnered with any more? Like have we increased the number of partners there?

Keshav Bhutada: No, for this product, the kind of market opportunity, the patients and the hospitals where we want to reach, I think we don't want to have a lot of partners who inturn would compete among each other. So it's more a strategic partnering what we have done for the product. And we feel, with this number of partners, we will be able to get a decent market share.

Shubham Sehgal: Okay. Understood. Just one clarification. So OLC, which we are supplying to Unicycive, are we expecting it to commercialize next financial year or by end of this financial year?

Keshav Bhutada: It will be next financial year, but this is purely anticipation, right? No one can give you a firm clarity on that. But based on our experience and current expertise, we feel it will be next financial year.

Shubham Sehgal: Okay. Got it. Just last question, and then I'll get back in the queue. Could you throw some color on our new peptide project, which we have supplied initial quantities through an MNC? Like, what kind of project is it? Like, could you provide any color on this?

Keshav Bhutada: See, we will not be able to disclose more about project. But what I can tell you is it's a significant potential project, which we have in peptide. And what Shilpa has been doing, if you see across last 3- to 5-year journey in peptides, we have invested in R&D. Today, we have 2 manufacturing lines.

Now we have invested in third high-capacity manufacturing line. And with the pipeline of GLP-1s, like Semaglutide, and then with some mix of CDMO projects, we feel that peptide going forward will be also an important revenue driver for our API business.

Shubham Sehgal: Okay. But is this project -- like, is this product apart from the other products that we are currently into and working towards?

Keshav Bhutada: Yes. But currently, the other program, which you are mentioning, the supplies initially, are done for the pilot quantities to our partner. And we are expecting the commercialization to happen in year 2027.

Moderator: Next question comes from the line of Ankit Gupta with Bamboo Capital.

Ankit Gupta: So we've seen a very healthy jump in the European Formulation revenues during this first half. So on a broader level, we have a very good portfolio on the Formulation side. So as a market, how do you see European oncology injectable? And what will be our strategy to take it to a higher level of revenue contributing, let's say, INR300 crores, INR400 crores of annual revenues. Anything you can share on that?

Keshav Bhutada: In Europe, if we see, as a company, we are developing both the generic -- complex generic products as well as differentiated products. So today, a major of our European revenue is coming from Nilotinib, a differentiated product which in launched last year. And similarly, we have a range of around 3 to 5 products which are in pipeline, which are complex generics.

And next year, we expect commercialization of at least one of them to happen, which is specialty complex generics. besides this we also have some other products which are me-too generics, but there is less competition. So what I'm trying to tell you is, in summary, going forward, European business is expected to grow continuously.

Ankit Gupta: Sure. But as a market, how do you see -- on oncology injectable side, how do you see the competitive intensity there? We also hear about some shortages in the key markets of Europe happening for some of the products, like in our portfolio also, we have something like docetaxel and also, we keep hearing that. So if you can give your views on the competitive intensity there, especially on the oncology injectables side?

Keshav Bhutada: Yes, Europe is a very competitive market. And here, if you just go with me-too generics, then there is a big competition, and you cannot get market share. So in Europe, if we really want to

grow and increase our market share we need to focus more on complex generics and differentiated early non-infringing formulations.

So to tell you, yes, there are shortages in market, but there is a severe competition for me-too generics in European market. Since Shilpa is end-to-end fully backward integrated, with the focus on complex generics we expect that we will be well positioned to get market share.

Moderator: Next question comes from the line of Kiran D. from TableTree Capital.

Kiran D.: Congratulations, Keshav and Shilpa team for launch of our first NCE on NorUDCA and obviously, a great set of results as well. A couple of questions, Keshav. First question, we're saying the NCE, one project will commercialize in FY '26, another project in FY '27. I know you can't share clients, but if you could share indications of this NCE molecule, at least for the launch of FY '26 and market size of this molecule, any potential competition? If you just give some color on this, that would be great?

Keshav Bhutada: I will not be able to disclose more on the indication. But what I can tell you the API, which we are supplying to our partner, it's for an NCE program. And the partner to whom we are supplying this product, they are a big pharma. So we can expect a sizable opportunity for Shilpa.

Kiran D.: Okay. Sure. Second question, Keshav, is -- I mean, there's always this confusion. Total service income for the quarter is INR72 crores, out of which is from the P&L. INR46 crores in Formulation, which is from the presentation. So there's a delta INR26 crores, is it coming from API or biosimilar biological? Second question is, service income, does it include profit sharing, or it's just pure licensing, that INR72 crores?

Alpesh Dalal: The overall licensing income is under all the 3 business divisions. So there is income that is coming in Biologics. There is business income that comes in our API business, also a small portion. And then there's licensing income coming in predominantly in our Formulation business.

Kiran D.: Yes. So INR46 crores is from Formulation. This is in the investor presentation, Alpesh ji, right? So your total service income in your P&L statement is INR72 crores. So there is a delta of INR26 crores. So is it coming from API or Biologics biosimilars?

Alpesh Dalal: INR72 crores will also have some of the CDMO income coming in. It's all other operating income. It is not necessarily just the licensing income.

Kiran D.: Okay. So service income includes CDMO development revenue plus licensing is what you're saying?

Alpesh Dalal: Correct.

Kiran D.: Got it. Sir last clarification, Keshav. We spent INR165 crores capex in H1. I mean we also see in the investor presentation that large capacities are unutilized, maybe different business units, right? Maybe biosimilar Biologics, large capacities are unutilized. Where are we spending this INR165 crores capex? And what's the capex program for FY '26 and '27?

Alpesh Dalal: Yes. So I think, the capex for H1 has been INR153 crores. And our Albumin facility is still being put up, so certain capex is going there. And certain capacity-related capex we are doing in our API business.

So those 2 are the major this thing. We also are looking at probably some small portions coming up in our Formulation business, but some of them is maintenance capex, but the growth capex is predominantly into our Albumin business as well as our API business.

Kiran D.: FY '26, what would be the capex? FY '27, what is the estimated capex?

Alpesh Dalal: Yes. So for FY '26, we should be doing another about INR75 crores to INR100 crores from here on. And I think, for FY '27, once we are through with this particular capex cycle, we'll update you a little later, say, around Q4 or so.

Moderator: Next question comes from the line of Sanjay Kumar of iThought PMS.

Sanjay Kumar: First question is on Albumin. Recently, I think, CDSCO SEC has asked us to revise Phase III protocol for Albumin. I thought we already had one protocol since September 2024, which was approved in Jan 2025. Now we have another protocol later July and on which there has been a revision -- another revision. So can you explain what's happening and why this latest revision? So how many more months will it take now? What is the delay from the revision?

Keshav Bhutada: No, I think, there is a confusion. We have 2 clinical studies for which we have put permission. One is for India, one more is for European clinical study, so the new protocol which we are talking that is for Europe clinical study, where we have submitted our recent protocol, and we have received comments.

And same way, we are also submitting in Europe, which we call it as the IMPD submission. Once that is done, then with the updated clinical study protocol, the approval and time line is sometime in Q3.

So we are expecting to start our clinical study, Phase III clinical study, in Q4 FY '26. So there is no delay. It's just the protocol, as you know, in any clinical study when we submit any protocol for any other market, there will be feedback against which we have to just revise the protocol and take approval. So this is as planned, and we are planning to start, if everything goes well, in Q4 FY '26 clinical study.

Sanjay Kumar: So in CTRI NIC, we will be registering 2 separate trials, is it?

Keshav Bhutada: Yes.

Sanjay Kumar: Okay. Got it. And second question on peptides. See, Semaglutide, you are saying it will be ready by Q4. And then we file it by H1 FY '27. But by then, everyone would have launched or filed, right? So who are we developing this for? Given the pricing drop, does it still make sense to do it? And a technical question, what process do we use to make Sema? Is it solid phase peptide synthesis? Or do we use our recombinant method? Or do we buy the P29 fragment like other companies and do the final 2 amino acid coupling?

Keshav Bhutada: Yes, we are late in Semaglutide, but what we have developed and the strategy which we have adopted is we are having both synthetic and semisynthetic API. And our major sales will also go to our captive formulation because we are developing the formulations. So with end-to-end backward integration on the process, we believe that we will be competitive.

And given the size of the opportunity in Semaglutide, we are not targeting like a 30% market or 50% market share. We are positioning ourselves as a reliable supplier for the product as of now. And the only advantage what Shilpa will have, and other competitors will have is the kind of regulatory approvals that we have in our facilities. So our interest is not only India market, but many of the rest of the world markets where we have partnered.

So overall, for us, opportunity in Semaglutide is, it's our own formulation with end-to-end backward integration with global regulatory accreditations. And coming to your second question, which is the technical of whether our process is semisynthetic or synthetic, we are doing both, and we are fully end-to-end integrated.

Sanjay Kumar: Okay. And extension on peptides. You said that you are planning a dedicated capacity. What will be the capacity you are planning? And what will be the revenue potential? And given these are new modalities, which are growing rapidly, do you want to keep doing the generic ones like Desmopressin and others? Or do you want to be a CDMO for innovators going forward?

In fact, I think, we have even listed one ARBM101, which I think is Methanobactin and who -- their website states that they will get into first-in-human trials in 2026. Are we still on that program?

Keshav Bhutada: Yes, we are still on that program, and that's in our Biologics business, where they will be starting the Phase I clinical study next financial year, for which we have received the order for supply of this Phase I material.

For any company generic products are always a cash flow. However in our case we will enter generics products only if there is a niche opportunity where the competition is also less, this is how we are positioned. And the kind of capacity what we are building, we will be disclosing that in the upcoming quarters.

Sanjay Kumar: Okay. And on polymers, we have one customer for now, it looks like. And you seem to manufacture very uniform high-purity polymers, which I don't see a lot of CDMOs or Indian companies have.

So do you see this capability becoming another strategic pillar for us over the next 3, 5 years? Or do you plan -- if you can comment on some of these projects? Are these multiyear development programs or these generic catalogue products that we are planning? And how large can this polymer business become for us over, say, next 3 years?

Keshav Bhutada: See, to answer your question, yes, it is a very complex expertise, which we have built over years. And yes, we have multiple programs. There are some other programs, which are in early stages of development, We are also supplying some polymer to big pharma customers also.

So what is our plan in polymer in next 3 to 5 years is, we expect to also add a significant revenue in our overall API business. How much it will be and all, I think, I will not be able to tell you today. But I can tell you, it will be significant. And the kind of programs that we are running, we are confident that in the upcoming years, it will really grow.

Sanjay Kumar: Okay. And Ondansetron, you've mentioned that the global size is $375 million. But can you give the -- given that we'll be launching only in India first, what is the potential in India? And what's the sort of competition for this product?

Keshav Bhutada: See, for Ondansetron, one of the unique things that we have done is developing a long-acting injection. And especially in the highly emetic patients, currently, Ondansetron is a very well-known safe drug. But the only thing which no one has thought is to develop a long-acting injection because usually when patients are in highly emetic conditions, they are using along with paclitaxel and various other taxels.

And currently, for this, there are competitive products like Palonosetron which are getting used. But being Ondansetron is such a safe drug and making a long-acting injection of that and entering into a long-acting injectable antiemetic patient space, is a good opportunity that we are targeting.

How big it will be? It is too early for us to comment. But now since our Phase III studies are completed, and we will be submitting to Indian government, and then we are expecting approval. We have also started to discuss with potential partners, and we will be able to give you some more clarity in the upcoming quarters.

Moderator: Next question comes from the line of Krisha Kansara with Molecule Ventures.

Krisha Kansara: Sir, in this quarter, we reported a licensing income of INR72 crores. If you can tell us how much of this was received from Orion Corporation for our Albumin contract?

Alpesh Dalal: We will not be able to provide client-specific information. That is confidential.

Krisha Kansara: Okay. And sir, second question on the OLC contract. Now that Unicycive is planning to resubmit the data by this year-end, and it is confident of getting approval in the first half of next year. So can we assume that in the quarter 2 of FY '27, we will start seeing the contribution from this contract in our books? And also because we are the exclusive supplier for them, our order book should be known to us beforehand only. So what kind of orders can we expect in the first year of launch?

Keshav Bhutada: On OLC opportunity, let me be very clear that today, all the focus is on getting the product approval by our partner. And here, the most important part is the submission of this new facility data. So I don't think we will get the approval in the first half of financial year. It will be more in the second half of next year financial. And yes, next year, surely, there will be a commercialization revenue if everything goes as planned.

How much it will be and all today, our partner and even us are purely focusing on submitting this new site data and getting approval. And as I already mentioned, there is a dedicated block, which we are building only for OLC. So once the commercial requirement comes, we are fully geared up for giving the supply.

Krisha Kansara: Okay. So you're saying that commercial revenues can come in the second half of '27 financial year?

Keshav Bhutada: Yes.

Krisha Kansara: Okay. And just one last question. So previously, we had indicated that Adalimumab market has doubled with additional indications in place. So what kind of growth did we see in this quarter? And in the Biologics segment, if you can give us the breakup in terms of how much came from Adalimumab sales and how much was our CDMO revenue, that would be helpful?

Keshav Bhutada: Yes. Coming to Adalimumab, I think the kind of revenues which our partner is doing is not significant because India as an opportunity is not very big in Adalimumab. But because we could launch with a high concentration and a differentiated product, we could get good market share.

But mainly the important part for us to launch Adalimumab was to give us confidence and a message in the Indian market that Shilpa is developing complex biosimilar and good products. And what we have seen even after launching so late, Adalimumab, we have got decent market share. And the kind of numbers what we are getting are not very significant. But it is like every quarter, we have some revenue contribution coming from the product.

Krisha Kansara: Okay. And would it be possible for you to give the breakup of the Biologics segment revenue, Adalimumab versus, let's say, CDMO revenue?

Keshav Bhutada: Yes, you can maybe contact Monish Shah, and we'll send you that later.

Moderator: Next question comes from the line of Kiran D. with TableTree Capital.

Kiran D.: I just have some quick clarification. So NorUDCA Phase III trial for Europe and U.S., are we planning to kick off that in Q4? Or will it be later? And is that market size as big as India? Because India is the highest number of NAFLD patients. So I just wanted to get some clarity on that.

Keshav Bhutada: Our global strategy is very unique in this product, and we will be updating that in the right time. But what I can tell you is, Europe clinical studies will be starting in next financial year.

Kiran D.: Next financial year. Got it. Second is around Androgenic Alopecia. We've completed Phase II. It's been more than 15 months. We have not started Phase III yet. Any particular reason? Or are we planning to start that soon?

Keshav Bhutada: Yes. The reason was there were some additional preclinical studies which were asked to be done, which we have recently completed. And now we have applied for Phase III clinical studies. And

we'll be starting our Phase III clinical studies for this product again in first half of next financial year.

Kiran D.: Got it. Last clarification, Afli, we have done Phase III only for India, right? The U.S. and Europe Phase III will be later in FY '27, if it all?

Keshav Bhutada: Yes.

Kiran D.: Okay. And Afli is a big molecule compared to Adali cases in India? Yes.

Keshav Bhutada: Yes.

Moderator: Thank you. Ladies and gentlemen, we have come to an end of question-and-answer session. I will now hand the conference over to Mr. Alpesh Dalal for closing comments.

Alpesh Dalal: Yes. Thank you, everyone, for taking time to attend the call. We continue to remain excited about the path forward. And in case you have any queries or any of your questions have remained unanswered, please reach out to our IR team, and we'll be happy to provide you the requested details. Thank you.

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