Relentless Pursuit.
Differentiated Growth.

Biocon Limited Q3 FY25 Earnings Conference Call Transcript

Jan 31st, 2025

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

- **Mr. Peter Bains** – *Group CEO, Biocon Limited*
- **Mr. Siddharth Mittal** – *CEO & Managing Director, Biocon Limited*
- **Mr. Shreehas Tambe** – *CEO & Managing Director, Biocon Biologics Limited*
- **Mr. Kedar Upadhye** – *Chief Financial Officer, Biocon Biologics Limited*
- **Ms. Rhonda Duffy** – *Chief Operating 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 Financial Officer, Syngene International Limited*
- **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** – *BofA Securities India Limited*
- **Shyam Srinivasan** – *Goldman Sachs India Securities Private Limited*
- **Amey Chalke** – *JM Financial Institutional Securities Private Limited*
- **Love Sharma** – *JP Morgan Securities (Asia Pacific) Limited*
- **Surya Patra** – *Phillip Capital (India) Private Limited*
- **Vivek Agrawal** – *Citi Investment Research (India)*
- **Nitin Agarwal** – *DAM Capital Advisors Limited*
- **Bharat Seth** – *Quest Investment Advisors Private Limited*
- **Alankar Garude** – *Kotak Securities Limited*

Prepared Remarks Session

Saurabh Paliwal:

Good morning, everyone. Thank you for joining us on this call to discuss Biocon's third quarter results for fiscal year 2025. I am Saurabh Paliwal from Biocon's Investor Relations team.

To discuss the financial business performance for the period, we have on the call today, Mr. Peter Bains, Biocon Group CEO; Mr. Siddharth Mittal, CEO and MD, Biocon Limited; Mr. Shreehas Tambe, CEO and MD Biocon Biologics Limited, along with other senior management colleagues across our business segments.

Before we get started, a few housekeeping points. All the participants line will be in a listen-only mode, and there will 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 reactions tab of the Zoom application. We will call out your name and unmute your line to enable you to ask a question. While asking a question please begin with your name and organization. Please note that this conference call is being recorded. The recording will be made available on the website within a day, and the transcript will be made available subsequently.

I want to remind everyone about the safe harbour related to today's investor call. Comments made during the call may be forward looking in nature based on management's current beliefs and expectations. They must be viewed in relation to 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 that, I would like to turn the call over to Mr. Peter Bains, for his opening remarks. Over to you, Peter.

Peter Bains:

Thank you, Saurabh, and good morning, everybody. Before presenting the results in detail, I would like to start with some high-level remarks. The third quarter of fiscal 2025 has been both important and progressive across the group companies, reflecting continued executional delivery as well as strategic strengthening in our regulatory, operational, and financial platforms that will underpin our short, medium, and long-term growth objectives.

Highlights include successful outcomes in 4 separate FDA audits across 3 sites in Biocon Biologics and Biocon, key product approvals in both our Biologics and Generics businesses with launches commencing in Q4 this fiscal, and completion of all BBLs deferred milestones under the acquisition agreement with Viatris, marking the full and final remittance of considerations towards the acquisition.

The overall group financial performance for the quarter was in line with our expectations and led by year-on-year operating revenue growth of 10% on a like-for-like basis after adjusting for revenues and a divestment gain from the India Branded Formulations unit in Q3 FY24. Performance for the quarter was driven by sustained growth in Biosimilars and a return to growth in Research Services with both verticals reporting healthy double-digit growth rates. Generics recorded a marginal year-on-year decline. On a sequential basis, all 3 verticals delivered growth.

With performance delivery in line with our expectations and with the strengthening of building blocks for future growth across our businesses, we maintain our outlook for a transition to growth in the second half of this year and into next fiscal with improved visibility across all businesses.

Syngene has returned to growth this quarter and is on the right trajectory for the rest of the financial year. Biosimilars has maintained its good growth momentum and now has a clear line of sight for new and important product launches, while recovery in the Generics business will be driven by the launch of our first GLP generic in the U.K. and EU, coupled with new launches in the United States.

Financial Highlights – Q3FY25

Revenue from operations was INR 3,821 crore, up 10% year-on-year and up 6% sequentially on a like-for-like basis. The like-for-like basis excludes revenues, and a divestment gain from the India Branded Formulations unit in Q3 FY24, and I will use this adjusted reference for comparisons in the course of my remarks.

As mentioned in my opening, this top line performance reflects the balance of performance at the segment level where, on a year-on-year basis, Biosimilars revenues from operations grew 14%, Research Services grew 11%, and Generics saw a marginal decline of 2%. On a sequential basis, all segments reported operating revenue growth with Generics growing by 10%, Research Services by 6% and Biosimilars 5%. Total group revenue for Q3 FY25 was INR 3,856 crore, a growth of 7% last year and 6% sequentially on a like for like basis when excluding revenues and a divestment gain from the India Branded Formulations unit and also a gain from Biocon's stake dilution/ fair valuation of its holding in Bicara Therapeutics, in Q3 FY24.

Group core EBITDA for the quarter stood at INR 1,007 crore, up 4% from last year and with a healthy core operating margin of 26%. Quarterly R&D investment spend stood at INR 199 crore, corresponding to 7% of revenues excluding Syngene. Reported EBITDA for the quarter stood at INR 787 crore with a margin of 20%. This represents a growth of 16% on a like-for-like basis.

Profit before tax and exceptional items was INR 138 crore, improving on a like-for-like basis from a loss last year. Reported Net Profit is INR 25 crore. Adjusting for exceptional items, Net Profit for the quarter stood at INR 13 crores. And here again, there was an improvement in performance as compared with net losses last year when adjusted for the one-off incomes.

Generics Business Update

Let me now turn to the business segment highlights and start with the Generics business and summarizing the quarter's financial profile.

Revenue from operations was INR 686 crores, growing a healthy 10% on a sequential basis while showing a marginal decline of 2% year-on-year. This performance was driven by higher API sales and supported by an improvement in the performance of generic formulations. While we still see pricing pressures that have persisted, we did see some volume recovery in the product mix.

Core EBITDA for the quarter was INR 102 crore with a margin of 15%.

R&D spend at INR 73 crore and representing 11% of segment revenues was up from INR 65 crore in the same period last year, reflecting our continued investments in the strategically important peptide portfolio and our complex molecules to fuel mid and longer-term growth opportunities.

EBITDA for the quarter stood at INR 39 crore compared with INR 91 crore last year and INR 36 crores the previous quarter, impacted by higher operating expenses linked to new facilities and the increased R&D investments. EBITDA

margin stood at 5%. Profit before tax for the quarter was a loss of INR 14 crores compared to a profit of INR 50 crores last year and a loss in Q2 of INR 9 crore.

Now moving on to operational updates, let me start with *regulatory*.

On the regulatory front, there have been significant milestones crossed during the quarter. We made progress with multiple market filings, including 2 ANDAs in the United States, and we received 7 approvals, including 1 in the United States.

Notable amongst these approvals was the receipt of the decentralized procedure or DCP approval for the generic GLP, Liraglutide, in the European Union for both diabetes and obesity indications. This approval positions Biocon for strategic growth in the region, and we are preparing to commercialize the product in fiscal 2026. Additionally, in China, approval was received for Tacrolimus capsules in various strengths, marking the second important drug product approval for Biocon in this strategically important market.

Another highlight in the quarter was the successful closure of the U.S. FDA inspections of our Bengaluru API sites conducted in September 2024. For both sites, we received Establishment Inspection Reports, EIRs, with a Voluntary Action Indicated classification from the agency.

Operational Highlights

Coming to operations. I am pleased to share that the oral solid dosage facility in Cranbury, New Jersey, which Biocon had acquired in September 2023 to strengthen its manufacturing infrastructure and footprint in the United States, is now qualified by the U.S. FDA for 3 of our vertically integrated statin products, and we have commenced commercial supplies. We will be adding more products for commercialization from this site on an ongoing basis.

Looking ahead, we expect performance in the fourth quarter and into the next fiscal to build upon the sequential revenue growth in Q3, driven by new product launches across markets, including the launch of our generic GLP, Liraglutide, in the UK and the EU, as well as additional new product launches, particularly in the United States.

Biosimilar Business Update

Let me now move to the biosimilars vertical where I am pleased to report a strong quarter with Biocon Biologics delivering:

- Sustained double-digit like-for-like operating revenue growth last year.
- Delivering strong in-market product performances, particularly in the United States market
- Securing multiple new product launch approvals to fuel growth in the coming year
- Successful closure of both the Bengaluru and Malaysia facilities U.S. FDA inspections with the receipt of VAI status for both sites, while
- We also continued the consolidation and strengthening of the Biologics vertically integrated model.

Let me now look at these highlights in a little bit more detail and start with commercial execution, where we are continuing to deliver a strong performance across our product portfolio in the United States. Our Oncology franchise, comprising of Ogivri, biosimilar Trastuzumab and Fulphila, biosimilar Pegfilgrastim, have seen significant increases in demand with the market share for Ogivri doubling to 22% from 11% last year, while Fulphila rose to 23% from 19% last year. Market shares of our Semglee. Insulin Glargine franchise also continued to be in the mid to high teens, including all channels.

Turning to Europe. Our market shares have remained stable at a regional level with strong uptake in key markets like Germany and France, where we hold double-digit shares for many products, and particularly Hulio, biosimilar Adalimumab, and where we are also now beginning to see the results of our focus on both geographic and product expansion, for example, in the Mediterranean and U.K. Nordics clusters. We are also seeing positive traction in the Japanese and Australian markets through our commercial partnerships.

The Emerging Markets business continues to expand the depth and breadth of its patient reach with 8 approvals and 14 new launches this quarter across key markets in the AFMET, LATAM and APAC regions. The company also won several tenders for its key products, further strengthened its insulin franchise, and has witnessed strong demand in both self-led and partner-led markets, leading to overall market share expansion.

Looking at the financial performance and the regulatory update.

The Biosimilars Revenue from operations was INR 2,289 crore, up a healthy 14% year-on-year on a like-to-like basis, again, after adjusting for the revenues in Q3 FY24 from the Branded Formulations Unit in India and the divestment gain of INR 350 crore. Sequentially, revenue grew 5%.

EBITDA for the quarter was INR 487 crore, and this includes a non-cash Forex translation loss of INR 20 crores. Excluding the Forex impact, the EBITDA margin stood at 22%. Last year's EBITDA was INR 714 crore on a reported basis, which included the gains mentioned related to the BFI investment. On a like-for-like growth basis, EBITDA grew 44% compared to last year.

We continue to invest in our pipeline with R&D spends at 6% of revenue to fuel the mid- and longer-term portfolio growth.

The company also crossed the milestone in fulfilling all its obligations towards all deferred milestones under the acquisition agreement with Viatris.

Regulatory Updates

Turning to regulatory, where I am pleased to share that the U.S. FDA has classified our multiproduct Biocon Park facilities in Bengaluru, India, and our insulins facilities in Johor in Malaysia, as VAI, or Voluntary Action Initiated following the inspections held in July 2024 and September 2024, respectively. These outcomes both reinforce the commitment of Biocon and Biocon Biologics to the highest standards of quality for our products. And they also, importantly, pave the way for the approvals of biosimilar Bevacizumab and Aspart products in the United States.

Further strengthening our new product launch outlook, we also received U.S. FDA approval for Yesintek, biosimilar Ustekinumab, a biosimilar to the reference product, Stelara, and are preparing for February 2025 launch next month. Yesintek also received a positive opinion from the European Medicines Agency Committee for Medicinal Products for Human Use, the CHMP and approval from Japan's Pharmaceuticals and Medical Device Agency, the PMDA, through our commercial partner. On the pipeline front, the U.S. FDA has validated our Biologics License Application filing for biosimilar Denosumab, which has also been filed in several other geographies.

Looking ahead, now having successfully secured the VAI classifications for all our manufacturing units from the U.S. FDA and with multiple new product launches now clearly in line of sight, Biocon Biologics operational focus will balance but also evolve between consolidating and strengthening the business, leveraging our vertically integrated model and global footprint and launch planning and preparation for commercial excellence delivery of the very strong pipeline that we now that we are now building up. Our priority will be to ensure that we bring our new products expeditiously to the market to provide patients with access to affordable treatment options. These new launches will serve as key growth catalysts for both revenue and for margin.

Research services update

Now coming to Research Services or Syngene.

Syngene' s performance for the third quarter built on its second quarter performance with revenue from operations coming in at INR 944 crores, up 11% on a year-on-year basis and up 6% sequentially.

Reported EBITDA at INR 302 crore was up 16% on a year-on-year basis and 16% also sequentially. The reported EBITDA margin improved to over 31% from 29.5% in the comparable quarter last year and 28.8% in Q2 this year.

Profit before tax was up 27% from last year and 32% sequentially to INR 181 crore. PBT margin stood at 19%. Business performance during the third quarter was broad-based with a return to growth across all divisions within Syngene.

Growth in the quarter suggests that market dynamics, particularly in U.S. biotech, are now stabilizing, albeit slightly later than expected.

Discovery Services contributed to growth during the quarter with continued collaborations with many large and midsize pharma companies on pilot projects in the initial China+1 pilots starting to convert to longer-term contracts during the quarter, providing visibility for growth for the next year. These conversions are a demonstration of Syngene's scientific capabilities and high operating and quality standards.

The performance of Development and Manufacturing services was also steady, driven by Biologics with repeat orders from existing customers and through new collaborations on integrated projects.

Overall, performance in Q3 was positive with momentum across all business divisions, positioning Syngene on the right track for future growth.

Conclusion

In conclusion, and as I said in my opening remarks, this was an important and very progressive quarter for the Biocon Group. The strengthening of operational building blocks for future growth has now provided us with clear improved growth visibility across all our businesses.

Syngene has returned to growth this quarter, is now on the right trajectory for the rest of this fiscal. The biosimilars business, while maintaining its strong growth momentum, now has a clear line of sight for multiple new product launches beginning in quarter 4 and the recovery in the Generics business will be driven by the launch of our first GLP generic in the U.K. and the European Union, coupled with new launches in the United States.

We maintain our outlook for a transition of growth in the remainder of this year and into next fiscal.

With this, I conclude my remarks, and I would like to open the floor now to the Q&A session.

Q&A Session

Saurabh Paliwal: Thank you, Peter. We will wait couple of minutes for the questions que to assemble. We will take the first question from Damayanti Kerai from HSBC. Please go ahead.

Damayanti Kerai: **My question is on Stelara biosimilar, which you will be launching soon. So just want to understand, based on your discussion with channel partners, what kind of sense you are getting for potential uptake of this product? Because we understand this is a Part D product, and what we heard from J&J is that they are expecting similar dynamics to play out, what we have seen in case of Adalimumab, Humira biosimilar, plus any change from the Part D redesign. So just want to get some sense what you have heard or any feedback, which you might have got from the channel partners?**

Peter Bains: Great. Thank you, Damayanti. Let me address that question to Shreehas and the U.S. team and then Matt. Shreehas, can you pick up on that?

Shreehas Tambe: Yes, sure. Thanks Peter. Thanks Damayanti, for the question. As you can imagine, we are very excited about the upcoming launch for biosimilar, Ustekinumab. We will be amongst that wave of products that will be coming to the United States. But I also want to draw your attention that this is a global launch. So, we will be looking to bring this product to Europe as well. There is a huge opportunity that we are looking forward to. I do acknowledge what you said about the Part D and the past that has been the case with the biosimilar Adalimumab. obviously, we are very conscious of that. Our teams are working very hard with customers, both commercial as well as the government customers as well. We believe we will be very competitive in this space, both for Ustekinumab and even as we progress the Adalimumab asset as we go forward. So very exciting times for us as we get into a global launch for a very large asset.

Damayanti Kerai: **My second question is on your existing biosimilars, where you continue to see market share gain. However, when we look at the profitability side, it is not in line with, I think, the kind of pickup seen on the revenue side. Can you just comment, like, whether most of the market share gain is on low realization channels? And how should we look at like further scope of increasing market share for these existing products?**

Peter Bains: Shreehas, again, I think I will pass that question to you.

Shreehas Tambe: Thanks, Peter. I think, Damayanti, I wouldn't say that it's a low-margin business or we have probably seen growth only in terms of the low profitability channels. If you look at the 2 large markets, and we also have seen huge gains even in emerging markets. But if you look at how growth has panned out, let's start with that perspective. I think growth has come because of the large increase in market share that you just referred to in the United States. That growth has not necessarily come in from low-margin business.

We have 2 products in the oncology space that operate in the Part B or the medical benefit space. And we have seen significant growth there in terms of how our products have performed both for Pegfilgrastim, which have seen a huge improvement from low double digits to actually mid-20s, which is a substantial shift. And that's come very profitably. So, it's not coming through the lower-margin channels. Likewise, with Trastuzumab as well. This is in the medical benefit space. Our growth in Glargine remains very strong, both in commercial as well as in the government channels, and that's remained the backbone. So that's the United States. It's not come at a lower margin. We had also said and guided in the past that growth will come from new geographies that we will expand into both in Europe which is where the EU 5 is, and you're seeing us play that's starting to play out this quarter. And you're also seeing us win tenders in emerging markets. And there are 8 of those that we had outlined as self-led. And you're starting to see that those are playing out.

The margins for the Biocon Biologics business have been quite healthy. And we continue to invest in R&D in that 6%, 7% to 9% range that we have guided. So that's been also quite healthy. And we continue to have an EBITDA margin of 22% to 23%. So that is, in my view, a very sustainable guidance that we have given in the past, and Biocon Biologics stays to that.

Kedar Upadhye: Shreehas and Peter, just to add. Damayanti, I think, for the quarter, you should model about 150 basis points of revenue as overhead charge on the inventory. So that's a timing in nature. We'll recover it in quarter 4. As we adjusted inventory, I think the overhead hits the gross margin line. So that's the adjustment and modelling you need to do.

Damayanti Kerai: **This is at consol level, right, or at the BBL level?**

Kedar Upadhye: This is for Biocon Biologics. This is at the BBL level. And costs are in control compared to Q2, Q3 and Q4 of last year. Total Opex, which includes staffing and other Opex is down by almost 10%. Once you model this overhead charge on the inventory adjustment in BBL, I think the number should stack up properly.

Saurabh Paliwal: Thank you, Damayanti. We will take the next question from Neha Manpuria from Bank of America.

Neha Manpuria: **My first question is, I think there was a separate announcement about Biocon buying 1.5% stake in BBL. Just wanted to understand what would be our diluted holding fully diluted holding in BBL after this deal? I think the last number was about 70%. And secondly, what would be our net debt? And how this purchase has been funded?**

Peter Bains: Sure. Neha, thank you for the question. Let me start and Sid you may want to add in here as well. So, Neha, just to pick up on that. This is the instrument we use as a short-term bridging loan. The purpose was to support meeting an obligation to an investor who exercised the liquidity option. And as you have pointed out, the conclusion of that would be that Biocon would pick up the shares that would be about 1.5% increase in the holding in BBL, which would move, and Sid will provide the numbers, but from roughly 70% to then add on 1.5%. Sid, is that roughly, correct? Do you want to clarify?

Siddharth Mittal: Yes, Peter. I think we will get closer to 72% after the acquisition.

Neha Manpuria: **Sid, but we were at 70%, right? And we're adding 1%? But on a fully diluted basis, wouldn't that number be lower?**

Siddharth Mittal: We were closer to ~ 70%.

Neha Manpuria: **Okay. So now after this, will be closer to 72%.**

Siddharth Mittal: Yes.

Neha Manpuria: **Okay. Understood. And what would be our net debt post the short-term bridging loan to fund this stake purchase at the consol level?**

Peter Bains: So about, I think it is USD 1.23 billion. Sid, again, can you clarify?

Siddharth Mittal: Yes, that is the right number. So Syngene is USD 100 million net cash positive. In Generics we have roughly similar amount of net debt. And at Biocon Biologics, that's roughly USD 1.25 billion. This is now in December. So, you will add another USD 65 million of the commercial paper, so that will get you to USD 1.3 billion.

Neha Manpuria: **Okay. USD 1.3 billion, got it. And my second question is on the Generics business. Obviously, we are starting to see some improvement quarter-on-quarter on that business. But if I remember, at one point, we had alluded to this business probably growing 15%, mid-teens sort of growth at some point. One, what takes us there? When do we get there? And when do we start seeing I think Liraglutide launch in the U.K. was supposed to happen in the third quarter. What is the timeline for that? And how should I think about the recovery in Generics?**

Peter Bains: Sid, do you want to pick that.

Siddharth Mittal: As you have seen in this quarter, we have had a 10% sequential growth, and a large part of that growth has come from increase in API business, so very little contribution from peptides yet during the third quarter. And as Peter mentioned in his opening remarks, Liraglutide would be launched in the U.K. in the fourth quarter. We have already shipped the material to our testing site in Europe. The product is getting tested and will get released and launched by a partner and us in the fourth quarter. Post the national approval of Liraglutide in Europe, we are doing national registries in each country, and we expect that launch to happen in the first quarter of next fiscal. We also mentioned that there are a couple of other launches in the United States in the fourth quarter. So, sum total of these would drive growth in the fourth quarter. But I think coming back to your point on teen's growth, that next year is going to be a big growth driver, Liraglutide contributing to that growth in U.K. And of course, U.K. is not that big a market as a standalone country, but when you look at Europe. And then subsequently, during the second half of year, we also expect an approval in the U.S. That product was filed from the injectable facility in Biologics, which has now received the VAI status and the review of the DMF for the API was complete and FDA is now reviewing the other data packs, and we expect that review to complete by middle of this calendar year, followed by a launch.

When you look at the additional capacities also that we have created in our API sites, which will drive incremental volumes. A combination of Liraglutide in U.K., Europe and subsequently U.S., plus the additional API volumes and some of the other OSD launches will drive that growth in next fiscal.

Neha Manpuria: **We should get back to mid-teens growth possibly in fiscal 2027, if not earlier, at least?**

Siddharth Mittal: Yes. Fiscal 2026 itself you will start seeing this growth.

Neha Manpuria: **And one last question on the BBL business. Now that the Malaysia facility is cleared, we also saw the biosimilar, Stelara, approval for both Beva and Aspart. Is there anything else that is pending from the U.S. FDA? Have we heard anything on the Aspart filing? Is there anything else pending for us to get approval for those 2 products?**

Peter Bains: Shreehas, I think if you want to take that. I mean obviously, a very important question with line of sight of up to 5 product launches in the U.S. Maybe you can step Neha through that.

Shreehas Tambe: Yes. Thanks, Peter. Thanks, Neha, for that question. We have said in the past as well that the only thing that it really which was open, there was no open question on the science or the dossier, both for Bevacizumab or for Aspart that and the agency had indicated that. The only piece that was remaining was the site GMP status. With that achieved, we have responded to them saying that we have now completed this. And we want them to reconsider our application at the earliest. So that is the process that is ongoing. And our regulatory team is in conversation with them to see how we can move this in an expedited manner.

Saurabh Paliwal: Thank you, Neha. We will take the next question from Shyam Srinivasan from Goldman Sachs.

Shyam Srinivasan: **Just the first one, just the Slides 12 and 13 on Biocon Biologics looking at market share and revenue growth, right? And I am just doing very simplistically and maybe I am getting something wrong. Most of our market shares for our commercial molecules in the U.S. have doubled like maybe close to doubled. We've also seen, say, for example, Ogivri in Europe go up in the last 12 months. Just trying to reconcile that with the revenue growth. When I do it in dollar terms, it's probably like 10%, USD 240 million going to some USD 265 million, something like that. Want to understand, has there been price erosion? What is the delta? On our volume shares have gone up significantly, but we have not seen the corresponding revenue growth. That's point one. And if you were to look at our quarterly trajectory, I think Peter had talked about the 5 launches and Shreehas as well. What should we be looking at trajectory in absolute terms of where our business could look like in the next 12, 18 months?**

Peter Bains: Shreehas, do you want to take that one?

Shreehas Tambe: Yes, certainly, and I will let Kedar weigh in as well. Shyam, great question. Part of it, I did respond when I was responding to Damayanti at the beginning. These market shares have

grown significantly across geographies. And if you would note, they have come at a steady, healthy contribution to the bottom line. The EBITDA margins have stayed consistent. The market share growth reflects the volume growth. And I think that is certainly a factor of how the market confidence has played out. Now whether that increased volumed directly reflects increased revenues as a proportional thing is not an expectation because as you look at how markets evolve, not every product will retain the value that it has a year ago.

We have, obviously, in any market, when you have competition, you will see a steady erosion, but it is not something that has been unexpected or unplanned that has impacted the gross margins, which have moved like Kedar pointed out in the previous call that have moved from Q3 to Q4 to 150 basis points. But beyond that, we have seen a very healthy contribution. To give you more additional colour, maybe Kedar, you can comment on that as well.

Kedar Upadhye: Yes, that is right. I think the price erosion is in line with what we had budgeted for. And in addition, Shyam, I think one adjustment you need to make in the reported numbers is the removal of the BFI revenues.

Shyam Srinivasan: **Yes, Kedar, I'm doing the like-for-like growth that you have given, that's 14%. And then I do whatever rupee change depreciation; it comes to 10%. So, I did the right number, I think, but yes.**

Kedar Upadhye: Got it. Got it. Number two, I think, like what Shreehas has answered, there is an erosion, but that's in line with what we had budgeted for. And once you make this BFI adjustment, that gives you the like-for-like number.

Shyam Srinivasan: **Kedar, so price erosion is would we say, low double-digit kind of price erosion? Or is it even higher?**

Kedar Upadhye: See, it varies product by product. The oncology portfolio is holding very strong in fact. It varies product by product, geography by geography. And the mix also comes in, so it is going to be difficult to give you one answer. But like what Shreehas said, we are a very value-based player, as you would know. And we will work based on the existing philosophy in the market.

Shyam Srinivasan: **Understood. And the second question is on we have bought back some stake in Biocon Biologics. You are selling stake in Syngene. So just from an overall capital allocation, can you walk us through what's happening? I know this is probably one of the investors asking using the put option. But just want to understand how should we look at some of the shareholdings in our subsidiaries? Syngene, can we go below 50%? so just help us understand and our measures to reduce net debt, right? It seems to be going up, not down.**

Peter Bains: Shyam, thank you. I will start on that question. Sid, you may want to come in as well. So, Shyam, I mean, it is a balancing act over time. We have had a series of obligations that we had to meet, and we've been meeting them properly, obviously, the Viatris full and final settlement on the acquisition, we have spoken about. We have had other financial obligations, which we have met. That is been balanced with the investment in the business

to prepare for this next wave of growth, which is now much more clearly in line of sight, both with the work that's been done to get these new products in place, like, Ustekinumab, like Generic Liraglutide and others. And of course, now with the release on Bengaluru facility and the Malaysia facility, we can look at Aspart and Beva in the U.S., but many other product improvements that were held up there. Those CRLs were a break on those 2 major facilities for Biologics. The break is now being released, and we'll see that coming through. We will continue to balance meeting the obligations that we have as and when they may come due as we have done very recently, as you pointed out, with this short-term loan to meet an obligation for an investor in BBL who exercise their liquidity option. That's a short-term measure of a bridging loan. But we are committed to and will continue to look to pay down debt as we move forward. But it is not a straight line. There will be occasions as this is one where there will be a slight increase. But overall, our commitment will be to continue to pay down debt as we move forward. And of course, there are a number of options that we continue to review that, and we will move forward on that basis. In regard to the specific question about the holding in Syngene, I think we're down now to around 52%. And I think we would like to keep it there, and we'll be exploring other options going forward. Sid, do you want to add anything to that?

Siddharth Mittal: No, I think Peter, you have covered it.

Saurabh Paliwal: Thank you, Shyam. We will take the next question from Amey Chalke.

Amey Chalke: **I have 2 questions, one on Sema and another one on the insulin plant. On Sema what would be our status at present? We are seeing patent expiry starting from Jan in Canada, then Brazil, China, and India, so how we are positioned in this product?**

Siddharth Mittal: The development is going well. We have already filed our DMF in the U.S. It is already listed on the FDA website. We have done the drug product development batches and charged it on stability. We have also completed India bioequivalence study, which is important for filing in many markets because certain markets require bioequivalence and that successfully passed. From a scientific perspective, the file is ready to file, and we will be looking at filing it in the markets. Some of the markets that you mentioned in first quarter of next fiscal, and of course, the review cycle varies in each of these countries. And depending on the approval, we will be looking at entering, may not be on day 1, but may not be too far from the other competitors who might launch the product on day 1. My expectation is that we should start receiving approvals in some of these markets by end of calendar 2026.

Amey Chalke: **Got it. And we will be partnering for any of value addition, let's say, pen assembly or anything or everything would be in-house like?**

Siddharth Mittal: Well, right now, the product is manufactured in a CMO. We are building our own injectable facility, which will be commissioned in the first quarter of next fiscal, followed by, first, the qualification and then we will take the batches. The idea is to bring the products, especially for the U.S. and Europe, in our own facility. But our launch would be from a contract manufacturer where we have already manufactured these batches. And the assembly will happen at the same site.

Amey Chalke: **Got it. And the second question I have on the insulin plant expansion, where does it stand? And how much capacity addition can happen, which will help going ahead online.**

Peter Bains: Shreehas and Rhonda, do you want to pick up on that one?

Shreehas Tambe: Yes. Thanks, Amey, for that question. The insulin, overall, is a very important product for us. And I think it is a very strategic play globally for us. There is no real biosimilar competition that we see for insulins across geographies. And we are seeing that with only the originator players ruling this for a very long time, we see this as a very large opportunity ahead of us. We made investments over the years and the most recent investment that you are referring to has doubled our capacity for drug product, which is expected to come online any time end of this quarter. So that is something that we expect to significantly boost our capacity for drug product manufacturing.

We are also expanding our insulin drug substance, which we had guided in the past, and that's underway. Once that's completed, we expect to see a doubling of that drug substance capacity in Malaysia as well. So that will take us another couple of years to do, but that's something that we had started about a year ago. And it's important to note that Biocon Biologics is amongst the top 3, 4 players of the insulins in the world. And we believe that's a huge opportunity and a differentiated play for Biocon Biologics going forward.

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

Love Sharma: **I have a question regarding the liquidity option which one of the investors have exercised. Could you elaborate what kind of other such options are still available with those investors? And what could we expect in the near term? Because I believe one of the conditions attached to some of those agreements probably seems to be the IPO of Biocon Biologics. So, any color there would be very useful.**

Peter Bains: We have a number of investors. We are working with all of them. We are looking to align their interest and satisfy them. And IPO clearly is one of the options that we have to do that. I think it would be inappropriate to go into details individually here, but I think it would be fair to say that we are working with all those investors to ensure that we align to satisfy them as the business is progressing. And I think we're making good progress on that front.

Love Sharma: **Maybe if I could just follow up. Would it be possible to share the amount which you think could be liable to be put back within this year or FY 2026?**

Peter Bains: No. I think we cannot do that, Sharma. I think we are working through that with our investor partners and ensuring that they are going to be satisfied and along with the progress of the business. I cannot break it down and give you a quantification on that.

Love Sharma: **Understood. No worries. Okay. Just one more last question for me. I think on the Viatris full and final settlement, could you share what is the amount which has been settled there in December quarter?**

Peter Bains: Shreehas, do you want to address that one? Or Kedar?

Shreehas Tambe: I think the Viatris settlement, Love, was about the deferred payment that we had to work on. And like we have said, we have been able to close out the entire USD 335 million, USD 175 million of that we had closed previously, which we had indicated and now we have closed the remaining USD 160 million. So, with this now, there is a full and final settlement and closure of all transaction that was related to the Viatris acquisition. That is now behind us though.

Love Sharma: **Understood. And just given these USD 160 million payments, could you give you a sense of how this was funded?**

Kedar Upadhye: So now like what Shreehas said, there were 2 milestones this year and both we have settled and it's not that we have paid the full amount, based upon the existing receivables that we had between both the parties and based on other arrangements, I think that is how the full settlement has been down, and the funding has been done through the existing liquidity sources.

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

Surya Patra: **My first question is on the biosimilar opportunities only. Could you give some sense of what is the kind of preparedness that you have done about Ustekinumab? And what is the likelihood or what is your expectation on that front? And the second is on the Denosumab when is the launch expectation that you are having for this molecule for U.S. market., these are the first two questions.**

Shreehas Tambe: Thanks Surya, for that question. And I will invite my colleague, who is the Chief Commercial Officer for Advanced Markets to respond to this along with me. Surya, we have been in this space now having run the business for a full year after we have integrated it and market shares for all our products have grown significantly over the course of the last year.

So that tells you that there's a lot of customer confidence in what we do and a lot of it is what Matt has led, and the North America team has led there. So, I will let Matt respond to that to your question on our confidence and our preparedness in the biosimilar Ustekinumab launch. Matt, would you like to comment to Surya's question?

Matthew Erick: Yes. Thank you, Shreehas. And I will add on to the original question. We are well underway in our launch planning with our customized with our customers in regard to the channel strategies we have in Part D. We are leveraging the existing relationships we have, and we will be driving the synergies that we have in the United States already established. I think what's clearly different, that's probably on a lot of people's minds is, how is this different than Adali? and how it's different than Adali is we've had plenty of time now to engage and also communicate to customers. Adali had a legal kind of hold where we couldn't speak to them because of all the settlements. The other thing that's different is that there's now a track record in this immunology piece in which players are more comfortable. And last thing I'll say here is that because of our active engagement, because of our sales force, we have already secured some important contracts that are part of our plan, and we look to continue to expand upon that as it gets closer and closer to our launch date. So, I couldn't be more positive about the team, about the opportunity in Ustekinumab, and we are well positioned. Last thing I will say is that I believe this is the power of our

portfolio, meaning that not only do we have the oncology portfolio in the United States, but we also have our immunology portfolio and we can drive those synergies across as we launch more products, as you are thinking about Bevacizumab or Aspart, all that is additive to our strategy in our platform that we fully integrated and consolidated, and now you're seeing the growth in our market share numbers. Thank you for the question.

Shreehas Tambe: Thanks. Surya, you had another question linked to it in terms of our expectation. I think we do definitely have very good clarity on what we expect from this asset. I only want to kind of guide you to the fact that this is a global launch for us. U.S. is a significant market. But if you look at how our Adali asset has performed for us, it's a global asset. We have been leaders in Europe as well. And that's a market that is also strategically very important for Biocon Biologics. So, while we will certainly focus on the U.S. because it is a big market, we are looking at biosimilar Ustekinumab as a global launch in several markets. And we believe that there will be opportunity beyond the United States as well. Sometimes that gets clouded in just focusing on the United States.

Surya Patra: **And the Denosumab launch timeline. Is it an FY 2026 opportunity in the U.S. for you?**

Shreehas Tambe: Denosumab, we have filed. The product has been filed with the U.S. and with the European authorities and with Japan. And we believe here too, we will be able to accelerate. If you noticed, when I say the Ustekinumab is global, and we are looking to launch that product globally, we have been able to accelerate the Ustekinumab launch by almost 4 months. So, it's moved from the next financial year, which is FY 2026, into maybe early FY 2026. And I think that's been a good positive traction. We expect Denosumab, also, to be something positive where we would be able to gain time so that we can bring the product closer to launch or market formation rates.

Surya Patra: **My second question on the Generic business. We have got now the China approval for Tacrolimus. Simultaneously that we have got now this Cranbury facility ready for U.S. manufacturing. How important these 2 developments are for our Generic business progress?**

Peter Bains: Sid, can you pick up on that?

Siddharth Mittal: Surya, both developments are important. I think you know China is a very difficult market where Indian companies have not been able to successfully penetrate in a large number of drugs. But Tacrolimus is an important drug for us and is an important drug in China. It is still a large value market in China with a very limited number of local players. Our partner CMS is getting ready to launch the drug in the retail market. Of course, retail penetration is not that easy, and we are looking at the tender, which opens up for this drug. China major volumes are driven by tender the government tender or VBP tender, which is a 3-year tender, and that is where the maximum volume is driven from. And I think we are expecting that tender to open sometime end of this calendar year with supplies commencing in 2026. We will, of course, be up against some of the other local Chinese companies. There are only 2 or 3 other generic approvals, so we will work out a strategy with our partner on how to secure part or full of the tender. We do have capacities. You

know that we have one of the largest manufacturing capacities of Tacrolimus in the world. We have enough product capacity. We are well placed.

In terms of U.S., Cranbury site was acquired because most of these drugs were manufactured at contract manufacturers in various parts of the world, we wanted to consolidate that and be closer to our customers and the facility allows us to participate in the local government business, which requires manufacturing in the U.S. So, we have got 3 approvals from that facility. We are also expanding the capacity of that facility, which will be ready by the middle of this calendar year, and we will use that facility for our future filings.

But in the meantime, there's not going to be revenue increase on account of the facility because we are now going to manufacture the products in this facility, which we were manufacturing earlier at CMS. But it definitely allows us to win the government business. We recently secured a national government contract for one of the statins, because of this facility.

Saurabh Paliwal: We will take the next question from Vivek Agrawal from Citibank.

Vivek Agrawal: **My question, it is on biosimilars. Shreehas, you have mentioned that the margins are expected to be in the range of 22% to 23% on a sustainable basis. I was surprised that given that you have cleared the facilities, expected to launch some of the new products like Stelara and also the other products like oncology segment, insulin etc. Is it not a conservative guidance? Or should we expect the margins to, let's say, over the next 18, 24 months move up from here on substantially?**

Shreehas Tambe: I like the optimism, Vivek, and I accept the positive feedback. We certainly have a lot of things moving in the right direction. For a company to be in this place where we've just integrated the business successfully, market share is moving up, keeping that healthy EBITDA was very important for us and we maintained that. The year ahead, we have 5 new launches coming up in the U.S. and 3 globally. So certainly, whenever you have a new product launch, you will see a slightly better-than-expected performance. So yes, your expectation is fair. But we also see that some of our products have been in the market for a while. We want to make sure that we have always said that we will continue to invest about 7% to 9% in R&D. We will have healthy strong gross margins and core EBITDAs in the mid-30s, which is where we are. And the EBITDA would be in the mid-20s, so some 22%, 23%, maybe 25%. I think we have been in that range, and we want to make sure that we continue to deliver to that. As we progress the year, we will probably see how some of these things play out. But I accept and thank you for your feedback, Vivek.

Vivek Agrawal: **This is quite clear. One question I have on Semaglutide. You have mentioned that you are expecting approval in some of the markets in 2026. Is it possible for you to outline which are the markets you are expecting approvals in the year?**

Siddharth Mittal: I think Vivek, it will be very difficult to comment on which might the approval comes in. Each regulator has a different lens on how they will review a drug filing and also depends on a number of approvals in that country for Semaglutide. if the number of approvals is less, then they will fast track the review. We do expect Canada to be an important market. The Canadian regulator has been proactive in reviewing the files, unlike maybe a Brazilian

regulator or a Mexican regulator who might take a little longer. As I mentioned, we have successfully also completed our bioequivalence in India, and we will soon be going for a clinical trial and then we will file in India some time once the clinical trial is done. And various other markets where we will be, or our partner will be filing. It will be difficult to say which country would give the first approval. But I think the broad message is the drug has completed its development journey. We have got the scientific data. It meets the requirement. API DMF has been filed. The products the product has been manufactured, charged on stability, the dossier is under preparation, and we'll start filing in various markets this year.

Peter Bains: I will add a comment in here because I think it ties a few of the questions together. The GLP market opportunity is clearly strategic for us, and it is going to come in waves. The first wave is Liraglutide, where Sid has described market posture with approvals in the U.K. and EU, but that is a phased rollout depending on the national approvals, and then into the U.S. and then globally. This is going to be phased rollouts that are dependent on the national registration timelines. Of course, we are pushing everything we can to be as near the front of the queue and a day 1 launch opportunity as we can. And there will be a wave that will be Lira and that will then overlap with a wave that will be Sema, which will follow a similar pattern, these are global opportunities, global assets, but they will roll out across the global geographies dependent on the regulatory approvals. But we are clearly well placed with Lira, and we are making strong advances with Sema as the

second wave and then there will be a wave beyond that. But Lira, in line of sight now. Sema, coming up to line of sight and getting exciting there.

Siddharth Mittal: Yes. And if I may add one more thing that we know the volume of the market opportunity for Semaglutide, which is expected at almost USD 50 billion in global sales and not fully penetrated in many parts of the world. The opportunity is huge. We know it, and it is a chronic drug. So even if you are not there on day 1 in a particular market, but there is a huge opportunity in the years to come. I think what is more important that we have seen from Lira is to get the right product in the market and we have seen that for Lira, a lot of companies had challenges for many years. And given the technicality of the drug and the complexity of the drug, not every company that filed were able to get the approval. We believe that given our whole expertise and the credibility now that we have established with Lira, we are very well placed in mid to long term to capture on this opportunity.

Vivek Agrawal: **Just one follow-up question on Canada market, right? Where we are in terms of filing? Are we close to filing? Or whether we have already filed into the particular market? That is part one. Second, when you get approval or you launch the product into the particular market, how you see the competitive intensity, right? Is it going to be, let's say, a 4-5 player market or maybe I think the 8-10 player market by the time we launch?**

Siddharth Mittal: As I mentioned, the filing has not started in any of the country. It will start by first quarter of next fiscal. Canada will be closer to the second quarter because Canada has additional SKUs, which are not there in some of the other markets. So, by middle of this calendar year when the filing would happen. Now in terms of competitive dynamics, it is very difficult for me to comment. I have read analyst reports which think that by calendar 2026 there

can be 3 to 4 players to be there in the market on day 1 with 5 to 6 players by end of the year. Now as I said that number of filings do not determine the number of approvals and launches. And it is all about supply chain. It is all about the complexity in manufacturing and getting the right profile of your product like that of an innovator. I will not hazard a guess how many of our competitors will be able to cross the finish line and how many will not be. But at least we are ready to face the competition. We expect even if it's not in 2026, but 2027, 2028, that time period, there will be many companies who will be there in the market. And finally, what is important is a cost leadership, having the right capacity, having the right device strategy, having the right focus, and I think we are very well placed. We are one of the few vertically integrated players who does our own drug substance manufacturing, drug product manufacturing, and we have multiple devices off-the-shelf and customized for some of the markets, and we think we will be very well placed to face the competition.

Vivek Agrawal: **Just last question, dragging on here. In terms of accrual complexity, right, so in Canada, how different it is compared to U.S., right? Is it the similar in terms of regulatory requirements, timeline, etc? Or is it relatively easier to get approval in Canada compared to the U.S.?**

Siddharth Mittal: I would say it's somewhat similar that there's the standards are equal or at the same level. And maybe the number of filings in Canada compared to number of filings with the FDA would be less. So Canadian health regulator might be able to review the file more expeditiously versus FDA who has a huge backlog of files under review.

Saurabh Paliwal: We will take the next question, Nitin Agarwal from DAM Capital.

Nitin Agarwal: **My question is on the biosimilar business. We have had a fair bit of discussions around the U.S. opportunity. Two things, one is in our business, what proportion is EU and RoW for the overall biologics? And how do you see these 2 geographies from a strategic perspective? In terms of the growth outlook for both business geographies of overall biosimilar business.**

Shreehas Tambe: Thanks, Nitin, for that question. All 3 geographies, we have broken it up as North America, which is U.S. and Canada. We have got Europe, that was very clear. And then we have got emerging markets, which is not in this part of the world. If you look at it roughly, our business is between advanced markets and emerging markets about 75%-25%. And between the advanced markets, if I were to take a split between North America and Europe, Japan, Australia, you roughly see it biased slightly towards the U.S., maybe 40%-35% is what it would be between North America and the rest of advanced markets. So that's the rough split, I would say, 40%-35%-25%. That is how the split would be between these 3 regions. How is our view on Europe and rest of the world? I think we are very, very bullish on these regions because we feel 'have got 8 products approved. We have got 3 more coming in Europe. We will have a double-digit portfolio will be amongst the 1 or 2 companies, which is having that kind of a portfolio in Europe. We will be the only one which is fully integrated. and the most important thing is that we haven't really explored the full potential of that region yet because we aren't present in very many countries, given that each country is quite diverse. Our presence in Germany, France and a few other countries is very large. But we have devised a strategy where we feel we will expand into

the 27 countries on a staggered basis, starting with the 5 large countries in EU, including the U.K. We feel that there's a lot of headroom for growth, Nitin. So that's why we're very bullish about it.

In emerging markets, we feel there are certain countries which are very strong in terms of the demand, in terms of the volumes, but also pricing is also quite healthy. We feel that those 8, 10 countries that we have identified where we want to be straight with the patients, with the customers, I think those are the countries we feel we will find a lot more traction than we have so far.

Nitin Agarwal: **And as a proportion, do you see these proportions continuing? Or you see some of these sorts of changing a bit from a revenue concentration perspective?**

Shreehas Tambe: We expect the ratios between this to be more or less the same because the size of the ticket between the U.S. versus the others are skewed that way. You will always see the U.S. taking a larger share than the rest. But given that we are fully integrated as an organization, we have the ability to take advantage of working in the other regions also.

Nitin Agarwal: **If I can squeeze in last one on that. On the insulin portfolio, you mentioned about it earlier. Now on the competitive dynamics in the insulin portfolio, you mentioned innovators are there, and not too many buyers, generic players are there apart from the innovators. With this increased sort of focus of the innovators on GLP-1s, what kind of market dynamics are you seeing across in the U.S. and some of the other markets? Are you seeing certain degree of lessening of competitive intensity from the innovators or the other players on insulins? And what does it really mean for us on more like a 3 - 5-year view on this segment?**

Shreehas Tambe: Yes. And I would not want to comment on what others are doing as a strategy, but I would certainly say that insulins are here to stay regardless of how the GLP-1 agonist strategy plays out because that is certainly an important therapy area in the segment, and we are very bullish about the GLP-1 segment as well. And you just heard Siddharth walk us through why we believe we're very strongly positioned in the GLP-1 space.

But the insulin space is unique, and we believe complementary to what the GLP-1s bring to the table. We are seeing a continued demand. We are seeing an increased focus on this. Globally, there is a requirement for this product, which continues to be there. You're right, they are out of the 3 large companies which were making insulins, 2 of them have GLP-1s in their portfolio and clearly more remunerative in their mind probably in the near term.

The focus and attention could be, like you said, being in another place. But we are very focused on both. Siddharth just talked about GLP-1s. And Biocon Biologics is very focused on insulins. And given our full integration from drug substance, drug product to devices, we are seeing an increase in the opportunity, particularly in emerging markets and then the United States as well, which is reflected in our market shares.

Nitin Agarwal: **And just last one on that, barring Aspart, which is filed now. I mean, how many more products are there in the development which can probably get commercialized in the insulin portfolio in the next, say, 3 years?**

Shreehas Tambe: There would be other products, Nitin, that you could develop. But broadly, there are 2 segments that I would look at from an insulin perspective. One would be the basal or the longer-acting segment. And the other one would be the rapid acting or the short-acting segment. One is which will maintain the blood glucose all through the day, which is where Glargine falls in. And the other one would be a post meal or a post-prandial insulin as they call it, and we have Aspart in that segment.

We are playing in both segments. And we believe that these products could occupy the broader space like we have seen with the basal insulin. We believe we will see a very similar trend when we bring the insulin Aspart, which is the rapid acting analog.

Saurabh Paliwal: Thank you, Nitin. We will take the next question from Bharat Sheth from Quest Investment Advisors.

Bharat Sheth: **I have one question Shreehas. In the recent times in international forum, we presented that biosimilar adoption is increasing globally as well as we expect that market to grow at that 75% CAGR from FY 2023 to FY 2028. And with coming back to our own company having a good amount of portfolio, having approval as well as both the plants are clear, so I mean, if we have to give little, longer-term trajectory for our biosimilar business? So how do we see that there is a growth?**

Shreehas Tambe: Bharat bhai, first off, thank you for your continued patronage. You are right. I think we presented recently at one of the investor conferences that there is a significantly large and exciting opportunity ahead of us. In fact, the opportunity ahead of us for biosimilars is much larger than the one that we've seen in the past 5 or 6 years. So, we are certainly very, very bullish about it.

We are also looking at the portfolio that we have developed. We have a large 20 product portfolio. 8 of them are approved or commercial, and we are looking to bring more products into the market. But these products, 5 of them in the U.S. in the next 12 months, 3 of them globally. And then you will see more products coming post 2028 and thereabouts. And that's where also the large assets that we've guided will move out.

The CAGRs that we mentioned are from 2023 onwards. And you're seeing us grow as well. And some of these things will tie up because not all therapy areas are what we represent. We have grown at a healthy clip if you look back from where we came. And while I do not want to provide specific guidance, we believe the future will also be predictably positive as we look to bring more products into the market. So even in the investor presentation at the conference, we have not given specific guidance, but it gives you a sense of where the opportunity is and how exciting the future looks like where we, as a company, are quite strongly positioned.

Bharat Sheth: **I mean, ballpark, I mean, whether will be better off than that 2025 or maybe so if we can give, I mean, some kind of a range?**

Shreehas Tambe: Yes, I would love to. And I think we have kind of tried to avoid giving specific guidance. But I think it is fair to say that as an integrated company with so many products being launched, with the opportunity opening up in the next few years, this is a very exciting space, Bharat bhai.

Bharat Sheth: **And same question with Siddharth. Siddharth, after investing so much in R&D as well as the capacity expansion and now some of the products that we have got approval, so how do we see from 3 years perspective Biocon standalone business?**

Siddharth Mittal: I had addressed a previous question where I had reaffirmed that we are looking at the mid-teen kind of growth. There could be periods when it's higher, there could be periods when it's lower. But overall, directionally, I think peptides is going to be an important growth contributor over the next couple of years, starting with Liraglutide in FY 2026 and start of Semaglutide in FY 2027.And in FY 2028, we will see a significant contribution coming from both Lira, Sema and even on the synthetic side, whether it's OSDs or the other injectables that we have or the increased capacities that we are creating for our fermentation products or the synthetic products. So, sum total of all, we definitely expect a good growth over the next 2 to 3 years.

Bharat Sheth: **Siddharth, how will that play out on our margin or profitability side?**

Siddharth Mittal: Margins, as you have seen in this quarter, our margins did go down because the Liraglutide facility of the drug substance Liraglutide facility, which we had created got commissioned, approved and that got capitalized during this quarter. We did have expenses come in for that facility. We also had the Vizag new facility, which got capitalized in the second quarter for which, again, we had expenses come in this quarter. So, the margins have gone down a bit. But as you start seeing sales coming from these facilities, we will see margins go up. And directionally, what I have guided for is an EBITDA margin of 10% to 12%. I mean, of course, it's gone down this quarter because of, again, increased R&D and expenses, but we will get closer to 13%, 14% in 1 or 2 years. Of course, the new product launches, margins are dependent on a number of players. If number of players are limited, we would see a better pricing and hence, better margins. But if it gets competitive, like you have seen in typical generic drugs, then the margins would be on an average of that 10%, 12%. So, a lot of unknowns are there to predict the margins accurately. But we are working on cost improvement. That was one of the challenges that we had in the last couple of years with the increased raw material prices, the strengthening dollar, and the selling prices of our APIs go down, we had an impact on margin. We embarked on a journey of cost optimization, raw material cost reduction CIPs. And all these initiatives, over the last 1 to 2 years, we have started seeing the results. And now we will see the volumes pick up again, and that is exactly what's happened in quarter 3 and over quarter 2, we did see an uptick in our API sales, and that momentum will continue. We will see lower raw material costs with better processes in the coming quarters. And all these things will add on to margin improvement.

Saurabh Paliwal: We are coming to the close of the call. And we take the final question from Alankar Garude from Kotak Securities.

Alankar Garude: **On the R&D front, you have spoken about the 7% to 9% range. But over the last few quarters, we have been closer to the lower end of that range. Sir, can you take us through the R&D progress on the biosimilar side in the prefiling stage in our portfolio over the next, say, 4, 5 years? And in that context, how should we look at the overall R&D spends going forward?**

Shreehas Tambe: Thanks, Alankar. I think what we have guided is in line with what the expectation was. Many of these R&D spends, Alankar, as you know, are cyclical in nature. So, as you take products past the clinical stage, then you will see a slightly lower spend in our investment in R&D, then you would see when products are in the clinical phase. Now, incidentally, for us, we had 3 products which were in the clinic at the same time, and which moved out of it also at the same time. What you are seeing effectively we filed for Aflibercept, we moved that out. We filed for Ustekinumab, that got approved. We have done Denosumab and that's got approved, too. You have seen products which would have then peaked at one time and then it's ebbed. And you see the next set of products, which we are developing, some of them undisclosed until we actually move past that stage. Once it gets into the Phase III clinic, where the larger amount of costs actually starts coming in, that's where you will see that move towards the higher end of the range. So, I think it's just a matter of phasing is what I would say. But the programs that we've guided for, we continue to be on track where we are. In fact, we moved some of them ahead of where we had initially guided.

Alankar Garude: **So broadly, Shreehas, how should we look at the timelines? I mean, I am not asking for a specific month or a year, but more in terms of how do you see the progress across some of the initial assets today? Is it going to be more 2, 3 years from now that some of these enter Phase III or maybe even longer? Any color on that would be helpful.**

Shreehas Tambe: Some of the assets that what we are currently developing in the next 2 years that are supposed to hit the market are already past their clinical phase or getting off it. The ones that are to come to the market post 2026, 2027 actually, I think those are the ones which will be entering the clinic.

If your question is, are we on track for it? To that question, the answer is yes. We would be tracking to it the way we believe. We have talked publicly about a few assets. I will reiterate the asset that we have publicly talked about. We have mentioned Pertuzumab in the public where we have said we are developing that asset. And I can tell you that we are progressing as per the plan that we have made. And as these assets will move towards the clinic, you will see those clinical spend starting to reflect because we expense all our R&D through the P&L. You will start seeing it there.

Alankar Garude: **Fair enough. Got it. And the second question for Sid, on the Vizag facility, is it being used more for captive consumption currently? And if you can help us with the clients lined up to procure APIs from this facility over the next 1, 2 years?**

Siddharth Mittal: It will be used for our API customers as well as our captive consumption. Our API customer base is much larger than our own formulations business. We have some very strategic customers in the U.S. and Brazil who are qualifying Vizag as well. And that is also to derisk their own dependency on 1 site, which is in Bengaluru. So that gives them a supply assurance from a second site. And we are also locking in additional customers from Vizag and that will drive the volume growth. And we will, of course, also looking at additional products, which we are going to qualify from this facility. We recently validated Pimecrolimus which did not have in our portfolio, which was again a big product that's

been validated now from Vizag. We will also be validating other Immunosuppressant uses from this facility.

Alankar Garude: **Understood. Are you commenting on the broader utilization of this facility at this point of time?**

Siddharth Mittal: No. I mean I think in the initial years, it will be low. We are looking at what's the best way of increasing the utilization from this facility. And the reason for it is in Bengaluru we had a capacity. And when we faced capacity constraints a couple of years back with a huge demand and when we were maxed out, when we were building Vizag and when the Vizag was being built and qualified, we significantly increased the capacity of our Bengaluru facility. So right now, Bengaluru while is fully sold out, we do look at additional volumes coming from Vizag. But as I mentioned, we are qualifying additional customers. And as these customers start taking the supplies from this facility, the capacity utilization will go up and we will be looking at supplying the new products, as I mentioned, Pimecrolimus also from this facility for the years to come.

Saurabh Paliwal: Ladies and gentlemen, that is the last question for the day. Thank you all for joining us today and if you have any follow-up questions, please do get in touch with the team. With that, have a good rest of the day, and thank you.

Peter Bains: Thank you.

- Ends –

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