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Biocon Limited Q4 FY25 Earnings Conference Call Transcript

May 9, 2025

Speakers and Participants from Biocon Limited, Biocon Biologics Limited & Syngene International Limited

- **Dr. Kiran Mazumdar Shaw** – *Executive Chairperson, Biocon Limited*
- **Mr. Siddharth Mittal** – CEO & Managing Director, Biocon Limited\
- **Mr. Shreehas Tambe** – *Chief Executive Officer & Managing Director, Biocon Biologics Limited*
- **Mr. Peter Bains** – *CEO & Managing Director, Syngene International*
- **Mr. Abhijit Zutshi** - Chief Commercial Officer, Biocon Limited
- **Mr. Manoj Kumar Pananchukunnath** – *Chief Scientific Officer, Biocon Limited*
- **Mr. Kedar Upadhye** – *Chief Financial Officer, Biocon Biologics Limited*
- **Ms. Rhonda Anne Duffy** – *EVP & Chief Operations Officer, Biocon Biologics Limited*
- **Mr. Matthew Erick** – *Chief Commercial Officer – Advanced Markets, Biocon Biologics Limited*
- **Mr. Susheel Umesh** - *Chief Commercial Officer – Emerging Markets, Biocon Biologics Limited*
- **Mr. Anuj Goel** - Chief Development Officer, Biocon Biologics Limited
- **Mr. Deepak Jain** – *Chief Finance Officer, Syngene International*
- **Mr. Saurabh Paliwal** – *Head - Investor Relations, Biocon Limited*

External Participants during Q&A session

- **Damayanti Kerai** – *HSBC Securities and Capital Markets (India) Private Limited*
- **Neha Manpuria** – *Bank of America Securities India Limited*
- **Harith Ahamed** – *Spark Institutional Equities Pvt. Ltd*
- **Surya Patra** – *Phillip Capital (India) Private Limited*
- **Prapti Gupta** – *AllianceBernstein (Singapore) Ltd.*
- **Amey Chalke** – *JM Financial Institutional Securities Private Limited*
- **Tushar Manudhane** – *Motilal Oswal Financial Services Ltd*
- **Nitin Agarwal** – *DAM Capital Advisors Limited*
- **Love Sharma** – *JP Morgan Securities (Asia Pacific) Limited*

Prepared Remarks Session

Saurabh Paliwal:

Good morning, everyone. Thank you for joining us on this call to discuss Biocon's fourth quarter and full-year results for FY'25. I am Saurabh Paliwal from Biocon's Investor Relations team.

Before we get started, let me introduce the management team on this call. We have today Biocon Chairperson, Dr. Kiran Mazumdar Shaw; Mr. Siddharth Mittal, CEO and MD of Biocon Limited; Mr. Shreehas Tambe, CEO and MD of Biocon Biologics Limited; Mr. Peter Bains, CEO and MD, Syngene International, along with other senior management colleagues across our business segments.

A few housekeeping points. We will start the call with opening remarks from Kiran, which will be followed by an interactive Q&A session. All the external participants line are muted and will be in a listen-only mode. There'll be an opportunity for you to ask questions after the opening remarks conclude. If you need to ask a question, please select the raise hand option in the reaction tab of the Zoom application. We will call out your name and unmute your line to enable you to ask the question. Please note that this webinar is being recorded. The recording will be made available on the website within a day, and the transcript will be made available subsequently.

Before we begin, I want to remind everyone about the safe harbour related to today's call. Comments made during the call may be forward-looking in nature and must be viewed in conjunction with the risks that our business faces that could cause our future results, performance or achievements to differ significantly from what is expressed or implied by such forward-looking statements.

With this, I would like to turn the call over to Kiran for opening remarks. Over to you, Kiran.

Kiran Mazumdar Shaw:

Thank you, Saurabh, and good morning, everyone. I'm delighted to return to hosting Biocon Limited's quarterly earnings calls. I'm pleased to provide a business and financial overview of the Biocon Group's Q4 and full year FY'25 performance. Before diving into the details, I'd like to share a few opening thoughts.

Building on our Q3 performance, our 3 divisions, Generics, Biosimilars and Research Services, ended the financial year on a strong growth trajectory.

Let me start with key highlights for Q4, and these include:

- The appointment of Peter Bains as MD and CEO of Syngene International
- The global launch of our first GLP-1 formulation, Liraglutide, in the U.K., and the introduction of Lenalidomide and Dasatinib in the U.S.
- The launch of Yesintek™ or biosimilar Ustekinumab was an important launch, which is one of the first biosimilars to Stelara® in the U.S. and the fifth product from our portfolio to enter the U.S. market.
- The settlement with Regeneron to secure a market entry date for Yesafili™, our biosimilar Aflibercept in the U.S., which is expected to be no later than the second half of 2026.
- Syngene's acquisition of a biologics manufacturing facility in the U.S., positioning us to meet the rising demand for biologics CDMO services, this time from a U.S. base.

The group achieved a robust 15% year-over-year and 16% sequential growth in operating revenue on a like-for-like basis. That is after excluding revenues from the India Branded Formulations unit, which was reflected in Q4 of FY'24. This quarter's performance was bolstered by strong growth in Generics, steady progress in Biosimilars and ongoing traction in Research Services.

Q4FY25 Financial Highlights

Revenue from operations reached INR 4,417 crores, reflecting a solid 15% year-on-year increase on a like-for-like basis and a 16% sequential growth. This growth was driven by a 46% year-on-year growth for Generics, 9% for Biosimilars and 11% for Research Services. Sequentially, all segments reported growth. Generics, particularly, was up 53%, while both Biosimilars and Research Services were up 8%.

Core EBITDA for the quarter stood at INR 1,363 crores, a 16% increase from last year with a healthy core operating margin of 31%. R&D investment for the quarter was INR 231 crores, accounting for 7% of revenues, which is, of course, excluding Syngene.

Reported EBITDA for Q4 was INR 1,115 crores, which is a 16% year-on-year growth on a like-for-like basis. Profit before tax, excluding exceptional items was INR 466 crores, a strong 45% increase on a like-for-like basis.

For the **full year, revenue from operations** totalled INR 15,262 crores, which is a 10% year-on-year increase on a like-for-like basis.

Group core EBITDA for the year was INR 4,264 crores with a margin of 28%.

EBITDA reached INR 4,374 crores, reflecting a 3% year-on-year growth on a like-for-like basis with a margin of 27%.

Reported Net Profit for FY'25 was INR 1,013 crores, which is a significant turnaround when considering the performance on a like-for-like basis.

I would now like to discuss our business performance in a segmental manner. Let me start with Generics.

Generics Business Update

Q4 has been the **strongest quarter** for the Generics business in FY'25 with **Revenue from Operations** reaching INR 1,048 crores, up 46% year-on-year and 53% sequentially, driven largely by the sale of launch quantities of Lenalidomide.

The **launch** of Liraglutide in the U.K. and Dasatinib in the U.S. also boosted revenue performance this quarter. In addition, we **received approvals** for Liraglutide in the EU and Everolimus (Zortress®) tablets in the U.S. We also commenced supplies of Tacrolimus to China, where our partner is expected to initiate commercialization in the first quarter of FY'26.

For the Generics business, **EBITDA** for the quarter was INR 243 crores, up significantly from last year and the previous quarter, bolstered as I mentioned earlier, by the Lenalidomide launch in the U.S. **EBITDA margin** stood at 23% this quarter.

For **FY'25, Revenue from Operations** was INR 3,017 crores, reflecting an 8% year-on-year increase. **R&D investments** rose to INR 286 crores, which is about 9.5% of segment revenues, aimed at driving future growth. Our peptide portfolio, especially GLP-1s will be our key drivers for future growth.

EBITDA for FY'25 was INR 377 crores with **EBITDA margin** at 12%. EBITDA performance for this year reflected pricing pressure and higher operational expenditure linked to new plant capitalizations, namely the peptide API facility, the Vizag fermentation capacity expansion, as well as the U.S. Cranberry facility.

Biosimilars Business Update

In Q4, Biocon Biologics marked its first anniversary as a fully integrated global biosimilars company with a footprint in 120 countries.

Key highlights include:

- Key product and site approvals from global regulators, including the U.S. FDA and EMA.
- We received the U.S. FDA approval for Jobevne™, our biosimilar Bevacizumab, and a positive EU CHMP opinion for biosimilar Denosumab.
- Strong commercial momentum was delivered with significant increase in market share across geographies. I would particularly like to call out Fulphila®, which is our biosimilar Pegfilgrastim, and Ogivri®, our biosimilar Trastuzumab, which registered market shares of 30% and 26%, respectively, in the U.S. market, which is a two-fold increase from last year.
- We had a successful launch of Yesintek™, which is our biosimilar Ustekinumab, with broad formulary coverage and physician adoption.
- Also, important this quarter was our announced partnership with Civica Inc., a U.S.-based not-for-profit supporting affordable insulin access for people with diabetes.

We are witnessing a surge in global demand for our insulins. Given our global scale manufacturing capacities, we are well placed to capitalize on this large opportunity. The Biocon Group is also, if I may say, uniquely positioned to address the growing global burden of what we describe as diabesity through its portfolio and pipeline of both insulins and GLP-1s.

Now moving to financials.

Biosimilars **revenue** for Q4 was INR 2,463 crores, which is a 9% year-on-year increase on a like-for-like basis. This growth translated into an **EBITDA** for Q4 FY '25 at INR 540 crores, representing a healthy **EBITDA margin** of 22%. R&D investments for the quarter were at 6% of revenues.

Full year revenue was INR 9,017 crores, up 15% year-on-year with 4 biosimilars recording revenues of USD 200 million each, demonstrating strong payer and prescriber confidence in our products. **Reported EBITDA** for the full year was INR 3,028 crores. Excluding the one-time gain from the BFI business divestment, EBITDA for the full year was

INR 1,971 crores with a margin of 22%. This R&D investments for the year were at 7% of revenue, which will fuel mid- to long-term growth.

Syngene Business Update

Now lastly moving to Research Services.

Syngene ended Q4 with **Revenue from Operations** of INR 1,018 crores, 11% year-on-year increase. Quarterly operating revenue crossed the INR 1,000 crore threshold for the first time. **EBITDA** was up 9% year-on-year and 20% sequentially to INR 363 crores with **EBITDA margin** at a strong 35%.

The acquisition of a state-of-the-art biologics facility in the U.S. enhances our capabilities in the global CRDO market and creates our first U.S. manufacturing footprint.

For **FY'25, Revenue from Operations** grew 4% to INR 3,642 crores, aligning with guidance following a challenging first half. **EBITDA** stood at INR 1,114 crores with **EBITDA margin** at 30%.

Conclusion

So let me conclude by saying that in summary, FY'25 has been a year of consolidation and transition, which has set us up to an exciting inflection point. We are now on a path of accelerating growth with a commitment to innovation, digital augmentation and operational excellence.

Thank you. With this, I open the floor to questions.

Q&A Session

Saurabh Paliwal: Thank you, Kiran. We'll wait a moment for the questions to assemble. We will start the first question with Damayanti Kerai from HSBC. Please go ahead.

Damayanti Kerai: **My first question is on your biosimilar, Stelara, where you recently updated that you have gained access with leading formularies in the U.S. So just want to understand what kind of market share you are building in view of this update. And if you could also comment on how the pricing scenario is playing out for this particular market?**

Kiran Mazumdar Shaw: I would hand this over to Matt to explain and answer your question, Damayanti.

Matthew Erick: Thank you, Kiran. Appreciate it. So as you know, we've had very successful market access. We have over 70% market access with the payers in the U.S. at the beginning of the start. With that comes the opportunity for us to continue to pull the product through in the U.S. We are very bullish on our market share. We haven't really been able to state that directly yet as we're starting to work with physicians and pulling it through. But we have over 100 million lives that are covered in the United States. It's one of our most

successful market access to date. So this allows us to continue to work with physicians, health care providers and pull this through. And as we go through, we'll continue to update you on our abilities and successes that we're having, but we remain very bullish on our opportunities as we go through the remaining quarters because of how we're set up with all the major payers and having that access position.

Damayanti Kerai: **Sure. And if you could also comment on the pricing scenario, please?**

Matthew Erick: Sorry, I'm not sure why my video is not working, I apologize. There we go. The pricing situation remains stable. We're certainly in a good position. As you know, in the United States, it is somewhat the economics. But clearly, the customers have seen the science behind this. Also, we built tremendous relationships with the payers and also the health care providers. So the pricing remains stable at this point as we go through the rest of the year. We don't see much changes in compression in the price points in the net selling price going forward.

Damayanti Kerai: **Sure. My next question is on 2 other products, Bevacizumab and Aspart. So Bevacizumab, have you launched in the U.S., or it's yet to be launched? And then what kind of timeline we are looking for Aspart launch in the U.S?**

Matthew Erick: Kiran, would you like me to take that or Shreehas? Either way, it's fine.

Kiran Mazumdar Shaw: Well, you can continue, Matt.

Matthew Erick: Sure. So sorry, Shreehas, did you want to say something before I jump in?

Shreehas Tambe: Go ahead, Matt.

Matthew Erick: On bBevacizumab, we do have positions with Bev and approval. So, you will be seeing that sometime in the first half year of a launch. As you know, with Aspart, we're still waiting on approval, but we are bullish on expectations of having that approval here in the first half and be ready to launch. As you know, we have a tremendous franchise with our biosimilars already in diabetes with our insulin Glargine. And our customers are very anxious in engaging with us as Aspart becomes available.

On the Bevacizumab, let me just touch base one more there. On the bevacizumab launch, as you know, we have an incredible Oncology portfolio, as Kiran stated. We have over 30% in Fulphila, 26% in Ogivri. This will be a nice addition to our Oncology portfolio, and we'll be well positioned with our sales force and being able to not only work with the payers, which will have a strategic initiative of getting access, and then we'll be able to work with the relationships, which we've been very successful with the oncologists, to be able to pull that through in certain channels.

Damayanti Kerai: **Sure. And my last question is on financial position of Biocon Biologics. So if you can comment on the current debt position? And also, how are the working capital looking compared to last year? So if you can comment anything on, say, inventory days for Biocon Biologics or on the receivable front, that will be helpful.**

Kiran Mazumdar Shaw: Maybe Kedar would like to take this.

Kedar Upadhye: So Damayanti, our working capital position has substantially improved compared to last year. Our receivables look quite healthy. The number of days across each markets vary, but roughly, they are around 90 days in terms of the credit that we offer to customers. Inventory, in fact, has come down dramatically compared to last year. So, the net inventory as on 31st March is about USD 390 million. In terms of the forward days, it's less than about 280. So both inventory, receivables and other parts of working capital has substantially improved. Net debt is about USD 1.1 billion as on 31st March. And if you normalize for the factoring and advance collections that we have done, it's about USD 1.2 billion. So, I think compared to March '24, March'25 position for net debt, inventory and receivables looks quite healthy. And we'll continue on this improvement here.

Damayanti Kerai: **Sure, Kedar. And this net debt is excluding the structured instruments, right?**

Kedar Upadhye: Yes, this excludes the structured instruments, correct.

Damayanti Kerai: **Okay. And just like on the inventory days, you said USD 390 million inventories, but on a forward basis, it's around 280. Just in terms of days, how does it translate? And then if you can just compare it against FY '24 numbers?**

Kedar Upadhye: Yes. So, March'24 DIO, days inventory outstanding, was in excess of 400. And as of March,'25, as I said, it's lower than 280.

Saurabh Paliwal: We'll take the next question from Neha Manpuria from Bank of America Securities.

Neha Manpuria: **My first question, Matt, on the Stelara comment that you mentioned that you're working physicians to try to pull through the market share. Realistically, when should we start seeing this reflect in market share trends? Would this take us 2 months, 3 months, much longer than that? Historically, what's been your sense in being able to work? I know this is only the second launch in the physician market, but what's your sense on when we start seeing this in market share trends?**

Matthew Erick: Thanks for the question. Certainly, as you know, the U.S. payers have different timing. You're going to see some of the U.S. payers when they decide to not cover the Stelara innovator. Some of this will be starting in July, then some in September, October, and then finally, the majority of them will not be covering the innovator in January '26. As you start looking at the IQVIA data, you'll start seeing sales already. They've started. And as we go through the remainder of this calendar year and then into the Biocon remainder of fiscal year, you'll start seeing more and more market share as the innovator is not covered by the payers. And remember in this, too, as we reported, we are covered by every major U.S. payer. When I say that, that's your Express Scripts, your Optum, your CVS Health, the major ones. This will allow us to utilize our tremendous sales force that we have already calling on Immunologists, Gastrologists to be able to pull this through. So the expectations you'll start seeing immediately in the information that you can see in the data in IQVIA, and we expect that market share to continue as the innovator Stelara is not covered as we go through the remainder of the calendar year.

Neha Manpuria: **Understood. That's very helpful. My second question is, if I look at BBL financials, the revenue growth of 15% for the year versus core EBITDA growth of 10%. When**

I look forward, is it fair to assume that some of these new launches will help us grow EBITDA better than revenue trends, either because of operating leverage or better pricing? Any color that you can give on why we are seeing lower EBITDA growth core EBITDA growth? Is it pricing pressure? And how should we look at this from an FY '26 perspective?

Kedar Upadhye: Yes. So Neha, as you are aware, we don't give forward-looking guidance. But you are right. I think as the launches do come in, the incremental gross margin on those launches is going to be higher than the existing business. So some kind of operating leverage as well as gross margin improvement is expected. We're not giving the guidance, but directionally, you are right.

Neha Manpuria: **And this year, the lower EBITDA growth is purely pricing pressure on the existing products? Would that be fair to assume?**

Kedar Upadhye: Actually, you should adjust for the licensing income that we got last year, Neha. In quarter 3 of last year, if you recollect, we had USD 40 million of profit from sale of brands that was booked as an operating income. So, if you adjust for some of those items, then you'll get an adjusted EBITDA growth which will look quite healthy.

Neha Manpuria: **No, but I'm talking about the core EBITDA growth.**

Kedar Upadhye: Yes. Core EBITDA reflects, to some extent, the investments that we have to make in the Opex. And yes, there has been some price pressure. But going forward, like what we said, once the new launches do kick in, the incremental gross margin and EBITDA contribution will look quite healthy.

Neha Manpuria: **Okay. Got it. And on the Generics business, we have launched Lira in U.K. Any color on when we should expect the launch in the U.S.? And in case of generic Revlimid, should we expect it to be lumpy? Or would it be similar trend in the quarters going forward, at least till the time we see patent expiry in Jan '26? Any color on the generic business, please?**

Siddharth Mittal: So Neha, the launch in U.K. was in quarter 4. Of course, we'll be supplying additional volumes in this quarter. And launch in Europe is planned in the second quarter, while we are trying to get the supplies to our partner, Zentiva, in the first quarter. And as far as U.S. is concerned, as you know, we had mentioned earlier that there were certain queries which we have responded to. The facility of Biocon Biologics, from where the product was filed, has been cleared. Again, we have responded to the FDA. And we have a target action date during the second half of this calendar year. And of course, subject to the approval, we will be ready to launch the product immediately after that. And as far as the generic Revlimid is concerned, you're right. We had a settlement with the innovator where we were allowed a certain market share, and a large part of that market share has already been serviced in the quarter 4. So to that extent, revenues will be lumpy before the market opens up in Jan '26, as you mentioned, when, of course, we will be supplying to various customers, along with other generic companies, who will also be looking at a much larger market share.

Saurabh Paliwal: We'll take the next question from Harith Ahamed from Avendus Spark.

Harith Ahamed: **So on insulin Aspart, just a follow-up, the partnership with Civica that you've announced to supply the drug substance. Can you talk a little bit about the rationale for this partnership given that we have our own product, and also the timelines that we can expect in terms of commencement of supplies here?**

Shreehas Tambe: Thanks, Harith, for that question. I think the idea was to see how we can get product close to customers as much as possible. And the relationship that we've essentially done with Civica Inc. is where we have local manufacturing of drug product within the United States. So a large part of it is also to see how we can localize manufacturing in the U.S. That's one. Two is it does give us access to those set of customers that Civica is able to access. And that income, that essentially is not competitive to Biocon Biologics and our brand but essentially is accretive to what we are trying to do there. And three, I think the cumulative effect of having more than one brand has been already a proven commercial strategy where we've seen the benefits of this in several markets, and we intend to see how we can bring our insulins to more patients across the world. So clearly, it's very synergistic with the strategy that we've developed.

Harith Ahamed: **And the timelines, Shreehas?**

Shreehas Tambe: From a timeline perspective, given that we will localize this, the sense we have is the initial supplies to make sure that they register the product with the agency would start during the year. And then once they have the approvals in place, then you would see much more of this starting to realize as they commercialize it.

Harith Ahamed: **Okay. Got it. And on Pegfilgrastim, good to see the market share inch up to 30%. My question is around some of the disruptions we've seen in this market. One of your competitors had supply issues. So, have those issues normalized? And have their supplies restarted? And in that context, how should we think about market shares going forward?**

Shreehas Tambe: So Harith, I wouldn't want to specifically talk about competitor positions and their strategies. But let me give you a sense. In the past also on our earnings call, I've indicated that the management of ASP is something that needs to be done very carefully, because ASP and market share are inversely proportional. So you could essentially move very quickly, gain market share, but then it comes at the cost of ASP, which makes you unattractive to the end provider. And which is why you've seen us steadily grow the market share, and there's not been a rapid movement in this pickup.

Now as competitors try to win market share, one of the strategies is, of course, discounting the ASP, and that leads to them not being available in the market anymore. That's where our market share has really gained. There are these one-offs that you referred to where specific competitors could be out of the market and customers do move on, and we've benefited from that. And once we do that, those customers tend to stay with you. So we're not seeing any aberration in terms of this movement. We see consolidation in the market, which we've talked about in the past.

Harith Ahamed: **Okay. Last one with your permission. You talked about 4 of your products achieving sales of over USD 200 million. And I am assuming Adalimumab is one of them. So in the past, we've had a few challenges in the U.S. with respect to this product. My question is whether U.S. is a material contributor to the overall USD 200 million sales that we're generating from this product?**

Shreehas Tambe: For Adalimumab, we haven't specifically broken down, Harith, every product by region. U.S. is a sizable portion for our business. It's about 40% of our overall sales. Adalimumab has been a product, like Matt was referring to, a lot of it depends on how long the originator stays on the formulary. We have seen the originator product, in this case, stay on longer than expected, which is why you have seen that biosimilars in general have not gained as much market share as we've seen in Oncology, where it's over 80% that we have seen biosimilars have adoption already. So we see that happening during the course of this year. We will see how that changes. Again, being a fully integrated player is very, very important. And that's an area where Biocon Biologics differentiates itself from the market. So we are here for this for the long. So we will be watching this space very closely as the success of Stelara, Yesintek, that we just talked to you about. The confidence is beginning to show where almost all commercial payers have got the product on its formulary, which is very contrary to how adalimumab.

Saurabh Paliwal: We'll take the next question from Surya Patra from Phillip Capital.

Surya Patra: **So my first question is on the Aflibercept. We have certainly got the launch date for U.S. market. Sir, could you please share what would be the profit-sharing arrangement there? And do you have any kind of exclusivity there in that product for any period initially?**

Shreehas Tambe: Surya, thanks for your question. We've not specifically disclosed contractual agreements and understandings with our customers. Needless to say, this is a product that we will first be launching in Canada in July of this year, where we will be the first to launch. So we're looking forward to that launch. We are also looking now clearly to a very risk-free, I would say, date for 2026 for aflibercept in the U.S. So I would say on both counts, we are at a place where we have certainty of when and where the product will be launched. Now how these will eventually translate in terms of exclusivity that you talked about, I think we are the first biosimilar to have been approved. There is, of course, others who have launched. But we have this position where our product will be approved as an interchangeable on approval, which it was when we got the approval from FDA.

Surya Patra: **Okay, okay. So then second point is about the Yesintek. See, in fact, it looks like that the formulary position what we have created for Yesintek for the U.S market, it looks like it is the strongest compared to our earlier product launches. So given that scenario, is it fair to expect a better market share position in the initial level itself for Biocon in the U.S.?**

Shreehas Tambe: Certainly fair to expect, Surya. I mean we've not guided anything specific, but we're very happy to see that the product has been very well received by all major commercial players in the U.S. market, like Matt just alluded to. And I should also give another piece of

information there that for Stelara, more than 80% of the market in the U.S. is commercial. And when you have 100% coverage on all commercial payers, then of course, it is fair to say that you will see a good uptick as compared to what we saw for Hulio.

Surya Patra: **Okay. Just one clarification, sir. The primary insulin, I believe that has also crossed USD 200 million when you say that, okay, 4 products have crossed USD 200 million. Am I right? And how sustainable this USD 200 million revenue size for these products given the kind of competition what we have in the recent past seen for various products? And now the kind of a trend change what we are witnessing in the biosimilar market of the U.S. in terms of the adoption by the payers and all that, how sustainable that USD 200 million for the established products?**

Shreehas Tambe: Yes. Surya, I think that's a very fair question. I do want to respond to it with fact again. We talked about insulin as one of the products. Kiran referred to the tremendous demand that we are seeing for insulin across geographies, where, of course, we are seeing in many countries, the innovators also starting to pull out. So clearly, that demand is exceptionally high. And to give you a sense from an established product perspective, that is a product we launched in 2004. So if you look at it, it's more than 20 years and the product continues to grow, and we expect to see even greater demand for insulin.

Now come to the other products, we launched the oncology products in the U.S. We were the first to launch Pegfilgrastim in 2018. And we were also the first Trastuzumab to be approved, and we launched that too in that same time frame. These products have been there in the U.S. now for almost 6, 7 years. And the market shares that Kiran just talked about in her opening remarks have grown over the course of the last year or so. So clearly, it tells you that the demand is there, the adoption is high and our product, given the fully integrated nature of our business, continues to grow.

In a year where we did not have new product launches for biosimilars, the business continued to grow, not just year-on-year, but also sequentially. And you've seen a very strong core EBITDA and EBITDA growth. And Kedar did clarify where these things are. But I think the important thing to see is that the future clearly is far more exciting than what we've seen before.

Surya Patra: **Okay. Just last one point from my side, sir. Regards the R&D and Capex one, particularly on the R&D, we have obviously seen some rationalization throughout FY '25 compared to the earlier year in terms of the spend. Given the accelerated growth what we are anticipating for the biosimilar business, given the kind of new launches, so what trend that we should see whether further kind of a moderation in the R&D spend as a percentage to sales going ahead that we would see? And if you can give some sense about your Capex plan for the next year?**

Shreehas Tambe: So let me start, and then Kedar, if you want to add, please do. Surya, I think the first thing is we've clarified even in the past in the terms of the nature of how R&D spends happen is very closely linked to how product development cycles move. And as products are in, say, in Phase III, you will see a far greater spend in R&D as compared to some other quarters. So sequentially, you can see that there is some movement between quarters as

products move through development cycles. For the full year, we had given a guidance of 7% to 9%. And we see that in that range, sometimes towards the lower bound, sometimes towards the higher bound. But one key thing to always note is there is no rationalization because the business itself has grown year-on-year and sequentially as well. So the same percentage for a higher revenue number will not indicate rationalization, but a reasonable effort in terms of what we have done in terms of the R&D investments. Kedar, if you would like to add something, please go ahead.

Kedar Upadhye: No, I think you have covered well. On the Capex side, like what you said, Surya, we expect to spend about USD 100 million over the next couple of years. After which, it's expected to get moderated down. Large part of this money will go to enhance the capacities in Malaysia, which, for us, is very rewarding given the global demand that we are seeing for the product.

Surya Patra: **This is for the consolidated level, sir?**

Kedar Upadhye: This is for Biologics. Sid can give you a consolidated view, but this is for the Biologics.

Siddharth Mittal: For Generics, again, we'll be looking at another USD 50 million next year. And I think with that majority of our ongoing Capex programs come to an end and it will be only small bit of maintenance Capex from FY '27 onwards.

Saurabh Paliwal: We'll take the next question from Prapti Gupta from Alliance Bernstein.

Prapti Gupta: **Just one small question from me is on the recent approvals on your potential capital raise. So if the team could elaborate a little more on what the company is looking to do, what timelines we can expect, progress so far, and potential use of proceeds, please, that would be very helpful.**

Kiran Mazumdar Shaw: Siddharth, maybe you should take this question.

Siddharth Mittal: So thanks, Prapti, for the question. I think what we have announced is that we intend to raise INR 4,500 crores through a combination of QIP and private placement, and we have sent out a shareholders' notice last week towards the same. We have started discussing with our bankers and investors and lawyers about the whole process. We expect to complete the first tranche, which we will decide the quantum of that first tranche in a few weeks. But this first tranche is expected to be complete by middle of June. And proceeds of the fund as you know, Biocon has certain financial obligations towards the commitments and the put options from the structured debt that we had from the investments in Biocon Biologics. So the proceeds of the fund will primarily be used to meet these obligations. And we will, of course, keep the investors updated in terms of the exact quantum and how we will accomplish the fundraise over the next few months.

Prapti Gupta: **Okay. And just as a follow-up. So is the company looking to clear the structured instruments in its entirety from your balance sheet?**

Siddharth Mittal: No, not in its entirety. I think the investors, of course, have a put option. So for those investors who have exercised their put option, we will look at giving them an exit, but it doesn't mean that all the investors are looking at exercising the put option.

Prapti Gupta: **Okay. Got it. One more, if I may, is on your Generics business. What I see is the Q4 has taken a lot of heavy lifting in terms of good performance vis-a-vis the other quarters. Just wanted to get some sense on how do we see, is this a quarterly trend? Or we can expect more normalization going forward?**

Siddharth Mittal: As I had indicated earlier that we did have launch supplies for generic lenalidomide in quarter 4. And whatever allocation we had from the innovator for the first few months of the launch, we have supplied majority of that in quarter 4. We do still have some volume that will be supplied in FY '26, but we have many more launches coming up in FY '26. So, as I had mentioned earlier that liraglutide in Europe would be launched in quarter 1 and quarter 2. We also expect to launch liraglutide in the U.S. We are expecting approval for generic Copaxone in the U.S. We recently announced the approval of generic Everolimus or Zortress in the U.S. All these launches will drive growth. So, while you would not see a large component of Lenalidomide in FY '26, because we all have to wait til January '26 when it becomes an unlimited volume launch by all the generic companies. But until then, we will see growth coming in from all the other launches I mentioned.

Saurabh Paliwal: We'll take the next question from Amey Chalke from JM Financial.

Amey Chalke: **So during the call, we heard our commentary on the insulin demand, which could increase in coming years. Is it possible to tell how much insulin capacity we are currently operating at in terms of volumes, and the utilization for the current capacity, and with Malaysia expansion, where this capacity would be at?**

Shreehas Tambe: Amey, thanks for that question. I think one of the things that we've refrained from giving is the specific insulin capacity for competitive reasons. So it would not be fair to talk about what exactly our capacity is. We do have made comments to indicate what our capacity expansions look like. And we've talked about the fact that at this point in time, we've just brought online another drug product facility in Malaysia, which increases our capacity of manufacturing drug product twofold. So it's a doubling of capacity that we have just completed, and we will go through the regulatory approval process to bring that product to patients. We are also in the midst of the capacity expansion, which will again twofold increase our capacity in Malaysia for our drug substance, which Kedar was referring to in that USD 100 million of Capex that we see being invested. So a large part of that Capex was already underway, and we will look to complete that Capex as we go forward. We believe that outside of the originators, we would be amongst the largest player of insulins, the largest manufacturer of insulins and the one which is fully integrated, not just drug substance, drug product, but also the devices that are required to deliver this, all these insulins and analogs across. So a very comprehensive capability and a large capacity to do so as well.

Amey Chalke: **The second question I have is on the GLP-1 specifically, because I heard the comment that on the generic side of the business, except the USD 50 million Capex, largely it would be a maintenance Capex. So if we are looking at a big opportunity in GLP-1, are we not looking to put up a capacity for GLP-1 as well? And what is our existing capacity for GLP-1 pens?**

Siddharth Mittal: So, we have already invested in a large-scale drug substance capacity of GLP-1s, which was capitalized in FY '25. That was one of the reasons that also led to increase in expenses. We have the new injectable facility for GLP-1s, which will be commissioned in FY '26. Now when you really look at the market opportunity for GLP-1s, there are 3 large drugs, as you are all aware, Ozempic or Semaglutide, Tirzepatide and Liraglutide. And liraglutide is the smallest in terms of the market revenues and the volume, but we have Semaglutide, which goes off patent in the U.S. and Europe starting 2031. And then you have Tirzepatide, which opens up after 2036. So of course, a large part of the volume over the next couple of years is going to be driven by Liraglutide and Semaglutide in emerging markets. So when you look at the capacities that we have created, of course, we have created capacities to address what we need over the next couple of years. But as the market expands, which is the biggest thing that we are seeing, given that innovators have been focusing on supplying these drugs mainly in the advanced markets or U.S., Europe, there's still a large unaddressed market, especially in the emerging markets. And we are, of course, keeping a track of the demand that we have in these markets, and we will look at expanding. But over the next 2 to 3 years, we don't need capacities for the demand that we expect in the near term. But at some point, in time as again, to reiterate that beyond '31 when Semaglutide opens up in the U.S., Europe and Tirzepatide after 2035, we will need additional capacities.

Amey Chalke: **At present, the liraglutide is totally internally manufactured? Or we are outsourcing some of the services?**

Siddharth Mittal: No. Everything is internally manufactured as far as drug substance is concerned. We do have external CMOs, as far as drug product is concerned. We, of course, also manufacture this in our own biologics facility.

Saurabh Paliwal: We'll take the next question from Tushar Manudhane from Motilal Oswal.

Tushar Manudhane: **On Insulin Aspart now that all facilities are cleared, Is there anything holding up or pending for approval in the U.S?**

Shreehas Tambe: There is nothing that is pending. We have a goal date coming up in a month or so. And then once the goal date is reached, we should receive the approval on or before that goal date. That's our expectation. Of course, we have to wait for the decision of the agency, but we are quite hopeful.

Tushar Manudhane: **And let's say the goal date and approval happens on time, then subsequently the formulary action and all that. So effectively, is this still an FY '26 opportunity, or...**

Shreehas Tambe: So you are right that the decisions for any calendar year happen in that July to October time frame. But given that there is no real biosimilar option available at this point of time for payers, there is an interest in '26 as well. So we will see how to launch this product in fiscal '26 in the U.S., and we'll see how that commercial opportunity shapes up. We'll keep you posted.

Tushar Manudhane: **Sure, sir. And secondly, on Copaxone also, like if you could share where are we in terms of queries, responding to U.S. FDA?**

Siddharth Mittal: We had indicated earlier, there were no outstanding scientific queries. It was only pending inspection outcome of the biologic facility, which got cleared in December. We have responded to the FDA. We again have a new target action date in a few months, a couple of months. So we are hoping to receive an approval by then. So there are no impediments in our mind.

Tushar Manudhane: **And this product is also manufactured entirely in-house?**

Siddharth Mittal: Yes, entirely, drug substance as well as the formulation.

Saurabh Paliwal: We'll take the next question from Nitin Agarwal from DAM Capital.

Nitin Agarwal: **Shreehas, on the presentation in the press release, we talked about launching 5 new biosimilars over the next 12 to 18 months. If you can just probably spell out which are these names that you have in mind for this calendar?**

Shreehas Tambe: Certainly, Nitin, thanks for that question. The 2 products that we just talked about even in the opening remarks, actually, Kiran did cover all of them. We've launched Stelara biosimilar, which is one of them. The other one is we've got approval for bevacizumab. We talked about Aspart just to Amey's question. So that's the third one. We discussed the Aflibercept settlement and the launch in July. We launched that in Canada. We have a clear launch date in the back half of '26. So that's the fourth one. And Denosumab was another product where we've just received approval from the European authorities, the CHMP positive opinion. We look to get that approval in a couple of months, which is the procedural piece for EMA. FDA approval is also expected by the end of this year. So these are the 5 products we expect to launch in that 12-to-18-month window.

Nitin Agarwal: **Helpful. And how do you see the pipeline of newer launches subsequently if you take a 2- to 3-year block subsequent to F '27?**

Shreehas Tambe: Nitin, in the past, we've said that -- I mean, apart from the bunching up that has happened in the current time period because of whatever reasons, we've said that from '25 to '30, we saw ourselves launching a product a year, which is what you're seeing us do now.

Nitin Agarwal: **Okay. And secondly, on the insulin, you touched upon that earlier, the recent instances of some of the innovators, largely Novo and Lilly, looking to go a little slow on some of their launches, some of the products in certain markets. I mean this was an instance definitely which happened in India. But are you seeing more of instances of the withdrawing certain SKUs across a range of emerging markets as well as developed markets in the insulin franchises?**

Shreehas Tambe: Yes. Again, I refrain from talking specifically about competition, but these are public events where, you are right, there are examples where innovators have withdrawn products. I mean the India example that you've just cited is true. And then there are other geographies as well where we see it happening. But that certainly creates a large opportunity for Biocon Biologics, because we are already present in many of these countries. We sell in over 80 countries at this point in time, and we see that demand increasing already.

Nitin Agarwal: **Last one. On Aflibercept, when we launch it next year, obviously, Amgen has already launched. Around the time, how do you see the competitive dynamics? It's going to be -- everyone else who's got approval comes in around the same time as you, or we get some sort of limited competition around the time when we come in a second wave?**

Shreehas Tambe: Yes. I think the first piece is that we see this as a very large market. Globally, this is a $9 billion opportunity. So it's a very large asset, and we are very well placed. We have a risk-free position. So we don't really see and discuss what competition would do when they launch at risk and the outcomes and consequences of that. So I would not want to comment on anybody else at this stage. But we certainly see ourselves in a very secure position there. And from how we've been able to competitively settle the litigation or the way our settlement terms are, I think, Nitin, you would appreciate that for competitive reasons, it's not fair for me to discuss.

Nitin Agarwal: **If I just squeeze in one last one, Saurabh. In the press release, we mentioned about a committee being appointed to evaluate a restructuring, including a possible merger of BL and BBL. Any color on the thought process behind that? And what are we - in terms of exploring that option?**

Kiran Mazumdar Shaw: So let me respond to that by saying that given the market volatility that we are seeing on the IPO front, I think the Board was of the opinion that we should look at other strategic options, which also includes evaluating a merger. So at this point in time, the Board has constituted a committee. We will evaluate all strategic options and then get back to you in a few months with what the Board recommend -- I mean what the committee recommends to the Board. So at this point in time, that's all I can share with you.

Saurabh Paliwal: We will take the next question from Love Sharma from JP Morgan.

Love Sharma: **Just wanted to follow up on some of the debt metrics or debt numbers. So I think if you could just highlight, I think on the short-term debt, which I think has increased somewhere close to, let's say, in dollar terms about USD 630 million, USD 640 million. Could you just give a breakdown how much is working capital related or how much is any other repayment which is coming due for FY '26?**

Kiran Mazumdar Shaw: May I suggest that you take these questions offline, because it will be easier for Kedar and Siddharth to explain this to you in more detail.

Love Sharma: Yes, that's okay.

Saurabh Paliwal: That was the last question for the day. Kiran, any final remarks?

Kiran Mazumdar Shaw: Well, thank you very much for all your questions. And if you have any further clarifications or queries, please do reach out to my colleagues, and we will be very happy to clear any of your queries. So, with that, I thank you for taking this analyst call, and I look forward to being with you again next quarter.

Saurabh Paliwal: Thank you, everyone. This concludes the call. Have a good day.

- Ends -

Note: The contents of this transcript have been edited to improve accuracy and readability