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affordable healthcare

Shilpa Medicare Limited

Corporate & Admin Office:

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

Date: 18th August, 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 Q1 FY26 Conference call

In furtherance to our intimation dated 6th August, 2025 with regard to the Q1 FY26 Conference call held on Wednesday, 13th August, 2025 at 17.00 hrs, please find the enclosed transcript of the call.

Thanking you

Yours faithfully,

For Shilpa Medicare Limited,

Ritu Tiwary
Company Secretary & Compliance Officer



**“Shilpa Medicare Limited
Q1 FY26 Earnings Conference Call”
August 13, 2025**



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

Moderator: Ladies and gentlemen, good day and welcome to Shilpa Medicare Limited Q1 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 this conference call, please signal an operator by pressing star then zero on your touchtone phone. Please note that this conference is being recorded.

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

Monish Shah: Thank You and welcome to our first Quarter FY '26 Results Conference Call. We are joined by Mr. Keshav Bhutada, Executive Director and CEO of Shilpa Pharma Lifesciences Limited; and Mr. Alpesh Dalal, our CFO. Before we begin the call, please note that the financial results and the presentation have been uploaded on the 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 the current expectations and assumptions. These statements are subject to risks and uncertainties that could cause 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: Thank you, Monish. Good evening, everyone. Thank you all for joining our call. We have had an exciting start to the new FY, delivering our highest ever quarterly EBITDA. With our relentless focus on monetization of assets, we are confident to continue the momentum in upcoming quarters.

Let me start with briefing you on each segment. My overall briefing will be divided into 3 main business verticals: API, Formulations and Biologics.

Let me start with the API business division. I'm happy to inform you all that for the current quarter, we have delivered our highest ever Q1 performance, which helps us understand that as an API business segment also, we have started focusing now on delivering good numbers. So let me start with the briefing from oncology segment, which is our key business segment in API division, we are currently working on the 2 main NCE programs. In the first program we are producing API for the customer, the NCE is filed by our customer, and we are expecting the commercialization in next financial year.

Similarly, the second NCE program, where we are delivering API to our customer, the Phase III study is ongoing, and they are expected to complete by next year. Apart from that, -- our all the generic molecules have strong order book in place, and we are confident of delivering good numbers in the upcoming quarters.

In the current quarter, we validated two new oncology products, where the product -- process validation is completed in the current quarter, and we'll be filing the DMF and CEP in next 6 months with 6-month stability. Our captive products, where we have developed some non-infringing API and wherein our formulation was also developed non-infringing, we are seeing good traction for our captive formulations in the end market and for which the API delivery to our captive is expected to grow quarter-on-quarter.

Now, coming to the non-oncology segment, we had completed capacity expansion of Tranexamic acid capacity and the commercial supplies were started from 1QFY26, with the rise in capacities there is an increase in our sales turnover.

Second product, where we have increased capacity is Ursodeoxycholic acid. So, as on date, our run rate is almost more than 10 metric tons per month. Third product, Nor-Ursodeoxycholic acid, which is an NCE molecule, we have developed the -- API for captive formulation. The API commercial supplies are expected to start from second quarter FY '26. Moving to the next product, Mycophenolate Mofetil, which is a new non-oncology product, which we have taken in the grid, and the process validation is completed in the current quarter, and we'll be filing DMF and CEP with 6-month stability.

Coming to CDMO, peptide and polymer, which are very strong growth driving segments for us. Currently, in CDMO, we have more than 25 active CDMO projects, which we are developing for our customers, wherein multiple programs are in preclinical, in Phase I, Phase II, Phase III.

In next year, we are expecting 2 CDMO projects to get commercialized, for which, our partners have filed the NCE. Apart from that, for polymer segment, the commercial supplies have started for a project from an MNC in Q1 and we expect to complete by 2HFY26. And after the supplies are completed, we expect to have a replenishment order. So this will be a steady business for us for the next few years. Second, we have developed another specialty polymer, for one more big pharma customer, and the specialty polymer manufacturing and supply was completed in current quarter. The customer will be using our polymer for their NCE application, which will open a good opportunity for the company in years to come.

Now, coming to peptides, we have three main products which we are working on are the GLP-1s viz. liraglutide, semaglutide and tirzepatide, where company is planning to do both API and formulation. So in API, liraglutide is ready with the manufacturing validation batches done, and 6-month stability completed. We are now working on registration of our formulation batches are which are expected to be completed by end of September. Once that is completed with 6-month stability, both API and formulation will be filed in global markets. Second product is semaglutide, where our API our development is completed, and we are planning to start the registration batches in Q3 FY '26. So by end of Q4, we are planning to complete semaglutide's API and formulation registration batch.

Tirzepatide, is a very interesting product in the GLP-1 space, our lab development is completed, and we will be starting the scale-up in Q3 FY '26. So I think API, as a business division, with a mix of oncology, non-oncology, CDMO, peptide and polymers, we are positive to have a good growth in the upcoming quarters to come.

Now, I'll start briefing about Formulation business division, where we have had a significant milestone in the current quarter by -- with the approval of Nor-Ursodeoxycholic acid, which is the first NCE which was developed by Shilpa. And globally, it will be the first country where we will be launching this product, which marks a significant footprint of Shilpa in launching new chemical entities in market. This will be the first of the kind NCE new chemical entity program, which Shilpa has developed and -- start to end, and also will be commercializing.

Apart from that, there are a total of three NDA products which are approved in U.S., and sold in the market via our partners. We are expecting a very reasonable contribution from all these three NDA molecules in the current financial year, where we will be starting to see the numbers in quarters to come once the reconciliation and profit shares are received.

Apart from that, Nilotinib, our flagship product in Europe where we were the first company to launch with a non-infringing formulation. The product is doing reasonably good, and we have a very strong order book for upcoming quarters. Apart from that, our Rotigotine transdermal patch, which is filed in Europe, we expect to get approval in 2HFY '26. We also doing U.S. our clinical studies which are expected to be completed soon, and we are planning to file Rotigotine in U.S. in Q3 FY '26. Apart from that, there are 4 more differentiated assets, which the company has in its pipeline and the details are provided in the investor presentation.

So the main focus in our Formulation division will be doing differentiated products and also working on NCEs, which will help us in having sustainable growth every quarter and for years to come. Also, I'm happy to inform everyone that in the current quarter, we have received EIR from U.S. FDA for our transdermal patch manufacturing facility, which will open opportunities in the U.S. market also for our transdermal patch facility.

Now, I'll start briefing about the Biologics division. So in Biologics division, as we have already publicly announced regarding the two NBE programs, Alveolus Bio and mAbTree. For both the NBE programs, the company has entered into agreement wherein for both the programs, we will be doing start-to-end development and manufacturing. So we are expecting both these NBE programs to enter into the human studies next year, which is the most important milestone. Apart from that, in the Biologics division, as on date, we are having five active CDMO projects, wherein each program is at different stages of preclinical and Phase I supplies. And as and when, in the quarters and years to come, the programs advances we will see a good revenue trajectory for Shilpa Biologics.

Apart from that, Antibody Drug Conjugate, which is our main focus area going forward, we have our first antibody drug conjugate product development under initiation, and we are planning to enter into human studies next year. And on the biosimilars front, Nivolumab which is our flagship product will be entering into the human studies by end of this year. We have completed the preclinical studies and we have put the application to start Phase I/III human clinical studies. Besides this, we also have four more biosimilar products under development, where the cell line development is completed. Apart from that, recombinant human albumin for which we have signed a partnership deal for Europe market with Orion, for the said product, the scale-up batches have started in the facility and we are planning to start the human studies by

end of this year as planned. We are also planning to submit our advice in U.S. for our clinical study strategy, and we are expecting to have outcome of that in Q4 FY '26. After that, we will be targeting the U.S. market for albumin. And on the excipient market, which is a DMF grade market, we have started sending samples to some of the customers, and the initial evaluation at various customers is going on.

With this, I will be happy to re-emphasize that our long-term focus is on complex pipeline and also working on NCEs and NBEs, which will help us in having sustainable and long-term growth. With that I would like to hand over to our CFO for financial highlights.

Alpesh Dalal:

Thanks, Keshav, and good evening, everyone. Let me briefly take you through the financial performance of the first quarter of current financial year. Our revenues for the quarter were at INR328 crores, recording a 9% growth YoY. And the growth for the quarter was largely driven by growth in API and Biologic verticals. Our gross margins for the quarter were at 76%, an improvement of 700 basis points compared to last year. And this improvement was mainly driven by a better product mix, and all these measures have resulted into us recording our highest ever EBITDA during the quarter, which stood at INR98 crores as compared to INR83 crores in Q1 of last year, showcasing a growth of 18% year-on-year, with EBITDA margins at 30%.

Our finance cost for the quarter was INR19 crores as compared to INR24 crores in Q1 of last year. I'm also happy to share that as indicated in my earlier communication, we have replaced our remaining high-cost NCD of INR75 crores with a low-cost debt, so this should help reduce our interest burden even further. And in another development, we have recently received approval from NCLT Bangalore for amalgamation of INM Technologies with Shilpa Medicare. And the tax impact of unabsorbed losses of INM is likely to result in lower tax outflow for the previous financial year, and the effect for the same has been captured in the current quarter. This has also been explained in our notes to the results that have been published. And because of this reduction in the tax component, our effective tax rate for this particular quarter has come down to 5.5%.

On the segmental performance, our API revenues on a consolidated basis were INR187 crores, growing at 8% year-on-year. And the growth was primarily on account of portfolio rationalization and improved offtake of our key products from the newly expanded capacities. The Formulation revenues for the quarter were INR98 crores, and the main drivers for the Formulation business were the ROW and the European businesses. And likewise, the biosimilars business recorded a revenue of INR73 crores during the quarter.

Let me also give you an overview of some of the balance sheet items. Our net debt was at INR550 crores as on 30th of June. And our capex during the quarter was INR70 crores, majorly for our fermentation plant being built at Kadachur. Additionally, I'm also happy to inform you that the Board, at the recently concluded meeting, has proposed a bonus issue of 1:1 for the benefit of all the shareholders.

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

- Moderator:** Thank you very much. We will now begin the question and answer session. The first question is from the line of Krisha Kansara from Molecule Ventures.
- Krishna Kansara:** Congratulations on a wonderful set of numbers. Sir, my first question is related to albumin and our partnership with Orion. So when Orion released its recent financial report, it mentioned that its cash flow also included the signing amount, which was paid to Shilpa for the albumin agreement. And the amount in their books was close to EUR 13 million. So can we assume that majority of this amount was related to the signing fee, which was paid to us by them? This is my first question?
- Keshav Bhutada:** We are under confidentiality with our customer on this product. So, as we've mentioned before also, we are not allowed to disclose any numbers on this. Sorry, I'll not be able to tell anything on this.
- Krishna Kansara:** Okay. But the INR57 crores licensing income in this quarter includes the signing amount, right, received from Orion?
- Alpesh Dalal:** We will not be able to provide the details. Whatever is recognizable as revenue at this point in time has been included in that INR57 crores.
- Krishna Kansara:** Sure. Understood. Okay. Sir, my second question is on Unicycive contract. Now that there is a delay in this contract because of the issues at our earlier CMO partners, I would like the management to throw some light on how do we plan to move forward. With Unicycive announcing that it has already found another CMO vendor, how long will it take for the FDA to get back and approve the product? And also, assuming this delay, how was our order book impacted? And just some light on this contract will be helpful?
- Keshav Bhutada:** On Unicycive, as I mentioned previously also, the financial number per se, the order book and the commercialization, the bigger values will reflect in the next financial year only. So there was no major revenues which we were projecting for the current year. Second part is, yes, with our current CMO site where we had issue, we have done a successful technology transfer into one more CMO partner, which is U.S. FDA, EU approved. And from the other facility, already the exhibit batches are completed. And with 1-year stability data, we have submitted this data to Unicycive team.
- So now, they will be taking it further with the U.S. FDA, whether the U.S. FDA wants them to wait for 6-month stability data or with 1-year stability data, they want us to file, that is what they will be checking with FDA. We will get to know in the upcoming quarters, but tentatively, what we feel is, even if FDA asks them to submit with 1-year stability data, they will be submitting it in next year. And once that is submitted, we can surely get the commercialization, or we can likely get the commercialization in next financial year itself because all the GMP data, clinical data is already reviewed by the agency. So this will be just the additional CMO data, which they will be reviewing.
- Krishna Kansara:** Yes. Clear. Understood. That was helpful, sir. And just one more question. So in this presentation, in this quarter's presentation, you have given the API sales breakup, including

captive consumption, like including captive sales. So would it be possible to give the same breakup excluding the captive sales just so that we can compare to previous quarters on the same line?

Alpesh Dalal: Yes, we'll provide that. That should not be a problem, Krisha.

Krisha Kansara: Okay. Sure. And just one more question. After the repayment of debt that we announced yesterday, as of now, what is the debt level at the consolidated company level?

Alpesh Dalal: As I mentioned during my speech that debt as on 30th of June was INR550 crores. This is only a replacement of high-cost debt with a lower cost debt. This is not repayment.

Krisha Kansara: Okay. The yesterday's announcement is related to refinancing is what you're saying?

Alpesh Dalal: Yes, it has been -- we have repaid that by a lower-cost debt.

Moderator: The next question is from the line of Suvaan Mittal from MFC.

Suvaan Mittal: I have two questions. Mainly on the gross margin front, it has increased to 76% from 69% on a Q-o-Q basis. So if you could give some color that is it because of an increasing consumption, captive consumption of API of the FDF client? What is the percentage of FDF for which the API is captively consumed? And some future outlook on two, three year perspective on do we intend on increasing that and to what level? That's the first.

Keshav Bhutada: The total API revenue including captive is INR227 crores, right, of that, around INR40-odd crores is of captive. And going forward, we are trying to align more revenues for our captive consumption because that is where our big growth drivers and sustainable growth is possible for this oncology segment. So that will continue to grow. Apart from that, our key products like Nor-Ursodeoxycholic acid or Nilotinib, Axitinib, are used for making our own formulations. So captive API consumption is surely expected to grow quarter-on-quarter. On the second query, Our gross margins are improving mainly based on the product mix and also on account of profit share, licensing fees, which are a part of our sales revenue. So it's a mix of product mix, licensing fees and sales revenue.

Alpesh Dalal: Yes. Just to add on to that, this margin improvement that has come in, at times, in certain quarters, you do have significantly higher-margin products going in. But obviously, that's not something we would say as a guidance should continue to be considered.

Suvaan Mittal: Okay, sir. My second question being, you have mentioned that our main growth did come from Biologics, and we have grown considerably from INR10 crores to INR37 crores Q-o-Q basis. So is it because that the Adalimumab is the main growth driver? And if you could quantify on your end that what is the CDMO revenue in that? And in terms of the licensing revenue from Biologics, do you expect it over a 2, 3-year period to mirror the licensing revenue we have from FDF?

Keshav Bhutada: To answer your first question on Biologics, it's mainly on the mix of multiple things, we have signed some new CDMO deals in the current quarter and apart from that, we also have a

licensing income, which Alpesh has mentioned, from our Orion albumin deal. So it's a mix of revenues, which is from albumin and also from our new CDMO contracts and existing CDMO contracts.

And going forward in next 1 year, will it be equivalent to our FDF? See, that's something we will be able to tell you maybe in the upcoming quarters to come how the things are progressing in Biologics. But as a company, we are very much interested to focus on Biologics, and we are confident that going forward, once our molecules like Nivolumab, the ADC program, the NBE programs are progressing well, we are expected to do good in Biologics also.

Moderator: The next question is from the line of Sanjay Kumar from ithought PMS.

Sanjay Kumar: First on NorUDCA, what is the marketing authorization timeline? And what revenue are we targeting in, say, FY '26 and '27?

Keshav Bhutada: NorUDCA is a very significant opportunity for the company, why it is so differentiated for us? It's one of its kind of molecule approved in India till date, which mainly works on liver health activity, which directly targets liver health and then thereby cures NAFLD. Marketing authorization from the central is already received, now, we will be going to state authorities and getting the license, which is a 15 to 20 days process, and then the artwork, everything we will be completed. So tentatively, we will be launching it by October. We have all the launch orders in place for NorUDCA. And for the said product, we have partnered with one of the top companies in India and a total of three companies are partnered for this product. We have signed licensing and there are some milestones also which we are expected to get with 6 months, 1 year of the sales. Besides these, we will also get the commercial revenue. And how big it will be? It's a different experience for us because it is the first NCE molecule which Shilpa will be launching in India. So we should see how it will be doing in the quarters to come. But NAFLD is a big disease in India, and more than 40% patients in India are going through this disease. So it's a very large population, which we'll be targeting this product.

Sanjay Kumar: Okay. And second on albumin. So has GMP approval -- what's the timeline for the GMP approval for the albumin new plant? Has Phase III kicked off? How many patients have we recruited? And when can we expect results? And if you can update on what the European and the U.S. FDA have commented on albumin?

Keshav Bhutada: On albumin, our clinical study design has been submitted to the EU agency, and we have got alignment on our clinical study. So our Phase III clinical study will be starting by end of the year or next year, early quarter. And all the things are already in place for us. And once the clinical study is starting, it will take us maybe 12 to 15 months to complete the study. And after that, we will be filing this product, after which, it is a 1-year approval process.

Sanjay Kumar: Okay. Will U.S. also be on the same timelines or will U.S. be much later?

Keshav Bhutada: U.S., we cannot tell you currently because as I mentioned in my speech, U.S., our clinical study strategy, we are submitting in Q3. And once we have response from the FDA on our clinical study approval by Q4, we will be able to give you good timelines or clear timelines on U.S. We

are trying to see that if the existing study can be bridged for U.S. also, but we need to see how the agency is accepting it or if they are asking us to do some additional studies. So it all depends on that.

Sanjay Kumar: Okay. And third question on the EU GMP approval for the biosimilar plant, which biosimilar products within our pipeline are you planning to take to EU, and if possible, U.S.? Do we -- can we file Phase III for, say, Aflibercept or the subsequent products in our pipeline?

Keshav Bhutada: Yes. We will be surely taking our biosimilars to Europe and U.S. So I feel our first product will be Nivolumab, for which the human studies will be starting by Q4 of this financial year.

Sanjay Kumar: Okay. So both albumin and biosimilar, we again take it global because a few quarters ago, we weren't fully convinced of going -- doing global studies for these products. So, that strategy has changed?

Keshav Bhutada: See, for albumin, it was always a global product. For biosimilars, we were first trying to do India study, and then we were going global. But recently, there are a lot of changes in the clinical study requirements globally. And there is good chance that whatever study we will be doing in India, with the same study, even Europe will accept that study. So we will be going with the same strategy for Europe. And even for U.S., we'll be trying it.

Sanjay Kumar: Okay. Final question. One is -- 2 products that we have listed as formulation, one is long-acting injectable, SMLINJ011. There, from the previous quarter PPT, the market size has dropped from \$930 million to \$375 million. If you can comment on this? And the second one is, the last formulation that we have listed, SMLOSD014, which is for anticoagulation segment, is it targeting Apixaban, where the patent is expiring in 2028?

And can we get some sort of exclusivity because this will go through the 505 route or the release mechanism is different? If you can comment on these 2 formulations, it will be very helpful?

Keshav Bhutada: For SMLINJ, right, the market size has not dropped. What we have done is that, earlier we were mentioning for various markets, apart from the one in the antiemetic space, there are globally many products that target this product. But now, after our study, the way we have designed it, what we have tried to do is mainly on the highly emetic patients, we have tried to segregate that global data. And that is what we have mentioned in the presentation. So the product, what we have developed is a very specialty product for highly antiemetic patients. And already, as we mentioned, our clinical study Phase III in India has been completed, and we are expecting to file this product in Q3 FY '26 in India market.

And on the second product, on SMLOSD014, that's a differentiated product, and we will not be able to disclose the name. But it's a differentiated opportunity, which at the right time, we will be able to disclose. But for the said product, already the registration batches, we have just completed last month.

Sanjay Kumar: Okay. And what are we doing in semiconductor? I saw that you are participating in SEMICON India, which is very surprising?

- Keshav Bhutada:** We are not doing anything in semiconductor. It's just that we are making some chemicals, which we feel can go into semiconductors. But this is very early for us to comment because we have just tried to present there and understand the market.
- Sanjay Kumar:** Okay. And one feedback before I join the queue. See, Krisha also had the same question. Most of us would have had the same question after yesterday's filing. If you could give a better explanation in all your filings, that will be very helpful because from what you filed yesterday, the understanding was that you have repaid that entity.
- We didn't know that you only refinanced that cost of debt. So if you could -- going forward, if you could have a better explanation in all your findings, that will be very helpful. Even your Nor-UDCA filing, we weren't sure what approval means. Is it MA approval or is it just product approval? That wasn't very clear from the filing. So that's one feedback.
- Moderator:** The next question is from the line of Kiran B from TripleTree Capital.
- Kiran B:** Congratulations, Shilpa team. I mean, one of the most optimistic presentations I've seen after a while. So congratulations on the optimistic tone as well. I have a few questions. One, on Lenvatinib adverse outcome, I mean, that we had 1 month, 1.5 months ago, are we challenging? Are we not challenging? Are we still doing at-risk launch? Is there something that you can share with us on the adverse outcome, please?
- Keshav Bhutada:** On Lenvatinib, as we mentioned previously also we will not be able to disclose currently to anyone because that's purely a market intelligence, and our strategy is very different. And we will be able to share with you the right insights at the right time once we have a reasonable outcome.
- Kiran B:** Got it. Okay. Perfect. Second question is, Phase III for albumin, you just mentioned that 12 to 15 months from the start, and then 1 year for approval. So we are basically about 2.5 to 3 years in total by the time we gather patients and everything else. So FY '29, is that a fair estimate of when we can potentially commercially launch?
- Keshav Bhutada:** Yes, end of FY'28 or early FY'29 should be a good time. We have to see.
- Kiran B:** Got it. And can you tell us a similar timeline for Aflibercept Phase III?
- Keshav Bhutada:** The Phase III study is ongoing for India and ROW launch, and we are expecting to complete this study in this financial year.
- Kiran B:** Got it. So commercialization will be next year?
- Keshav Bhutada:** Yes. Next year, we'll be commercial. You're right.
- Kiran B:** Got it. Sorry, on the albumin thing, did we already start on Phase III? Or are we still gathering patients and getting the stuff from Kadachur plant and so on and so forth?
- Keshav Bhutada:** As I mentioned, the clinical study will be starting in Q4FY26.

- Kiran B:** Got it. Last question, Formulation FDA approval, do we have any sense of -- or did we get a visit from FDA already on the Formulation plant? Because that can be a big driver, given our pipeline. So just wanted to understand if we have had any indications from FDA as to when they can potentially visit?
- Keshav Bhutada:** FDA, it will be a surprise inspection surely. We don't know when they will come, but we surely know that they will be coming any time.
- Kiran B:** Got it. Sorry, last, one clarification question for Alpesh. Alpesh, the finance expense, Q4 FY '25 was INR14 crores. We suddenly jumped to INR19 crores in Q1 FY '26. Is there any particular reason why there's a Q-o-Q INR5 crore jump of finance cost?
- Alpesh Dalal:** See, basically, in one of our subsidiaries, we have taken an interest swap loan, so it has got converted into a euro loan. And with appreciation in euro, there is a M-to-M impact that has come in. So, that M-to-M impact is to the tune of INR6.5 crores. So in reality, the cost has actually come down by INR1.5 crores. But because of that M-to-M impact, which is more of a book entry that we have to take, it has jumped to INR19 crores.
- Kiran B:** Got it. So if you go back to normalization, given INR550 crores end of June, on a steady-state basis, we are expecting a INR14 crore kind of run rate on interest, right?
- Alpesh Dalal:** We should be able to reduce that a bit with NCD getting replaced.
- Kiran B:** Got it. Okay. Sorry, Keshav, if I can ask one last question. Nilotinib, Axitinib and Rotigotine may be Q3, Q4 approval. But from a formulation perspective, in export markets, Nilotinib, we've already launched last year. Axitinib, we -- I think we launched early April. Is there any other pipeline molecule that we're going to launch in Europe from a formulation perspective for the next 6 or 8 months?
- Keshav Bhutada:** Yes, we have some other products also, which we will be launching in 8 months' time. But at the right time, we will be disclosing that.
- Moderator:** The next question is from the line of Suvaan Mittal from MFC.
- Suvaan Mittal:** My first question being, in the previous con call, you had suggested that you will be starting to list CDMO revenue from all your verticals separately also. So if you could just clarify the CDMO revenue from combined FDF, API and Biologics in the Q1?
- Keshav Bhutada:** Yes, we are still working on it because there is a lot of consolidation, which we need to do on the group level. I'm sure, in the upcoming quarters, at the right time, we will be starting to report CDMO separately.
- Moderator:** The next question is from the line of Haresh Bilakhia, an Individual Investor.
- Haresh Bilakhia:** Yes, sir. Last year, company had entered into an agreement with Unicycive, some company, for supply of some tablets by June 2025. So I just wanted to know whether the company has started activity with Unicycive?

- Keshav Bhutada:** As we already clarified it. For the Unicycive opportunity, where the commercialization was expected to start this year, because of the facility issue of our CMO partner, it has been delayed by 1 year, and the commercial revenues will start in next financial year.
- Moderator:** The next question is from the line of Gaurav from Antique.
- Gaurav:** Sir, just taking cue from an earlier participant question, could we quantify the biosimilar sales this quarter and the Biologics CDMO revenue in this quarter?
- Keshav Bhutada:** Of the total revenue, our major revenues in Biologics today is from CDMO and licensing only. Our major biosimilar revenues will start once we have more products in the market, especially in Europe and U.S. or in the export market.
- Gaurav:** Okay. So is it fair to assume that the Orion licensing income, if any, would be booked in the Biologics segment?
- Alpesh Dalal:** That's correct.
- Gaurav:** Got it, sir. Coming to NorUDCA, on the go-to-market strategy, now the patient population is huge, but diagnosis is a problem. And we see another peer with a similar product having partners for this launch. So would that be a go-to-market strategy as well? Because the front end is not large. So will we look for partners and that announcement should be made in the next quarter or two?
- Keshav Bhutada:** So, as I mentioned, for the said product, already we have partnered with the 3 big companies, and these are amongst the top 10 companies in IPM who will be commercializing this product for us. Apart from that we have also kept a license with us as well. So totally, there will be four people who will be launching. For the said products from the three big companies whom we have partnered, we have a licensing income, and also there will be a supply sales what we will be securing. We already have launch orders from all the 3 big companies in place.
- Gaurav:** Got it, sir. Okay. Sorry, last question on the -- so Pemetrexed, you've been gaining market share. I think profit share is expected in the subsequent quarters. So that's an upside. Borte, we've been in the market for a couple of months. Any indication how the ramp-up has been? And how soon can we see market share further inching up?
- Keshav Bhutada:** It will be same like Pemetrexed. So you will see that Bortezomib is also a very differentiated product. However, the product was launched recently. We expect to see a reasonable contribution from Pemetrexed and Bortezomib, and it will continue in the upcoming financial year.
- Gaurav:** Yes. But just a clarification on that. So Pemetrexed market share ramp-up took almost 10 months since launch. So we can see a similar kind of a timeline for uptake in Borte or that could be faster as well, given no competition?
- Keshav Bhutada:** We feel it can be 1 quarter early, because we have now some good experience on Pemetrexed. So maybe 1 quarter early, we will start seeing better realization.

- Moderator:** The next question is from the line of Kiran B, TripleTree Capital.
- Kiran B:** Sorry, just a quick clarification, Keshav. The reason -- again, we have three competitors for NorUDCA, and we are very excited about that product launch. So Zydus does Saro. Sun does Ursocol. Abbott does Udiliv. So I mean, do we -- you said there are three partners. Is there any point -- at any point, you will reveal who those three partners are or we should just wait for Q3 launch or are these the same partners who already have competitive products in the market?
- Keshav Bhutada:** We would prefer to wait for one quarter to disclose.
- Moderator:** The next question is from the line of Sanjay Kumar from ithought PMS.
- Sanjay Kumar:** So you've mentioned two NCE projects to commercialize in FY '27. This is under the CDMO division. If you can give what product, what indication or the market size for these 2 products?
- Keshav Bhutada:** The first product which is an NCE is filed by our U.S. partner, the NCE is for gall bladder indication, and they have developed a very differentiated product for which we will be supplying only one part of the total product, which is API. And that commercialization will be starting next financial year. And the second product is OLC, Unicycive, which already all the details are available with you.
- Sanjay Kumar:** Okay. And what could be the market size for the first gallbladder product?
- Keshav Bhutada:** See, that all depends on our partner because they will be the one who will be selling this product, right? But we feel that it could do good.
- Sanjay Kumar:** Okay. Second, so I see that, at least in my mind, we'll take albumin, NorUDCA, SMLINJ011 and a few of our biosimilars global. That means that will need a lot of capex for these global trials. So what capex plan do you have for the next 2, 3 years? And how are we going to fund it? Because I was just worried if we'll have to go into another leveraging cycle again?
- Keshav Bhutada:** As we already mentioned to everyone, for all these assets, usually, what we are doing now is, after one stage, we are usually partnering so that we have a partner who is also giving us licensing fees, which is further taking care of the cost for our clinical studies. So we don't foresee any significant change in capex because of these products going into global or going into multiple studies because for each of them will be partnered at the right time and this also hedges our risks.
- Sanjay Kumar:** Okay. But capex numbers for FY '26 and '27?
- Keshav Bhutada:** On capex numbers for FY '26 and '27, we are working on it, we want to do some additional capex in our API business. So we would be able to finalize that in this quarter. So I think we'll be able to give you a good picture in next quarterly call.
- Sanjay Kumar:** Okay. Sure, sure. All right. And just an extension to the gallbladder. Is the same drug as the FDA Breakthrough designation drug that you mentioned?
- Keshav Bhutada:** Yes, you are right.

- Sanjay Kumar:** Okay. And any reason for doing bonus, any particular reason for issuing bonus?
- Alpesh Dalal:** I think what we believe is that the way the company is growing, the current equity base is small. There are less than 10 crore shares on the market. And the way the interest in the company has been increasing whatever we have been hearing from generally the investors and all, I think improving the liquidity of the stock is an important aspect. So, that was one of the driving forces. And generally, also, we felt that investors, who have been with us for a longer period of time, we also need to, in a way, provide them the right kind of benefit.
- Sanjay Kumar:** Got it. Final question. Since you can't disclose many things because it's market intelligence related to our products, can you provide an overall guidance on revenue growth for, say, FY '26 and FY '27? In fact, we should have a separate call for each of our divisions. That's how complex our business is. So any revenue growth guidance for the next 2 years?
- Alpesh Dalal:** Generally, we do not provide any guidance, but we have indicated what the drivers are for the businesses for the next couple of years. So, that should provide a decent understanding of what kind of growth can be expected. But we don't provide specific guidance per se.
- Moderator:** The next question is from the line of Gaurav from Antique.
- Gaurav:** Sir, on the novel biologics and the 2 investments, minority that you've done in Alveolus and mAbTree, you're expecting them to enter Phase I in FY '27. Would that entail an additional investment from Shilpa for progressing those trials or an inch-up in R&D cost for FY '27 for us?
- Keshav Bhutada:** Majorly for both the deals our main interest is in developing and manufacturing these assets at our facility, for which all the major infrastructure required is available with us. So there will not be any significant change in our expenditure because of these 2 programs.
- Gaurav:** So we would be supplying clinical trial supplies for Phase I?
- Keshav Bhutada:** Yes. For the clinical studies going forward, we will be their exclusive suppliers.
- Gaurav:** Got it. On the tax rate for the remainder of the year, how should we look at it? This quarter, we had a benefit. But for the remainder of the year, what would be our expected tax rate, please?
- Alpesh Dalal:** Generally, we are in the region of about 35%, 36% tax rate.
- Moderator:** The next question is from the line of Shubham Sehgal from SIMPL.
- Shubham Sehgal:** Yes. I just wanted the latest update on a few of our molecules. So from API like the three molecules, Palbociclib, Olaparib and Teriflunomide?
- Keshav Bhutada:** So in API on Palbociclib, our validation batches are completed, and we will be filing the DMF for the product in 3 months' time. And coming to Olaparib, the validation batches have started, and we are expecting to complete by October of this financial year. And after that, with 6-month stability, we will be filing this product. And on Teriflunomide, our formulation is completed, and our API is already commercialized.

- Shubham Sehgal:** Okay. And just lastly, on peptide, so I think we have these two. One is Desmopressin and the other one is Octreotide Acetate?
- Keshav Bhutada:** Yes. On Desmopressin and Octreotide, both the products already are commercialized. And we have a strong order book for Desmopressin already for next 2 quarters.
- Shubham Sehgal:** Okay. I'm sorry, but could you just mention in which regions have we commercialized these two?
- Keshav Bhutada:** Yes. Mainly, we are supplying to some customers in Europe and U.S. and ROW. So it's a mix, where they have started giving us initial quantities of the current commercial product. So going forward, in next year, we expect that value to further increase.
- Shubham Sehgal:** Okay. Got it. And so the major increase we saw in ROW sales for this quarter, was it like driven by mainly one or two products or was it like again a mix of products?
- Keshav Bhutada:** It's a mix of multiple products as we have multiple registrations in ROW, which were done in last 3 years. Our focus remains on monetizing these products in various markets.
- Shubham Sehgal:** Okay. Got it. That's all from my side. Thank you.
- Moderator:** Thank you. Ladies and gentlemen, that was the last question for today. I now hand over the conference to Mr. Alpesh for closing comments.
- Alpesh Dalal:** Thanks, Pari. Thank you, everyone, for taking time to attend the call. We continue to be 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 help you. Thank you.
- Moderator:** Thank you. On behalf of Shilpa Medicare Limited, concludes this conference. Thank you for joining us and you may now disconnect your lines.