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Date: 26 May 2026

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 Q4FY26 Conference call

In furtherance to our intimation dated 14 May 2026 with regard to the Q4FY26 Conference call held on Friday, 22 May 2026, at 16.00 hrs., please find enclosed transcript of the call.

Thanking you

Yours faithfully,

For SHILPA MEDICARE LIMITED

Ritu Tiwary
Digitally signed by Ritu Tiwary
Date: 2026.05.26 13:03:22 +05'30'

Ritu Tiwary
Company Secretary & Compliance Officer

“Shilpa Medicare Limited

Q4 FY26 Results Conference Call”

May 22, 2026

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

Moderator: Ladies and gentlemen, good day, and welcome to the Q4 FY26 Results Conference Call of Shilpa Medicare Limited. As a reminder, all participant lines will be in 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 assistant by pressing star then zero on your touch-tone phone.

I now hand the conference over to Mr. Monish Shah from Shilpa Medicare. Thank you, and over to you, sir.

Monish Shah: Thank you, Ria, and welcome to our fourth quarter and full year FY26 results conference call. Today, we have with us Mr. Keshav Bhutada, Executive Director and CEO of Shilpa Pharma Life Sciences; and Mr. Alpesh Dalal, our CFO. The financial results and the presentation are uploaded on the stock exchanges, and the transcript along with the audio will be available on our website and the stock exchanges as well.

Please note 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.

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

Keshav Bhutada: Very good evening, everyone. There are certain years in company's journey where performance improves, and there are certain years where foundation for next decade is built. For Shilpa Medicare, FY26 has been one such year where we have built our foundation. Today, Shilpa is no longer defined by single vertical.

We are building a highly differentiated pharmaceutical platform spanning across complex APIs, specialty formulations, biologics and ADCs with integrated CDMO capabilities. Few companies in India operate with a breadth of technology and capabilities across both small molecule and biologics.

Importantly, we believe we are still in early stage of monetizing few of our platforms. As utilization improves across our manufacturing infrastructure and more differentiated products enter into our commercial phases, we see a clear path towards sustainable growth, stronger margins and increased return ratios in coming years. Let me walk you through our Q4 FY26 performance and for the full financial year.

I'll start with our API business. So, in specialty CDMO segment, our first U.S. NCE program, which was launched in Q4 by our big pharma company. Our second U.S. NCE program with one of our partners where we are supplying them API for their Phase III program, the Phase III studies are ongoing.

The third U.S. NCE program, where we are developing API and formulation for our U.S. customer, Unicycive Therapeutics. The program submissions are already done, and we are

expecting approval in this financial year FY27. The dedicated manufacturing production blocks for OLC was successfully commissioned in Q4 FY26. And we are planning to do the validation batches in this new block in Q1 FY27. Two new NCE programs where the client audits were scheduled were successfully completed in Q4 FY26, and we are expecting to start initial development revenues in FY27.

Apart from that, on the generic side, we have added more than 15 new oncology products to our pipeline, these are top oncology blockbusters at global level, having patent expiry up to 2032. One new non-oncology product, which is completely import substitute product, process validation was successfully completed in Q4 FY26.

Methotrexate, which is again very complex import substitute oncology API, CEP for the product was received in Q4 FY26. We have added a new oncology block to our existing set up, increasing overall oncology API capacity. The block is expected to get commissioned in FY27.

On peptides, we continue to remain optimistic on the growth for peptides, where we are working on multiple generic peptides and CDMO peptides. New dedicated peptide large-scale manufacturing block, the equipment ordering is already completed, and we are expecting to commission the facility in FY27.

We are also working on multiple payloads and linkers, which are going into ADC program. In Q4 FY26, the payload which we had supplied to one of the big pharma companies, the registration batches were completed at their end using our payload. So subsequently, it will be taken in the filing at the end. Overall, API business is likely to have a steady growth in next financial year FY27.

Coming to formulations. Our first new chemical entity, which is Nor Ursodeoxycholic acid. As explained in the previous quarter, the product is really doing good, and we see very good clinical results in the patient. And we continue to see good traction in FY27. NorUDCA as a product, we are also planning to take globally.

We have done scientific advice and submission in U.S. and Europe, and we are planning to start human studies in FY27. Three commercial 505(b)(2) products are currently approved in U.S.A. and all products are doing good, and we expect the volumes to grow steadily quarter-on-quarter.

Abraxane, which is paclitaxel albumin-bound product, is a very complex injectable product. Exhibit batches were successfully completed in Q4 FY26, and we are expecting launch of this product in FY28. Enzalutamide tablets, which is a very complex product, we have successfully completed the registration batches for this product, having non-infringing route and we are planning to file this product in U.S. and Europe in FY27.

So, both Abraxane and Enzalutamide tablets are expected to get commercialized in FY28. Rotigotine Transdermal Patch Europe launch, as explained in the previous call, will be launched in Europe in FY27. We have also successfully submitted with U.S. FDA Rotigotine Transdermal Patch in Q4 FY26.

Ondansetron extended-release injection, which is one of a very complex injectable product developed by us, we are expecting to launch in FY27 in India. We are also planning to take this product globally, and we'll be starting human studies in FY27. Apart from above, we have very good complex differentiated 505(b)(2) product pipeline, for which details are provided in our investor presentation.

Overall, with existing and new product launches, there is likely to be a good growth possibility in FY27 in the formulation division.

Now coming to Biologics. Aflibercept, which is one of our most complex ophthalmic product, our human clinical study is on-going, and we are on track for launch for FY27. Our second product, which is Nivolumab, our human clinical study approval received for India. And also for EMA, we have submitted our scientific advice. We are expecting response in Q1 FY27. Four new biosimilars were added in portfolio in Q4 FY26.

Coming to new biological entity pipeline. Our first program with mAbTree Biologics, the program development is successfully completed, and we are planning to enter human Phase I studies in FY27. Our second program where we have partnered on this product with Alveolus Bio, the program development work has been initiated, and we are expecting the program to enter into human studies in FY27.

Two NBE programs will be entering in the Phase I studies in FY27. Coming to CDMO business. As mentioned previously, 5 active CDMO and NBE programs are ongoing. And in the Q4 FY26, the Phase I clinical study batches for one of the innovator program was initiated, and we are planning to finish the supplies in FY27.

Our first ADC biosimilar, which we have developed completely using payload, linker and conjugation was successfully completed. The development work was successfully completed, and we are planning to enter human studies in FY27. We have also initiated development of second ADC biosimilar product.

The main strength, what we are building in the ADC space is we are building our own ADC manufacturing suite, which will have manufacturing of mAb, manufacturing of payload, linker and conjugation. With that integrated manufacturing capability, it will be one of its kind in India.

Now coming to our recombinant human albumin program. Global Phase III clinical study approval was received from CDSCO for our Europe study. We are also planning to submit IMPD, which is required to be submitted in Europe when we are planning to start a study in Europe. That submission is planned in first half of FY27. Overall, our focus remains on monetization of all our investments, and we remain confident that work we are doing today is shaping Shilpa into a global technology-driven health care company in years ahead.

Thank you, everyone. And I will now hand it over to Mr. Alpesh Dalal.

Alpesh Dalal: Yes. Good evening, everyone. A warm welcome to each one of you to our Q4 results call. Let me briefly take you through the financial performance for Q4 as well as the full year ended in

March. I'm pleased to report that we have delivered our highest ever quarterly revenues of INR439 crores, recording a growth of 30% year-on-year. And for the full year '26, we have had historic revenue number, delivering INR1,549 crores, growing at 18%.

Our gross margin continued to remain healthy at 68% for the quarter and 70% for the full year. And along with our highest revenue that we have reported, we continue to report highest ever EBITDA also, both on a quarterly as well as yearly basis. For the quarter, EBITDA was at INR121 crores, growing at 40% year-on-year with an EBITDA margin of 28%, improving around 2% year-on-year, whereas for the full year, EBITDA was at INR445 crores, reflecting a growth of 30% year-on-year, with yearly EBITDA margin of 29%, an, ~3% year-on-year improvement. This improvement in EBITDA was largely driven by increased revenue from key verticals driving positive operating leverage.

Moving to our other financial highlights. Our interest outgo for FY26 has seen reduction on a year-on-year basis, and we believe that it has now stabilized at the current quarter run rate for the near future as we expect to fund our capex programs broadly via internal accruals. During the quarter, we also had an exceptional gain amounting to INR30 crores on account of stake sale in one of our JV company, Sravathi Advance, where we have sold 31% stake and now hold 34% stake.

This company no longer remains a JV company. Now -- it is now classified as an associate company. Overall, our adjusted PAT before considering any exceptional gain for the quarter was INR87 crores. And for the full year, it was INR232 crores, growing at about 135% year-on-year.

On the debt front, our net debt for the year increased to INR613 crores from INR550 crores in the previous year, which is in line with the growth in our business operations. And our capex of INR361 crores in FY26 was primarily funded by internal accruals and deployed in key verticals of API, CDMO and albumin facility.

I would also like to draw your attention to our improving ROCE profile, where our adjusted ROCE, excluding investments made in high-growth potential businesses like biologics and albumin, has seen a significant improvement from 4% in FY23 to 17.4% in FY26. And all these have been contributed by all the verticals across the board.

And with our formulations and biologics business showing steady growth. We remain confident that this improving operating leverage will help us achieve better ROCE in the future. Now on the segmental performance.

Our API business clocked a revenue of INR259 crores for the quarter and INR985 crores for the full year, growing at 16%, both on a quarterly as well as yearly basis. The growth was on account of improved uptake of key products from newly expanded capacities, coupled with strong captive demand from our finished formulation vertical. This vertical integration of our formulation products helped improve the overall margin profile of the entire group.

Formulation revenue for the quarter were INR205 crores, growing at 54% year-on-year, and revenue for the full year were INR618 crores, growing at 30% year-on-year. But importantly,

excluding the licensing income, the base business reported robust growth of 64% for the quarter and 75% for the full year.

Now to sustain this momentum in our FDF vertical, we continue advancing a pipeline of complex products and our strategy of developing and launching niche products globally through strategic partners is gaining very good traction, as evidenced by our European formulation business, which delivered revenues of over INR200 crores, growing by more than 100% year-on-year. Our Novel product, NorUDCA, which was launched in India in the previous quarter, continues to gain traction, and the strong reception has translated directly into a healthy order book for the upcoming quarters.

Moving to the Biologics segment. The revenue for the year were INR150 crores, growing roughly 100% year-on-year. And the strong growth was driven by continued deal momentum that we are witnessing in our CDMO business. With that brief introduction, I would now like to open the session for Q&A.

Moderator: First question is from the line of Kiran D. from TableTree Capital.

Kiran D.: A couple of questions. The first question, especially our U.S. partner has significantly grown its market share in 35% in Pemetrexed and 5% in Bortezomib, based on prescription data. However, our U.S. formulation revenue has grown only from INR54 crores in FY25 to INR80 crores in FY26, and it's kind of flatlined over the last 2, 3 quarters, right, around INR28 crores, despite all this.. So my question why aren't we seeing a steep growth in our U.S. revenues in line with our U.S. partner market share gains?

Keshav Bhutada: So I think on the U.S. revenue front, as you rightly mentioned we have seen an increase in revenue, and that will most likely continue in the FY27 also. Only against last year, this year, we have stopped selling our generic product, which was azacitidine in U.S. Since the market dynamics have changed for the product we have discontinued. So now we are focusing more on selling super specialty products.

Kiran D.: What was the Azacitidine revenue in FY25?

Keshav Bhutada: We can share that offline.

Kiran D.: Second question, sir, is in terms of our NorUDCA scaling with three of our partners and our own brand and so on and so forth. Are we seeing a steep scale up? Or have we kind of flatlined over the last four months in terms of demand and there are multiple other studies going on or the doctors are still trying to test it.

So what I'm trying to understand is, are we going to see a steep scale up in FY27 of this NorUDCA along with our partners? Or are we kind of saying, okay, last quarter results is what might get repeated for the following year?

Keshav Bhutada: If you see NorUDCA, we have launched the product in Q3, sometime in November. We have seen steep growth on QoQ basis. So we must see how the trajectory will be for the upcoming

quarters because the disease curability duration is 6 months. So once the 6 months duration is completed, then we will have more data from doctors, from hospitals.

Kiran D.: Understood, sir. So we will probably get a better handle by the end of FY27?

Keshav Bhutada: So yes, as I mentioned, NorUDCA, we have just launched in November, and it's a 6-month disease duration. So we must observe how the volumes will further grow. So we will be able to give you a clearer picture in sometimes in second quarter of this year.

Kiran D.: Last question, sir, is our EBITDA margin for the year, again, is 29%. Do we expect over the next 1 to 2 years as and when Shilpa scales for our EBITDA margins to go to 35% back -- and second question is service income is around INR200 crores. Do we expect a similar kind of run rate, I mean, expectation, similar or more in FY27?

Alpesh Dalal: As far as EBITDA margins are concerned, Kiran, the fact is that as the business grows, a bit of operational leverage does kick in, right? But obviously 35% is an ambitious target, which we would be working towards achieving. But we can't really say that it would be achieved immediately because whilst we grow the business, we also have to spend more for growing the business.

And on other question, Licensing income is something which at times could be a bit lopsided. But you can see in our presentation also that we have a very robust pipeline of molecules coming in. So there is certain visibility that we have got for our existing deals that we have signed. And then there are a lot of other things which are in the pipeline. So it will depend on some of those aspects. But generally, we do expect our licensing revenue to remain in similar range at least.

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

Ankit Gupta: Congratulations for a good set of numbers and for the full year as well as for the quarter. So the first question is on the European formulation business. So if you see Rotigotine doing well and we have scaled up well during FY26. So given when do you expect the first -- the second generic launch for Nilotinib happening?

And secondly, we know about the Rotigotine launch in this financial year. Apart from this, you have mentioned 7 products. So which will be the remaining 6 products that we are planning to launch? What can be the scale of these products? If you can elaborate on that? And how should we see the Europe formulation scaling for us in FY27?

Keshav Bhutada: So Ankit, there are two questions here. So first part on Nilotinib, right? As I mentioned in the previous calls also, we are expecting some generic competition to come in current financial year. But as Europe is a very typical market where usually the tender contracts and all are for more than one year or even two years for many of the markets.

So we don't see that for the current financial year, there will be a significant change in the Nilotinib volumes with respect to value. The more impact will be there for the FY28. So to answer you, that is what is the answer for Nilotinib.

And on second question on the launches for Europe, apart from Rotigotine, there are many other generic products also like I mentioned previously, we have Tadalafil oral disintegrating film that will be launched in Europe in this financial year. And apart from that, there are some generic products like Axitinib and many other products, which we will be launching and further market share will be improving in FY27.

Ankit Gupta: So we should be assuming decent 40%, 50% growth in Europe in FY27 as well given the base of FY26?

Alpesh Dalal: We may not be in a position to provide any guidance, but we do expect the European business to have a healthy growth.

Ankit Gupta: And the second question was on the biologics business. So if we look at it, like this year, we had INR150 crores sales, we would have gone -- got some milestone payment from Orion also for albumin. So like how should we look at the growth for FY27 and FY28? FY27, what will be the key triggers -- because Adali as a molecule in India is growing at a decent pace, but it's still a small molecule.

So how should we look at this number for FY27 and FY28, especially given Afli will be launched towards the later half of FY27 and the remaining Nivo, Pembro launches will happen only in late FY28. And like the other -- the CDMO business on the biologics side is something if you can elaborate more, how should we see the growth? So if you can broadly talk about the biologics business, the key drivers for the business for FY27? And what kind of growth should we expect in FY27 and FY28?

Keshav Bhutada: I think in biologics, the most important part in biologics is if you see till last year, right, we have launched 1 product and partnering was done more for India. We just started in Q4 where we have partnered our first product, Nivolumab, that also for LatAm market with a company called SteinCares, right? So for the current year, you will see mainly in biologics, the main growth drivers will be CDMO.

We have existing CDMO programs, which are going on and some more programs which are in discussion. We'll surely convert some programs. So there will be good revenue contribution from our CDMO business. And, we will be doing licensing for biosimilars as well for global markets especially in Europe and ROW markets. So there will be a good amount of licensing income also what we would achieve in FY27.

Ankit Gupta: Sure. So in this, can we expect the growth rate for last year to continue this year, given our base is still small currently, but last year also had the Orion milestone payment. So despite that, what kind of growth rate should we expect for FY27? And FY28, I can clearly see the triggers, but for FY27, how should we look at it? And even in FY28, can this segment ex of albumin become a INR400 crores, INR500 crores revenue generator for us?

Keshav Bhutada: We don't provide guidance on any specific divisions. But what I can tell you is there are a lot of growth figures which are possible in biologics. And we are seriously working towards monetizing of each of these assets. So yes, there is a good growth possibility. What would be

that percentage? How much we will grow? I think we have to observe that. More details you will get to know in upcoming quarters.

Ankit Gupta: And last question on OLC. The PDUFA date is approaching. And in your presentation, you still mentioned that we are hopeful for launch in FY27. So like how should we look at this because it becomes a very key growth driver for us for the current financial year, given we'll receive milestone as well as our formulation supplies for the product. So like how sure are we on getting clearance for the product and going ahead with the manufacturing here?

Keshav Bhutada: We don't project any meaningful contribution coming from OLC in FY27. When they will get approval, how is their filing strategy, many of these details, are confidential in nature.

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

Krisha Kansara: So first, congratulations on a very good set of numbers. The first question is quickly on the P&L side. The share of profit of INR18 crores from associates and JVs, which we have reported in this quarter. So from which entity or rather from which joint venture or which associate entity has this profit come? Was there any one-off in both companies because we have never reported this kind of profit from our JVs? That is my first question.

Alpesh Dalal: Yes. So Krisha, this particular entity is our associate entity. It is not a joint venture. It's an associate entity by the name of Maaia, where we hold 35% stake. It has been a research-driven company, which over a period of time has been investing in a lot of programs. And hence, we were taking our share of their accumulated losses that were coming up, which made our investments in consolidated results come to zero, right?

Obviously, the business in the company was not good. So we have never impaired those assets in our stand-alone books of accounts. But in our consolidated results, we -- as per accounting standards, we had to take impact of our share of loss. This year, when we have received their financials, they have shown a very significant improvement in the performance based on which the entire value has been reinstated.

Also, the profit part of our profit share of our portion has also been accounted for. So this is something that the company has started generating revenues and which is showing up. Whether it can continue with the same set of performance or not is very difficult for us to comment because that's not an entity that we control.

But we are in touch with them. We closely monitor their operations. But at this stage, we will not be in a position to comment whether this is something that can continue as a regular feature.

Krisha Kansara: Okay. Understood. And sir, my second question is on biologics segment on Aflibercept. So we had out-licensed this molecule for India and Russia markets. So have we received some part of the licensing income from these two partners or it is expected after the Phase III completion? And will the licensing income in case of Aflibercept be higher than that of Adalimumab?

Keshav Bhutada: So, we have received only a few milestones in last few financial years. But a major part of milestone will be received in the current financial year on launch and then on one year completion. And the licensing income Is higher than Adalimumab.

Krisha Kansara: Okay. Okay. And sir, the INR150 crores of biologics revenue, which we see in FY26, would it be possible for you to break it up in terms of how much was from CDMO, how much was from our own biosimilar revenue? And what kind of revenue was from licensing income?

Alpesh Dalal: Yes. you can reach out to Monish to get those details later on.

Moderator: Next question is from the line of Parth Mehta from Vallum Capital. The line of Mr. Parth has been disconnected. Next question is from the line of Raghav.

Raghav: Sir, my question is on the biologics side. So when do we see our biologics portfolio entering Europe and U.S. developed markets?

Keshav Bhutada: I think in the current financial year, Nivolumab. ADC product and 2 NBE products, will be entering human global studies in current financial year. We expect sometime in FY29, the commercial revenues to start in from Europe and ROW.

Raghav: Okay. But Adali and Aflibercept, we don't expect that to be launched...

Keshav Bhutada: Adalimumab already we are getting India revenue. And Europe and ROW market revenues will come in FY29. And for Aflibercept, currently, there is no plan of going into Europe market because it's a very long study and very costly study, and we feel that we are late for Europe market. So we are not planning to go for this product until and unless there is some partner who is ready to invest in the clinical study.

Raghav: Understood, sir. And sir, what would be the time line for same for NorUDCA? When do we see that reach larger parts in the developed markets?

Keshav Bhutada: Even NorUDCA would be in FY29 for Europe, but if I tell you about ROW market, we will start seeing revenues in FY28 in ROW markets.

Raghav: Any color, sir, on what would be the opportunity size for this in ROW market?

Keshav Bhutada: I think that can only be told maybe in the second half of this year, because now we have started discussing with some ROW partners. And we will have a lot of Indian study data as well. So I think once with that, when we start working with our ROW partners, we will be able to throw more insight. But we feel there is a decent potential.

Moderator: Next question is from the line of Shaikh Mohammad, an Individual Investor.

Shaikh Mohammad: Congratulations for the excellent set of numbers. I'm not having that much knowledge about company products because it is very in detail products. I just want to know regarding the FY27 guidance and top line and bottom line, if any, if you can provide?

Alpesh Dalal: I think as we have been explaining that we do not provide any guidance per se. But I think we have been growing since past 2, 3 years at a very healthy rate, and we expect that trajectory to continue.

Shaikh Mohammad: Okay. Sir, Tranexamic Acid spray product has been launched in India or it is exclusively for any particular country?

Keshav Bhutada: No, it is currently not launched in India because we are working on some government regulations.

Shaikh Mohamad: Sir, previously, we have launched Green Tea Film, right? So is that product continue or we have discontinued that product?

Keshav Bhutada: We have discontinued.

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

Sanjay Kumar: First set of questions on dutasteride. Correct me if I'm wrong, it seems to be a blockbuster product based on the Phase II trials. Yet -- despite completing Phase II in late 2022, you didn't file for Phase III until April '24, you didn't start Phase III till Jan 2026.

Now that we are going global for most of our products, we should speed up our clinical trials processes, right? And on that note, do you feel this is not a good product? Can you talk about this product and the potential for topical dutasteride?

Keshav Bhutada: Yes. SMLTOP09, why we did not start in last year human studies because there were additional preclinical study data, which were requested by the regulatory bodies that we were generating, now all that data generation is completed. And now we are entering into global studies. So that is what we will be starting in the current financial year.

Sanjay Kumar: Okay. Can you talk about the potential of this product and it is better to sell it? And do we have any out-licensing conversations for India at least for this product?

Keshav Bhutada: No, currently, we don't have any out-licensing discussion. Because the product is still in clinic and especially androgenic alopecia is a very big market, but there is a lot of data generation on safety, which is a very important requirement. So the data what we will be generating in the Phase III study, I think after that, we will discuss more on the partnering.

Sanjay Kumar: Okay. Okay. Got it. And you have three novel products in India which is NorUDCA, Ondansetron and the one that you just discussed dutasteride. Can these three products do like cumulative -- all three put together, INR500 crores, INR600 crores in two, three years because all three are very niche novel and huge potential.

Keshav Bhutada: I think that will depend on our partners also, right? Because you will see for many of the products, we partner and our partner's performance is very important for us. As you know for important products we have partnered with good companies, right? So even for the other

products, we would love to partner with the best companies in India. I think if we get a good partner and the product is performing well, we feel it's a very good possibility.

Sanjay Kumar: Okay. Just last question before I come back. On the patent and the FTO question for Ondansetron and NorUDCA because NorUDCA, I think Falk has a polymer patent in EU and I think globally. So do we have a different crystalline form that's on NorUDCA? And then on Ondansetron, do we have a Freedom to Operate versus Heron, the innovator. I know Ondansetron is not polymer-based. It's insoluble salt, but do we -- will our patent be at risk when we go global for both these products?

Keshav Bhutada: These are very confidential strategies. But what I can tell you, we are having our own IP strategy on this, and we are starting human studies for global markets. Obviously, all this work we would have done.

Moderator: Next question is from the line of Girish Bakhru from OrbiMed.

Girish Bakhru: Yes. Just wanted to actually talk on albumin. Why is the IMPD submission delayed? I think last quarter, we mentioned it would be Q4 and now we are saying first half?

Keshav Bhutada: I think as I mentioned previously also, on IMPD submission, what we are planning to do is we are planning to do it from our new facility, right? So in the new facility, the batches for IMPD submission are ongoing. So once that is complete, then we will be submitting. That is the reason I mentioned it will be in first half of FY27.

Girish Bakhru: And typically, after submission, how much time does the regulator take for giving you trial approval?

Keshav Bhutada: It takes usually 3 to 4 months.

Girish Bakhru: Okay.

Keshav Bhutada: So the Europe study is divided into two parts, the Indian patients and Europe patients, okay? So in Indian patients, the study approval already we have received. So once the batches are completed, we will be starting our India study, which is for Europe submission as well.

Girish Bakhru: Can you again explain these two patients studies, what individual differences are there in between two studies?

Keshav Bhutada: So there is no individual difference. Only there is a requirement in Europe when you submit such complex products. They want some patient data also on European patients.

Girish Bakhru: Understood. Okay. And Phase III, let's say, does it -- I mean, addresses again more data on -- whether this can be therapeutic grade or immunogenicity. What exactly would the outcome be focused on here?

Keshav Bhutada: In Phase III, we will be evaluating both safety and efficacy of the product on more number of patients, and that is the data we will be submitting to the agency.

Girish Bakhru: And because -- I mean, I'm just asking because it's a new technology, right? And there are very few products out there, recombinant ones. So would you say this would not require any further investments or additional studies before you see some revenues from FY29?

Keshav Bhutada: I think if you have followed our previous conference calls, we have successfully completed with European agency scientific advice. So scientific advice is like a written document, which you submit to the agency and take their approval on our clinical study. So that approval is already in place and we don't expect after this any other additional studies are required.

Girish Bakhru: Understood. Understood. And just lastly, I mean, so how big would you say would be the market size in India, particularly? And because it's a largely import-dependent product, right? So would there be, let's say, some sort of incentives that we can see even if the product is approved?

Keshav Bhutada: Albumin, everyone knows it's a very good and decent opportunity, and there is always scarcity in the market. The product itself will have a differentiation, the recombinant highly pure product. So I think that should drive the volumes.

Moderator: Next question is from the line of Pratik Shrivastava from Nivesh Wisdom.

Pratik Shrivastava: First of all, congratulations for great set of numbers. My first question is on the API, oncology side of things, sir. So, we have this new oncology block expansion, which is underway and is about to be completed by FY27 for around like 15-plus new oncology APIs, right? Sir, how does that translate into contribution to the revenues per quarter?

Because most of the time, I think our contribution has been like lower than INR130 crores per quarter for the last several quarters. I know that some of this has been translated to formulations. But can you share some more color on this -- on the contribution to the revenue from this side?

Keshav Bhutada: In API, oncology side, you will always see that even in future, a lot of our sales will be to our captive formulation because our main strength in oncology API is we are very strong in developing non-infringing APIs. And we usually try to forward integrate with our formulation and then go to the market that will have maximum realization.

So even going forward, it's not that these products are something which will be launched once the batches are done like next day. So oncology as a business for us in API will further grow, but it is not a steep growth. It will be a steady growth.

Pratik Shrivastava: Got it. And you're saying it will continue to contribute more towards the formulation business. This is more of a backward integration story? Or this will have its own sales cycle, sales channel, different commercial DMF filings, things like that, sir?

Keshav Bhutada: So it will be both, but major contribution will be to formulation, our own captive formulation.

Pratik Shrivastava: And my second question is on the semaglutide GLP-1 side of things, sir. We completed the validation in Q4. Congratulations for that, sir. And what I read is DMF is to be ready by first half of '27. Sir, there are -- I see in the market now, there are lots of different players. A lot of

Indian -- several Indian players are also developing semaglutide story. So what will be our differentiation?

Keshav Bhutada: For Semaglutide, our main strength is that we are doing both synthetic and semisynthetic API. And, we are forward integrating with our own formulation. So, semaglutide itself is a very big opportunity. And because our facility has the global accreditations, we still feel in such a big opportunity if we get even small pie of that market share, will give us a decent revenue.

Pratik Shrivastava: Got it. And are we targeting India first and then the regulated market, ROW?

Keshav Bhutada: No, our main focus will be on the export market.

Pratik Shrivastava: Okay. Got it. For that, have we identified any partner for commercialization, sir?

Keshav Bhutada: As I mentioned, we are also doing our own formulation. API will be launched by us and formulations will be launched in various markets via partners.

Moderator: Next question is from the line of Amish Kanani from Knowise Investment Managers.

Amish Kanani: Sir, one thing which is noted is API is now 50% of the business and formulation and biologics is 50%. So congratulations on kind of going in that direction where we are value adding. The question, sir, is, as we grow at a high rate and given our gross margins are high, our EBITDA margins also are reaching at a very healthy level.

But given the programs that we have and the R&D needs that we have, we'll also have reinvestment that will be done. So how do you think, sir, about EBITDA margins given that otherwise, if we restrict our investment, it can go really very high. And obviously, as a businessman, we would like to reinvest back.

So how do you think about investment versus increasing the EBITDA margin at some level, you will reinvest back. So any thoughts there, sir, it will be helpful. And on the API side, sir, any challenges on the RM or key starting materials because of the supply chain disruptions globally, if any -- are there any issues that you need to worry about?

Keshav Bhutada: See, I think on your first question, Amish, as we previously mentioned also, Shilpa as a company, principally, what we are doing is we are not investing into anything which is long term. So whatever investments we are doing, are going to have revenue generation in near term and midterm.

So yes, we don't want to invest anything, which has long gestation. So if we continue this investment in our existing near-term and long-term opportunities, then only there will be a decent growth, which is possible. So we will continue to do that. And on second question on the raw material and solvent availability, yes, we don't see any major challenges on that, but only the prices have gone up significantly. So that is the only thing, but availability is there, no problem.

Amish Kanani: Okay. And sir, quickly, can you recap the capex for this year and next year, if possible?

Keshav Bhutada: Like for the current year already, it's available. So we don't see any significant capex growth than last year. It will continue to sustain.

Moderator: Next question is from the line of Abhishek from Padmaja Investments.

Abhishek: On the Jadcherla USFDA audit, it should not come by now, right? Is there any issue with this as such?

Keshav Bhutada: So Abhishek, I think as previously mentioned in our quarterly calls also for majority of products which are being sold in U.S. are now being done from third-party CMO sites. And we don't have a pipeline of like 10, 20 products launches every year. So we have very complex differentiated products, which we want to launch.

So our major focus on U.S. will be from third-party CMOs. There is no issue with the FDA. It's just that the facility when the audit happened, the FDA has given some observations. We have done the compliance. And now we are again waiting for the reaudit of that. So we can come out in some time. It's not that we will never come out, but it will not have any impact on our revenues.

Abhishek: Okay. But the audit already happened and the decision is still pending, if I understand it. Is that the case as of now...

Keshav Bhutada: Yes, correct. So we are working closely with FDA on the next steps with U.S. FDA audit.

Abhishek: Okay. And the plant utilization, even though it is not actually being used for U.S.A. is being used for other geographies?

Keshav Bhutada: Yes, because our facility has all the global accreditation starting from Europe, LatAm, Saudi, all the markets. So the plant occupancy is not at all an issue. And because we have such a strong pipeline of differentiated products. We don't see any capacity crunch issues currently in our formulation facility.

Abhishek: But there are certain tentative approvals pending because of this audit issue, how many products are in that current...

Keshav Bhutada: See, whatever products which are in tentative approval space, many of them are already genericized, and we don't see much potential even if we get the approval for these products.. However, there are few products which are having high value and have tentative approval, but the patent expiry and the launch for those products are late.

Moderator: Next question is from the line of Vishal Manchanda from Systematix.

Vishal Manchanda: On Rotigotine patch Europe launch, can you share like what time can we take to reach full potential? And any sense on the peak potential that you expect from the product?

Keshav Bhutada: Rotigotine transdermal patch, as you know, is very complex product, and we have approval for this product. So in the current year, it will be more like initial launch and ramp up will happen in the subsequent which is FY28.

Vishal Manchanda: So you can reach full potential by next year. Substitution will not take long once you are approved across markets?

Keshav Bhutada: Yes, you're right.

Vishal Manchanda: Okay. And on Nilotinib, do we expect approvals in other markets? Or we are kind of fully in terms of geographic reach, we are there...

Keshav Bhutada: Actually, Nilotinib in our rest of the world market is also expected to do well. And we will be launching in some of the rest of the world markets also in next financial year.

Vishal Manchanda: Okay. And Europe, you are fully entrenched in terms of the potential opportunity?

Keshav Bhutada: Yes, you're right.

Vishal Manchanda: Okay. And if you could share what -- on our CDMO business, like what was the total CDMO business across all domains, API, formulations and biologics?

Keshav Bhutada: For the full year on the API side of the business, we have clocked approximately around INR110 crores of CDMO business. And we are also doing similar CDMO business on the biologics side also. So majorly, our CDMO revenues are in API and biologics.

Vishal Manchanda: Got it. And on the licensing fee number, do we have any contribution of the CDMO business or that licensing fee doesn't have any CDMO contribution?

Keshav Bhutada: That doesn't have any CDMO. That's pure product licensing.

Vishal Manchanda: Okay. And just one final one. The oncology breakthrough molecule that you are servicing to an innovator, any color there? Can that be meaningful this year or next year?

Keshav Bhutada: Yes, we expect it should be meaningful in FY28.

Vishal Manchanda: Okay. And so would that be larger than the numbers you would have attained in the past?

Keshav Bhutada: No.

Moderator: The last question is from the line of Kiran D. from TableTree Capital.

Kiran D.: So a couple of questions. One, sir, the polymer business, we had a contract 4 million contract, I think, was mentioned in the annual report last year. So this year, what is the kind of revenue? And more importantly, more than the polymer revenue this year, how do you see the potential of our polymer business in the next one to two years? Has it a potential to reach a 20 million kind of run rate? If you could just elaborate, that would be great.

Keshav Bhutada: I will not be able to give you exact numbers, but polymer as a business, it's a business which will have good growth possibility, but it takes some time. So like currently, we already have one commercial product in the polymer space. Which has added decent revenue in FY26. So we will

see how the opportunities are scaling up in FY27. But yes, going forward, few of years ahead, it has a good potential.

Kiran D.: Got it, sir. Okay. Cool. And one question for Alpesh. Alpesh, you mentioned ROCE 17.4% in FY26, excluding investments made in potential high-growth biologics and NBE business, it's in the investor presentation as well. So our gross block is INR2,281 crores. So when you say excluding investments made in potential high-growth biologics and NBE, how much is that? Is it like approximate INR700 crores, INR800 crores? Is that the right number?

Alpesh Dalal: Yes. I think some of those numbers, you should reach out to Monish to get those details.

Moderator: Due to time constraints, that was the last question of the day. I now hand the conference over to Mr. Alpesh Dalal for closing comments. Over to you, sir.

Alpesh Dalal: Thank you, everyone, for your time and your thoughtful questions. Each year, we remain committed to growing and scaling the company to new heights and your continued interest and support mean a great deal to us. Should you have any questions that have remained unanswered, please reach out to Monish, and we'll be happy to provide those answers to you. Thank you.

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