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## **Biocon Limited Q1 FY26 Earnings Conference Call Transcript**

***Aug 08, 2025***

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

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- # **Dr. Kiran Mazumdar Shaw** – Executive Chairperson, 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. Abhijit Zutshi** - Chief Commercial Officer, Biocon 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

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- # **Damayanti Kerai** – HSBC Securities and Capital Markets (India) Private Limited
- # **Surya Patra** – Phillip Capital (India) Private Limited
- # **Neha Manpuria** – Bank of America Securities India Limited
- # **Harith Ahamed** – Spark Institutional Equities Pvt. Ltd
- # **Shyam Srinivasan** – Goldman Sachs India Securities Private Limited
- # **Tushar Manudhane** – Motilal Oswal Financial Services Ltd
- # **Neha Kharodia** – Abakkus Asset Manager LLP
- # **Vipulkumar Shah** -Sumangal Investments
- # **Nitin Agarwal** – DAM Capital Advisors Limited

## Prepared Remarks Session

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### ***Saurabh Paliwal:***

Good morning, everyone. Thank you for joining us on this call to discuss Biocon's first quarter results for FY '26. I am Saurabh Paliwal from Biocon's Investor Relations team. Before we get started, let me introduce the management on this call. We have today Biocon's Chairperson, Dr. Kiran Mazumdar Shaw; Mr. Siddharth Mittal, CEO and Managing Director, Biocon Limited; and Mr. Shreehas Tambe, CEO and Managing Director of Biocon Biologics, along with other senior management colleagues across our business segments.

A few housekeeping points. We will start the call with the opening remarks by Kiran, which will be followed by an interactive Q&A session. All the external participants lines are muted and are in the listen-only mode. 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 under the reaction tab of your Zoom application. We will call out your name and unmute your line to enable you to ask a question. Please note that this webinar is being recorded. The recording will be made available on our 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 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 this, I would like to turn the call over to Kiran for her opening remarks. Over to you, Kiran.

### ***Kiran Mazumdar Shaw:***

Thank you, Saurabh. Good morning, everyone. I'm pleased to present an overview of the Biocon Group's performance for the first quarter of FY '26. And before we get into the segmental and financial details, let me highlight some of the key developments during the quarter.

#### **Equity Fundraise**

As a part of our strategy to strengthen the group's financial position and reduce our exposure to structured equity investments, we successfully completed a qualified institutions placement or QIP, of INR 4,500 crores, which is our first equity raise since Biocon's IPO in 2004. The offering was oversubscribed and received strong interest from a diverse and a mix of global and domestic institutional investors, reflecting confidence in our long-term strategy and value creation potential. The funds raised will enable us to increase our stake in Biocon Biologics by facilitating the exit of structured equity investors, which reinforces our strategic focus on the huge biosimilars opportunity ahead.

#### **Product Launches and Approvals**

We achieved several significant milestones this quarter that strengthened our global biosimilars portfolio.

- The U.S. FDA approved Kirsty™, our biosimilar Insulin Aspart, making it the first and only interchangeable rapid-acting insulin in the U.S. This marks a major regulatory milestone and builds on the strong foundation established by Semglee our long-acting insulin further reinforcing our leadership in the U.S. Insulins market.



- We launched the first biosimilar Aflibercept, Yesafili™, in Canada. And this marks our tenth biosimilar to reach commercial markets globally, underscoring our expanding global footprint.
- We also secured approvals for biosimilar Denosumab from both the European Commission and U.K. MHRA. And these approvals mark Biocon Biologics anticipated entry into the bone health therapy area, opening up a new therapeutic segment for our biosimilars business.

### Facility Expansions and Strategic Capability Building

- Our injectables facility primarily focused on GLP-1s has been commissioned with commercial supply expected to begin in FY '27. This facility strengthens our position in the fast-evolving Metabolic and Diabetes care space and is part of our broader commitment to building advanced manufacturing capacity aligned with future portfolio needs.
- At Syngene, we inaugurated a state-of-the-art Peptide laboratory, adding to our integrated discovery and development platforms, which already include Monoclonal Antibodies, Antibody Drug Conjugates, Oligonucleotides and PROTACs, thus reinforcing our position as a technology-driven research partner.

### Sustainability

We continue to make meaningful strides in our sustainability journey.

- Biocon received a Gold rating in the 2024 EcoVadis Corporate Sustainability Assessment with an improvement score of 77 up from 70 last year. This places us in the top 5% of companies globally and represents our highest sustainability rating to date.
- Syngene was recognized by Time Magazine and Statista as one of the world's most sustainable companies in 2025, and it ranks #1 among Indian pharma and biotech firms, placing it in the top 20 globally within its sector. This recognition underscores our collective commitment to responsible growth, environmental stewardship and sustainable business practices.

### Performance Summary

We commenced FY '26 on a strong note.

Adjusting for the one-time gain from the divestment of our Branded Formulations India business in Q1 FY '25 on a like-for-like basis, the group delivered 15% year-on-year growth in operating revenue, led by **accelerated growth in biosimilars, continued growth in CRDMO and a steady performance in generics.**

Let me walk you through the financial highlights.

Operating revenue stood at **INR 3,942 crores**, up **15% year-on-year**. Biosimilars grew **18%** on a year-on-year basis; CRDMO, which is really our research services business, and pertains to Syngene, grew **11%** year-on-year; and Generics grew **6%** year-on-year.

**Core EBITDA** was **INR 1,003 crores**, up **11% year-on-year**, with a margin of **25%**.

**R&D investments** were at **INR 205 crores** or **7% of revenues** (excluding Syngene), reflecting continued pipeline investment. **Reported EBITDA** grew **19% year-on-year** to **INR 829 crores** on a like-for-like basis. And **profit before tax**, excluding exceptionals, rose 72% to **INR 97 crores** on a like-for-like basis.

## Q1FY26 Segmental Business Performance

### Generics

Generics business delivered in line with expectations. The exceptional revenue spike that we saw in Q4 of FY '25 was driven by the launch of Lenalidomide or gRevlimid, which should be viewed as a onetime upside. Growth in Q1 was supported by

- New product launches, including Liraglutide in the EU, and Lenalidomide and Dasatinib in the U.S.
- Stronger volumes in key APIs were seen this quarter
- Continued traction in our Peptide portfolio with Liraglutide approved for Diabetes in India is expected to be launched shortly through our commercial partners.

When it comes to **revenue from operations**, it was at INR 697 crores, up **6% year-on-year**. **Product sales** grew **13% year-on-year**.

**EBITDA** reflects ramp-up costs linked to operationalizing **new facilities, including**

- Our peptide API plant
- Our expanded fermentation capacity in Vizag; and
- Our Cranbury, New Jersey facility in the U.S.

And while these costs impact margins in the near term, these new capacities are expected to deliver strong ROCE as utilization ramps up, especially in GLP-1s.

**R&D Spend** was at INR 70 crores or 10% of segment revenue, primarily directed towards advancing our GLP-1 portfolio.

**Higher interest and depreciation costs** from recent Capex also impacted **PBT** performance.

### Biosimilars

Q1 FY '26 marks our sixth quarter as a fully integrated global biosimilars company. And following our last year's consolidation, **we have now entered the accelerate phase**, where we are focusing on:

- Scaling existing commercial products
- Deepening our presence in key markets
- Preparing for future launches to drive sustainable and profitable growth.

Before we dive into Biocon Biologics business performance, I'm very pleased to share that we have had a **successful outcome with NHS**, securing 4 out of 7 regional awards for **Yesafili**. This marks a 100% success rate across our national tender submissions in the U.K. and highlights the team's consistent strategic execution.

Now coming to key highlights.

### North America:



- Received **U.S. FDA approval for Kirsty™**, our interchangeable biosimilar Insulin Aspart, the first and only rapid acting Insulin with this designation in the U.S.
- I would like to also talk about partnering with **Civica, Inc.** to locally manufacture Insulin Aspart in the U.S., enhancing supply security and affordability.
- Our **Oncology portfolio** delivered strong performance with Ogivri®, our biosimilar Trastuzumab and Fulphila®, biosimilar Pegfilgrastim, both maintaining 27% market share.
- **Yesintek™, our biosimilar Ustekinumab, emerged as a leader** in early Immunology uptake with strong formulary coverage across major payers, including CVS, UnitedHealth, Express Scripts and Blue Cross Blue Shield plans.

#### Europe:

- **Hulio®, which is our biosimilar Adalimumab**, continues to be one of the market leaders in Germany with a market share of 18%.
- Our **Oncology portfolio** led by Abevmy®, our biosimilar bevacizumab, and Ogivri®, biosimilar Trastuzumab, demonstrated **strong momentum** on the back of successful tender wins in major markets.
- **Yesintek®, our biosimilar Ustekinumab, received a very strong reception** in key EU markets, including Germany, Spain, Italy and Portugal.

#### Emerging markets:

- Growth was led by our **strategic focus on 8 high-impact, self-led markets**, significantly increasing revenue share.
- We **secured large tenders**, including a **multiyear contract with Malaysia's Ministry of Health for rh-Insulin and Insulin Glargine**.

When it comes to segmental financials,

- Revenue was up 18% year-on-year at **INR 2,458 crores**.
- EBITDA was up **36% year-on-year** on a like-for-like basis at **INR 645 crores**.
- **EBITDA margin**, excluding Forex and other items, was at **24% with an approximately 300 basis points year-on-year expansion**, reflecting improved operating leverage and the benefits of economies of scale.

#### CRDMO

Our Research Services business segment has been renamed as CRDMO, representing the new profile of Syngene's business. Syngene had a positive start to FY '26 with **revenue of INR 875 crores, which is 11% year-on-year increase**. **EBITDA of INR 224 crores**, which is **19% year-on-year increase with a 25% margin**, and growth was driven by pilot programs transitioning into long-term contracts as well as continued client trust in Syngene scientific and operational excellence.

Biologics manufacturing has made good progress in terms of capacity expansion. Unit III, which is our biologics facility in Bengaluru, is now operational. The Bayview facility in the U.S. remains on track for commissioning later this year. Despite macroeconomic uncertainties, Syngene sees robust demand from large and mid-sized pharma clients and remains on track to deliver FY '26 guidance.

So, to wrap up I would like to end with some **Concluding Remarks** where I would like to summarise a few key points

1. **All three businesses, namely our Biosimilars, CRDMO and Generics, are seeing accelerated growth.**  
Each has clear growth drivers and focused leadership, working to strengthen fundamentals and improve return ratios. The progress we've made on product launches, market share and customer traction demonstrate that we are winning in the market.
2. **Our balance sheet is stronger.**  
Through our QIP, we've enhanced financial flexibility to increase our stake in Biocon Biologics, provide an exit to structured equity investors and reduce interest burden and improve leverage ratios.
3. **We are aligning our business with shifting global policy and supply chain dynamics.**  
Biocon and Syngene have now two manufacturing setups in the U.S. The oral solid dosage facility in Cranbury, New Jersey whose capacity has been significantly expanded to support our U.S. sales is going to be shortly inaugurated. Through our Civica alliance in the U.S., local manufacturing of insulin will assure access and affordability. And Syngene's Bayview biologics facility will enhance capacity and give direct access to the U.S. biologics CRDMO market. Additionally, the facility will also be utilized by Biocon Biologics for select biosimilars for the U.S. market.

**Our growing global manufacturing and commercial footprint reflects our agility and readiness to serve patients and partners worldwide in an increasingly localized world.**

In terms of an **Outlook**, I'd like to say that **we made a strong start to FY '26.**

- Biosimilars is well positioned to build on its momentum with recent launches and approvals expected to fuel accelerated growth.
- CRDMO continues to benefit from favourable demand trends, and Syngene is actively investing to future-proof its capabilities.
- And in generics, our early investments in GLP-1s and peptide APIs are indeed gaining traction. Multiple product launches are planned in the coming quarters, which will support strong double-digit growth for the full year.

And with this, I would like to now open it up for a Q&A. [Q&A Session](#)

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

**Damayanti Kerai:** **My first question is, when we look at your performance year-on-year for biosimilars segment, you have recorded growth of 18%. At the same time, Generics and Syngene also grew year-on-year. But when we look at the gross margin part, there is a decline of, say, 150 basis points or so. So just want to understand, especially from biosimilars sale, whatever incremental sales you are**



**recording, is that coming from more discounted tender channels, et cetera? And how should we look at the trend ahead? If you can explain this, please?**

**Kiran Mazumdar Shaw:** Over to you, Shreehas and Kedar.

**Shreehas Tambe:** Damayanti, we thank you for the question. I think if you noted Kiran's commentary, the biosimilars, Biologics business has performed very strongly in the quarter, not only has the revenue grown 18% year-on-year. There's also been an improvement in the EBITDA margin. There's a 36% increase in EBITDA on a quarter-on-quarter basis. There's a 300-basis point improvement that we are demonstrating, which is actually coming on the back of operating leverage that you see starting to play out.

So, I would say the biosimilars business, Damayanti, has really been in a very good shape. We are starting to see margins improvement as we go forward. And as this business scales up further with the new launches that we are expecting to start to show towards the later part of the year and in the subsequent financial year, we see this only getting better from where it is today.

**Damayanti Kerai:** **Shreehas, I understand at the EBITDA level, but I was trying to understand more at the gross level performance.**

**Shreehas Tambe:** Kedar, do you want to comment on this? I think my sense is the gross margins are also quite strong, but...

**Kedar Upadhye:** Yes, I can do. I'll just add to what Shreehas said, the gross margins, Damayanti, Biologics business have held quite steady, and operating leverage has played out. That's why EBITDA growth is stronger. We can take this off-line, Damayanti, but the Biologics gross margins have held steady and Opex, as a percentage of revenue has started seeing an improving trend.

**Damayanti Kerai:** **Sure. So I just have another question on interest expense. So before that, if you can say like what is the debt level at the parent as well as the Biocon Biologics Limited level. And we have been talking about debt reduction for a couple of quarters. But when we look at the interest expense for the quarter, I think it has gone up. Can you explain that as well?**

**Kedar Upadhye:** Yes. Maybe Siddharth, do you want to take the group level interest questions?

**Siddharth Mittal:** Sure. So I think, Damayanti, the debt, I think we have said that mainly it's at Biocon Biologics level. We have a net debt of roughly USD 1.1 billion in June at biosimilars level, approximately USD100 million at the Generics level and USD 120 million cash positive in Research. And the funds that we have raised through QIP, as you're aware, has been used partially to retire the OCD of Goldman Sachs and the interest that we were accruing on that OCD would start showing a reduction from quarter 2 onwards. But the bank interest will continue for a foreseeable future because these are primarily on the bonds, which are 5 years bond, which will be due for repayment in '29. So -- as



we also retire some of the NCDs with Kotak and Edelweiss during the course of this fiscal, we will gradually start seeing interest costs come down, but there's been no increase per se in the interest costs compared to Q1 of last year. So, it's remained stable because the amount linked to instruments whether OCD, NCD, the bank debt has remained at the similar levels in Q1 at least.

**Damayanti Kerai:** **Okay. So, with some of these repayments under way, should we assume interest burden to go down from 2Q itself or it will happen in a more gradual manner?**

**Siddharth Mittal:** See, Q2 will definitely go down for Goldman Sachs, which had the 5% coupon on USD 180 million. So that would go down. And as I mentioned, Kotak and Edelweiss will be more later part of this fiscal.

**Damayanti Kerai:** **Okay. So just like this USD 1.1 billion net debt, that is at the parent level? Sorry, I missed that.**

**Siddharth Mittal:** That is at the Biologics level. So Biocon Biologics has USD1.15 billion of our net debt.

**Damayanti Kerai:** **And the parent?**

**Siddharth Mittal:** Parent, as I mentioned, Biocon has USD 100 million of debt.

**Damayanti Kerai:** **Okay, USD 100 million. Okay. Got it. And my last question is for biosimilars.**

**Kiran Mazumdar Shaw:** I'd like you to take this off-line because your understanding of increased interest is not correct. So, I think you should take this off-line with the team.

**Damayanti Kerai:** **Sure. Sure. I'll do that. My last question is for biosimilars, can you give us the regional split, say, like U.S. and other markets?**

**Kedar Upadhye:** Yes. See, this quarter, Emerging Markets is about 23%. Advanced Markets is about 77%. But on a full year basis, you should factor 75%, 25%, Damayanti. And within 75% of the Advanced Markets, U.S., then North America will be 40% plus and the balance will be Europe.

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

**Surya Patra:** **First, again, a clarification on the gross debt, sorry, I missed that. So what is the gross debt level that we are having right now, on the consolidated level basis?**

**Siddharth Mittal:** That's that USD 1.1 billion. So again, I'll repeat. Biocon Biologics has a net debt of USD 1.15 billion, USD 100 million debt in generics, USD 100 million cash in Syngene. So when you add these 3, it's USD 1.15 billion, which is primarily the debt in Biocon Biologics.

**Surya Patra:** **And continuing with the Generics business. So we have seen in that in this current quarter, there is a kind of impact on the EBITDA level, both Y-o-Y as well as sequential level. So two things, sir, whether there is no Revlimid sale in this**

**quarter, that is one. And is there any onetime kind of spend because of the facility commercialization and all that and which may not be there in the subsequent quarters? Is it that right understanding? And if that is yes, can you quantify the onetime impact?**

**Siddharth Mittal:**

So the Revlimid launch impact, as we mentioned, was in quarter 4 of last year, which had boosted the profits and revenue in fourth quarter of FY '25. We did have a very small component of sale in quarter 1 which, of course, did not have a significant impact. So Till the product is launched in an unlimited quantity, which is going to happen at the beginning of next calendar year, we are not going to have any more continuing sales of Lenalidomide for at least the first 3 quarters of this fiscal.

And as far as the cost is concerned, we did have 3 facilities, as Kiran mentioned in her opening remarks, which were capitalized in last fiscal. These are very large investments, the Immunosuppressants facility in Vizag, the drug substance facility for Peptides in Bangalore, as well as the new Cranbury facility that we had acquired in the U.S. And the impact of all these facilities operating costs is in the P&L, which is going to be on an ongoing basis. The impact is roughly INR 60 crores a quarter. So, when you look at the EBITDA or the margins or gross margins from the sales that Generics business has recorded, it is in line with the quarter 1 of last year EBITDA, but that has been impacted by these facility payroll and other operating costs for these 3 facilities, and which will continue for now going forward.

**Surya Patra:**

**Okay. Sir, then if I just extrapolate it about the margin for the consolidated business level because we are anticipating a kind of a moderated margin scenario for the Syngene business due to the capacity implementation the status unit and sure generics that we will have some pressure, while we would be seeing a kind of a ramp-up on the biologic front. So on a consol basis, how should one think about the margin kind of expansion or kind of moderation, if you can give some clarity for the full year?**

**Siddharth Mittal:**

Okay. I'll quickly give my comments on Generics and maybe Deepak can add his comments for Syngene margins. But see, the first quarter and first half will be under pressure. We have multiple launches coming up. We are launching liraglutide in the Europe this quarter, along with our partners, Zentiva, we are expecting a few other launches. In fact, we also launched Sacubitril/Valsartan or Entresto in the U.S. on day 1 recently, which will be reflected in our Q2 numbers. And the margins are going to ramp up, by H2 is when you will see the impact of all these launches coming in. And on a full year basis, again, I do expect generics to get back to the profitable and growth trajectory on the margins front. And I think Kiran already alluded in her concluding remarks that with all these upcoming launches, generics will have a strong double-digit growth on a revenue front.

**Kiran Mazumdar Shaw:**

I think Surya, I also want to add. I think what you're seeing right now is the impact of operating cost expenses on some of these capitalized facilities. But I think as I mentioned, starting Q2, you're going to start seeing these capacities being utilized. And



once you ramp up these capacities, you will start seeing a very good delivery of profitability.

**Surya Patra:** **Sure, ma'am. Okay. One clarification further about this fund raise and the repayment to Goldman Sachs and others. What is the minority interest then Biocon would be having enhanced in Biocon Biologics now?**

**Siddharth Mittal:** See, we've raised INR 4,500 crores, of which we have used roughly USD 200 million to repay Goldman Sachs. The repayment has been done as of end of June. We have a commercial paper, which we had borrowed money to repay ADQ in January earlier this year, and that commercial paper is due in September. Now apart from that, the remaining funds will be used to repay Kotak and Edelweiss as their payments become due. But on a fully diluted basis, assuming all these I mean, Goldman and Kotak/ Edelweiss is paid out, we'll be up to 78% stake in Biocon Biologics.

**Surya Patra:** **Okay. With this, sir, is it fair to believe that there is no compulsion on Biocon Biologics to go for a listing?**

**Siddharth Mittal:** No, there's no compulsion. I think we have said that IPO is -- I mean the commitment to Viatris that we had was the best effort, and we have time to give exit to investors, which is in few years. So there's no compulsion as such.

**Surya Patra:** **Sure, sir. Just last one point, sir, from my side about the biosimilar business. So two points basically. One is the Ustekinumab, whether we have seen any kind of a ramp-up or any revenue contribution from the U.S. market from that? And second point was about the launch of Aspart when we would be having dual brands from Civica as well as from our own. So whether the pricing would be similar or whether we will have the advantage of the limited competition as well as the interchangeability benefit or not because Civica pricing is likely to be relatively lower.**

**Shreehas Tambe:** Let me respond to both your questions, Surya, I think very relevant questions. Let me first talk about the bUstekinumab, Yesintek launch that we've had in the U.S., and it's been a very successful launch led by our U.S. team there. I think one of the key things to bring to your attention is that we've had very strong formulary coverage for this product. We've got all of the big commercial payers, whether it is CVS, United Health, Express Scripts, all of them have listed Yesintek on their main formularies. So that's a very strong positive sign.

Two is we are also starting to see initial trends in terms of how prescriptions have moved. And we have seen that a very large share of the prescriptions have moved towards Yesintek, which is a good thing. Apart from the fact that it's actually an interchangeable product, which helps that is showing that the product is starting to gain initial early leads as biosimilars start taking more market share once the originator product gets knocked off from the formularies starting July and then progressively towards the end of the year. So we feel good about how Yesintek has performed, Surya,



and we are looking forward to a sustained performance in the coming quarters as well. On the second question that you asked about insulin Aspart, we are very proud of being the first and the only interchangeable rapid-acting insulin analogue in the U.S. market at this point. So it's not just the Aspart market, but we also believe there's a larger rapid-acting opportunity that Insulin Aspart can target.

With regards to your question on Civica, I think that's a very, very smart strategy, I would think the U.S. commercial team has come up with, where we are bringing product closer to patients in the United States. So the product will be manufactured locally in the U.S. giving us an opportunity to have 2 products and 2 product brands to be in a position to supply to the patients in the U.S. in a more comprehensive way.

You've seen some articles where originators have made statements that they may be looking to withdraw some of these products, particularly in the rapid-acting insulins in the near term or towards the end of this calendar year. And we want to be in a position, and we believe we will be in a position to meet that demand as it comes up in calendar '26 and beyond.

**Saurabh Paliwal:**

We will take the next question from Neha Manpuria from Bank of America.

**Neha Manpuria:**

**Shreehas, just another question on Stelara. If I look at the IQVIA number, we've seen very strong market share trends. But this does not necessarily reflect all of the contracts as yet, right? So we could continue to see this momentum build as we see new contracts coming in, in July, and I think you mentioned some in Jan. So is there a fair bit of runway to improve market share still in Stelara?**

**Shreehas Tambe:**

Yes. And Neha, I think that's a fair observation. As I said, these are still early days. We've got a good start. I think Matt Erick, who is our Head of Commercial in Advanced Market has been leading this effort from the front. And maybe I would want him to jump in here to add some more color to give you a sense of how we see this ramping up. Matt, if you could jump in, that would be helpful.

**Matthew Erick:**

Thanks, Shreehas So, as the products continue to transition the Stelara from the payer starting July 1, you're starting to see what Shreehas said, early uptake of Ustekinumab. So these products will continue to see one full basis point that has contributed to that increase in June.

Remember, most of these products where Stelara will come off of the payer starts in July and then will continue to accelerate as we go through the end of the year. So we've got a great start. We have a massive amount of coverage from the payer side, and our sales force are in tune out there already talking to health care providers, and you're seeing this opportunity take place. So you'll see more growth as we go through the remainder of the quarter and into next calendar year. Thank you, Shreehas.

**Neha Manpuria:**

**Matt, just an extension to that question. Given that this is a fairly competitive product, how should I think about the stickiness of the market share for Stelara?**



**I'm just trying to understand, is there a risk that you could see the competition probably chip away on share come of the next contract cycle. I mean from a physician perspective, how sticky is the Biocon BBL biosimilar?**

**Matthew Erick:**

Great question. Look, we're early leaders like we are with Biocon. Doctors are getting used to writing Yesintek. And remember, interchangeability is not to each biosimilar. It's only to the brand. So as the patients and doctors get used to utilizing the Biocon Yesintek, it becomes very sticky. And I can tell you, we're in a great position, as we've spoken about before, being vertically integrated. We are well positioned to continue to compete and compete profitably in this market as the dynamics change and shift.

But early on, we have the next 12 months, of a great run rate because of what Shreehas has indicated in our coverage, and we have all expectations of continue to brand ourselves with Yesintek and getting patients familiar and doctors familiar to keep that stickiness as we go into that next payor cycle.

**Neha Manpuria:**

**My second question is the oncology biosimilars. Given that we are seeing competition now come back into the market. So some of the gains that we've seen earlier this year seems to be coming off, given there is more competition expected in Oncology biosimilars, should we expect that margins for BBL will probably be at these levels with whatever the gain in Stelara being offset by the Oncology biosimilars seeing pressure?**

**Shreehas Tambe:**

Let me respond to this, and if needed Matt can give you additional color. I think first up, Neha, we can look at the data points that you're referring to, but we believe that the oncology franchise for us in the U.S. has been very, very strong. In fact, we still have over 1/4<sup>th</sup> of the market with the 2 biosimilars that we've launched and continues to be very, very profitable. It's seven years since we've launched these products, and they continue to hold value. Another way of looking at it is to see how do you really operate in the medical benefit space, the Part B archetype of the market and I think that's a credit to the North America team in managing how to gain market share and retain value. And I think the team has really been able to demonstrate that. We continue to retain market share, grow that to 1/4<sup>th</sup> of the market and continue to hold value. So that continues to be an area of strength. As we bring Abevmy, which is our biosimilar bevacizumab into the market, it only further strengthens our oncology franchise. We've talked to you about our approvals that are coming in, in other parts of the world and U.S. shortly with Denosumab, which will be branded Vevzuo and Evfraxy, which will also then bring in.

....

**Matthew Erick:**

Did Shreehas freeze there?

**Kiran Mazumdar Shaw:**

I think you can continue, Matt.

**Matthew Erick:** Yes. What he was building upon is that we're continuing to have our franchise of oncology, and we'll continue to build on these launches that he was speaking about in regard to Denosumab. So in regards, just to recap that, we still see strong performance in our oncology portfolio with the addition of Bevacizumab. And then we're going to start layering on new product launches within our full portfolio, not just in the United States, but across the rest of the globe in Advanced Markets and also Emerging Markets.

**Neha Manpuria:** **Just one last question. When do we launch Aspart and what's the timeline for the Beva launch?**

**Matthew Erick:** Sure. Sure. On the Aspart piece, we'll be launching immediately. We have approval. We'll start seeing more pull-through. As you remember, the U.S. is set on a July basis and a January basis. So aspart will be strategically launching between now and the end of the year and leveraging our relationships and our great franchise that we set up with Semglee. But that will be a ramp-up because of timing in regard to the payor cycles. And in regard to Bevacizumab, you'll see this launching towards the end of the summer around the October time frame and which will continue to start leveraging our oncology portfolio and ramping up our payor strategies as we go into the first of the year.

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

**Harith Ahamed:** **So my first question is regarding the opportunity in recombinant human insulin, which you've talked about in the past and how Novo's plans to exit during this year can translate to a meaningful opportunity for us. So if you can talk a little bit about how we are positioned to capture this opportunity from a capacity standpoint and especially on the drug substance side. And if you could also, in this context, touch on the Phase II expansion that's ongoing in Malaysia and where exactly are we in that.**

**Kiran Mazumdar Shaw:** So since Shreehas not yet been able to rejoin, let me start by saying that the Malaysia facility, as you know, we have doubled the expansion of the drug product line, and that is going to be operational very imminently. However, it obviously will only cater to certain markets till all the regulatory inspections are through.

Having said that, I think from a positioning point of view, the insulin opportunity is very, very large, and we are addressing this as much as we can. We do have a growing capacity in Malaysia in terms of I think drug substance, we have adequate supplies, but it's really the drug product that we need to ramp up. We have a large global network of drug product manufacturing.

But I think from the Malaysia facility, we are really focusing on Advanced Markets supplies largely with some of it going to certain Emerging Markets. So to answer your question, yes, we are ramping up. We are trying to address the large opportunity that is emerging in the best way possible. I think by the end of the year, we'll be in a much better place to address most of this demand that we are seeing.



**Harith Ahamed:** Excellent. That's helpful. My second question is on the Generics business. Siddharth, you touched on Liraglutide launch in Europe. Can you give an update on the status of our filing in the U.S. for this product? And on Semaglutide, as we are approaching market formation across various emerging markets, can you give us some color on our preparedness to launch the product?

**Siddharth Mittal:** So the Lira U.S. file is under review with the FDA, and we should hear back shortly. We definitely do expect the approval to come in sometime this fiscal. I cannot comment on the timing exactly, but we do expect a launch in the U.S. during this fiscal. And as far as Semaglutide is concerned, I think even in the last quarter, we had said that development is done. We are going to file in quarter 2, which is this quarter in many emerging markets in Canada. And we are expecting early approvals in some of the markets where we'll file this quarter by end of calendar '26/early calendar '27. So while the market, as you rightly said, is going to open up in calendar '26, we do not expect many companies to have received the approvals, but we will not be too far from those companies.

**Saurabh Paliwal:** We'll take the next question from Shyam Srinivasan from Goldman Sachs.

**Shyam Srinivasan:** Just the first one on what's happening to Adalimumab in the U.S. So it's been two years since we have launched. I know there's been a lot of issues from a market share, not only for you, for everyone. But how does this pan out in the next 12 months? And could you also comment on like the pricing trends have been because of private label influence has also been not as per original thought process. So how should we look at Adalimumab progress for us in the U.S.?

**Matthew Erick:** Kiran, do you want me to take that one, real quick?

**Kiran Mazumdar Shaw:** Yes, please.

**Matthew Erick:** Okay. Yes. So first of all, thanks for the question. The Adalimumab for Biocon continues to be work in progress. We are going through a payor cycle in which we're bidding aggressively. But the attributes in the U.S. are still high concentration. But don't forget, we have a huge franchise in Europe in which Adalimumab has been very successful, as Kiran stated in her opening remarks. So we are definitely leveraging our global platform. As we see the trends, as you asked, with Adalimumab, we see the pricing starting to soften, meaning that we believe the market price is settling on Adalimumab. And we won't see these huge swings that we saw in the beginning. So more to come after the January 1, but we're in the mix. We continue to fight. But the attributes that are currently being driven in the U.S. preferred by most of the payors are still the high concentration. And then, as we see you talked about the private labels. As you know, Sandoz and CVS have the majority of that share. They just recently decided to not report that. So it's going to be hard for all of us to see it in IQVIA. But we do see a trend of Humira starting to fall off of the payor contracts starting at 1/1/26. So the market will continue to be open. Biocon will continue to compete, and we'll continue to press





forward on Adalimumab. But we do have a lot of products coming, not only in the U.S. but around the globe in which we're very successful, and we'll continue to leverage.

**Shyam Srinivasan:** **Got it. Just a second one again on Yesafili in Canada. I think the press release talks about it. So how should we look at that particular launch?**

**Matthew Erick:** In what way, looking at it from what perspective? I mean, we're ready, we're launching. We've already started working with key customers in which we're putting in bids now in Canada. Primarily, the business is in two spots, Quebec and Ontario, which we have our sales force, which we're very familiar with. We remain very optimistic in our opportunity, because of our position in that launch and being the first one of the first in the market in Canada.

**Shyam Srinivasan:** **Helpful. This last question is for Siddharth. Just on the Generics. Siddharth, you talked about the Lenalidomide not appearing again in quarter 1. And you also alluded to the double-digit growth. So what are the product launches we are looking forward to? And I think lira in India, is it going to be a significant opportunity or the sema next year is the one that's going to be the one to watch out for?**

**Siddharth Mittal:** I think, the biggest growth driver is going to be Lira in Europe, where we have already supplied partially in quarter 1. We will continue to supply to Zentiva and to other markets where we are direct in quarter 2 onwards. So we have, in fact, won some tenders also in Europe for liraglutide directly. And that would be the main growth driver. Apart from that, we do have a couple of other launches. I think we have spoken about Micafungin injection being launched in quarter 2. We also have Norepinephrine injection coming off a launch in quarter 2. We had received an approval for Everolimus Zortress, which is being launched in quarter 2. I mentioned about Entresto or Sacubitril Valsartan launched in quarter 2. Like that, there are a few other small molecule OSDs and injectables on top of lira in Europe. And again, lira U.S. is, of course, a big opportunity; still a very lucrative 700 million, 800 million market with limited number of players. And as I mentioned earlier that we do expect an approval in the U.S., and we will launch it in the U.S. after the approval is received.

**Shyam Srinivasan:** **Yes. And Siddharth, sorry, just continuing on the Sema in Canada or other markets and your update for from Biocon for Canada, Brazil, rest of the markets?**

**Siddharth Mittal:** So as I addressed the previous question that we will be filing in Canada, Brazil and many other markets this quarter, and with an expected best-case approval by end of calendar '26, but more likely launch in '27.

And India, just to close your question on India. We will be launching liraglutide also in India this quarter through our partners. And of course, there's a limited opportunity before Semaglutide is commercialized sometime in calendar '26. But still, we believe that given the whole availability of drug from innovators, whether if it's for Ozempic or

from Mounjaro in India, there is a huge market that can be created by our partners in India before Semaglutide comes in.

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

**Tushar Manudhane:** **Sir, firstly, on Canada Semaglutide, like tentatively, what would be the timeline to get the approval?**

**Siddharth Mittal:** I just mentioned that best case would be by end of calendar '26. We'll be filing this quarter. And so far, let me remind you, Canada has not approved a single GLP-1, whether it is generic liraglutide as well. So Canadian health regulator is taking its own time to approve the GLP-1. So even with Liraglutide filing done by many other companies, at least 5, 6 years back, there's not a single approval, and there's not a single approval yet for Semaglutide. So we have been interacting with Health Canada on a Liraglutide file. We, of course, understand a little bit better in terms of what they are expecting. And our teams are addressing proactively now for Semaglutide as we file that drug this quarter. And the review cycle, while is short in Canada, it's post filing, it's 8 to 9 months, if it's a first cycle approval. But as I mentioned that given Health Canada has not approved a single generic GLP-1, we do best case, expect an approval by end of calendar '26, but more likely in calendar '27, followed by the launch.

**Tushar Manudhane:** **Sir, So just curious to understand the thought process in terms of what concern they have as far as GLP-1 approvals for, let's say, generics or biosimilars is concerned?**

**Siddharth Mittal:** That's difficult for me, Tushar, to comment. Each regulator has their own way of reviewing the files. Of course, I mean, our own liraglutide, which was approved by MHRA and EU regulator, of course, U.S. has asked a different set of questions. Canadian regulators have asked for different set of questions. And I think it's also sometimes if it's the first or second drug in a particular class, they just want to make sure that their guidelines and their review process is aligned with what they are expecting. So if we can take it offline in terms of some of the questions that they ask which probably the other regulators have not asked, but again, it's something that's a part of standard review procedure for a new class of drug that gets approved in these major countries.

**Tushar Manudhane:** **Got it. And sir, just on the Generic side, approximately how do you think about the operational cost, while you have highlighted on the new launches pipeline, but let's say, how much in terms of quantum, one should think about the operational cost? Is that more or less settled as far as new capacity, new facility is concerned? Or we will see still some increase in the operational cost?**

**Siddharth Mittal:** See, the cost which is there in quarter 1 P&L relating to the three new facilities, roughly INR 60 crores. So on a full year basis, it's roughly INR 240 crores. Now we have a few more facilities which will get capitalized during the later part of this year. Of course, the injectable facility, which we have just commissioned and where we're going to do the



qualification and the filings, that facility will get qualified next fiscal. But we will see some increase during the remaining quarters for the new facilities that will get capitalized. But not a significant change. But as I said, that the impact of all these new launches and increase in gross margin would offset these additional costs that have hit the P&L and more from H2 onwards.

**Tushar Manudhane:** **Got it. Sir, thirdly, on the Lira U.S. FDA, any queries which is pending to be addressed and hence, some time for the approval?**

**Siddharth Mittal:** We have addressed all the queries. We had two open points with the FDA in the last CRL. One was related to the facility clearance, which, of course, the facility has been subsequently cleared, received VAI. And there was some specific data that the FDA asked, which we had responded to, and we have a target action date being assigned by FDA, and we will wait to hear back from them on the outcome. As far as Biocon is concerned, there's no outstanding query that we are working on.

**Tushar Manudhane:** **And sir, just lastly, like Biocon, as such has been, sort of, experts interestingly on the biologics side as well as on the synthetic side as far as GLP set of products is concerned. We're still sort of trying through the generic route, whereby the cost of operation seems to be much, much lower when it goes to the biologic route. So, if you could throw some light in terms of, we could have done in terms of, at least, cost of manufacturing, much lower, it would have gone by biologic route.**

**Siddharth Mittal:** So as cost of manufacturing, but you also have to look at the regulatory part figure. If you look at GLPs today, in the generics, whether it's in Europe or U.S., comes under the synthetic part. Of course, the recombinant route of making drug substances there, Biocon does have recombinant API as well. And we, of course, look at the time to develop a drug and the regulatory part to get it approved versus the cost of manufacturing the drug substance. And we are very competitive in terms of manufacturing our drug substance. We are vertically integrated. We know what the Chinese companies, who are supplying to a few other generic companies, what cost what selling price they're supplying the drug substance, and we know our own costs. So we think we are very well placed compared to our competitors as far as the costing is concerned. The recombinant API is definitely going to be required for the Oral Semaglutide. Because there, the cost of goods sold is primarily influenced by a drug substance cost, unlike injectable where drug substance does have an important influence, but not that it's not going to make a big difference, whether it's synthetic or recombinant as far as injectable is concerned.

**Saurabh Paliwal:** We'll take the next question from Dr. Neha Kharodia from Abakkus.

**Neha Kharodia:** **So my question is on the biosimilar business, more from a longer-term perspective. So in our previous corporate presentation, it refers to Frost & Sullivan report, which mentions that global biosimilar market itself can become 3x over FY 2024 to 2029. So just wanted to understand our biosimilar business**



**growth versus the industry growth, can we grow better? And how are we looking at this growth considering the part of the patent expiry that we are catering to?**

**Shreehas Tambe:** Neha, thanks for that question. Let me respond to that. I think the report that's been put out by Frost & Sullivan is very fair. Because it does cite two things. One is that the biologics opportunity itself is very large, which is before it gets to biosimilars, given that biologics are increasingly becoming the standard of care. So I think that is clearly set out. But the report also establishes the fact that biosimilars are here to stay, and that's the next large opportunity where Biocon Biologics is very well placed in the current set of circumstances where we have one of the largest portfolios, one of the deepest in certain key therapy areas, which is in Oncology, in Diabetes, and in Autoimmune diseases. So these are the three large areas that the report talks about where investments are happening. And if you look at our portfolio, we've got a very, very rich portfolio in these therapy areas. So from an outlook perspective, we've always said that we'll invest in debilitating diseases. We are getting products to market. We've got five products ready for launch in the next 12 to 18 months is what we had guided. Four of those five are already now getting to launch, four of them we've launched. Fifth is on the way from an approval standpoint. We have approval in the U.S. and in the EU and in Canada. U.S. approval should follow, which is for bevacizumab. That tells you that we are well on our way to realizing the opportunity that lies ahead of us. And I've said probably several times that the opportunity ahead is far more exciting than what we've seen at Biocon Biologics so far.

**Neha Kharodia:** **But to understand it more quantitatively, as an even ballpark numbers are fine. So can we grow better based on your commentary, somehow, I sense is that, our growth can be better. But is that understanding, correct?**

**Shreehas Tambe:** 100% share your sentiment. And I appreciate that your confidence in how our trajectory should be. So Neha, I think we are aligned in terms of how we see the future.

**Saurabh Paliwal:** We'll take the next question from Vipulkumar Shah from Sumangal Investments.

**Vipulkumar Shah:** **Yes. Can you give the market share movement for various biosimilars in various geographies? And what were the same last year in the same quarter?**

**Shreehas Tambe:** So Vipul, I think let me give at a headline level, let me give you a sense of how our market shares have grown. Let me start with the United States, which is a large part of our business. It's about 35% to 40%.

Oncology portfolio, as I've said earlier on the call, has been leading the way. I think we've got two products, which is Fulphila and Ogivri. Fulphila is a Pegfilgrastim, which has a market share of close to 27% or a little more than that. It was -- if you look back a year, it was trending in that 15-odd % rate. So it's grown significantly. If you look at Ogivri, which is our biosimilar trastuzumab, that's at 25%. A year or a little more than a year ago, it would have been at that 10%, 11% range. Again, you are seeing a very strong growth in terms of how the market has grown. Again, they continue to grow



profitably, so you can take that confidence in terms of how we are growing that business. We continue to maintain steady market share in our Insulins portfolio, both in the U.S. and in the rest of the world because it's really up to us. We do not see a major competition. We actually see no competition from any biosimilar Insulin makers. We are the only biosimilar insulin that's approved in the U.S. So we continue to see good demand as much as we can make.

In terms of Europe, which is the other large geography, I would point you out to some of the other previous guidances that we had shared. I talked about it in Q3 of last fiscal where we had said, we have a very good performance with our Hulo adalimumab in Germany, where we have a leading market share of 18%. And we've held that steady. But we will grow into other geographies and in other therapy areas. And if you look at the recent reported market shares, our Oncology portfolio, led by Abevmy, which is our Bevacizumab, and Ogivri, which is Trastuzumab, have shown significant growth of 15% and 20%, which gives you, again, a sense that while we've said that we will grow beyond our therapy areas, it is actually starting to play out, which is as per the guidance we had provided before.

We continue to see Europe as an opportunity for growth. We have more than 10 products approved in Europe and in the U.S., now in Canada, and we are looking to see how we can build this given that there is headroom for growth.

**Vipulkumar Shah:** **So then, why it is not reflected in the profitability, this market share gains.**

**Shreehas Tambe:** And Vipul, we will discuss this offline. If you would need to, we will be happy to spend time with you and see how the operating leverage is beginning to show. Kedar can, of course, come in and talk to you more on this. Kedar, feel free to jump in. But you're already starting to see the EBITDA margin starting to improve, and we expect this to strengthen, Vipul, over a period of time.

**Vipulkumar Shah:** **And my last question is for Kiran ma'am. So when we conceived the acquisition of this Viartis business, so do we feel that it has met all the goals which we had set at that time? Because when you look at the stock price, when you look at the market cap, it is below that debt, although we have spent close to USD 2 billion on that. We had to dilute Syngene stakes twice. We had to dilute stake in Biocon. So as an investor who is with the company since IPO, I don't find that it has worked that way. So I would request, Kiran, ma'am, to have her views.**

**Kiran Mazumdar Shaw:** So let me respond to it by saying that I think the acquisition has been a very important acquisition for us. I think, without the Viartis acquisition, we could never be a global biopharmaceutical company. You are right that the debt burden is what is dragging down the perspective or the perception of what investors feel about this acquisition. But let me assure you that we are now in a very healthy financial state. I think the fact that we have done the QIP and the bond issue has made us far more financially robust. And I can tell you that you will see a huge improvement in the way we are approaching this business in the coming quarters and coming years. And this is going to be a game-



changing transformative acquisition that we have made that will actually make us true global leaders. As you already know, we're in the top 5 biosimilars companies in the world, and I think we are very well positioned to really surge into a leadership position in the next 5 years. That is what our aim is.

I don't think you should, as an investor, keep focusing on near-term perceptions about servicing the debt. We have done everything we can to lower this particular apprehension. And I think what we've done, thus far, is extremely encouraging as far as I'm concerned as a promoter. I think, you will see that this is also a time where you're seeing profitable growth in the biosimilars business. And as the provisioning of interest comes off, it goes straight to the bottom line. So I think you should really look at this business and understand what we're trying to do. I think, the problem is that we are just looking at broad numbers and panicking. But I think if you look at the real business health, if you look at the way the numbers are improving, the leverage is improving. I think you will get far more confidence. Right now, you can see that in this quarter alone, the biosimilars business has turned positive, which up until now was only sort of either flat or negative. So this actually tells you about the kind of business prospects that are emerging before us. So I would not really comment on this business like you are commenting. I would like you to basically understand the business. And maybe I think you should take this offline to understand how the business is growing, how we are becoming far more profitable. And in the coming years, you will see that everything that we are doing is going to go straight to the bottom line.

**Saurabh Paliwal:**

We'll take next question from Nitin Agarwal from DAM Capital.

**Nitin Agarwal:**

**Shreehas, on the long-acting insulin, you talked about certain product certain competitors withdrawing from the market. And we also have seen certainly, there's been a sharp improvement in Novo sales on Novo Rapid in the first half of the year. So if you can just throw some light on what are the dynamics which is driving this uptick in the value of the market itself over the last few quarters?**

**Shreehas Tambe:**

See, Nitin, thanks for the question. Usually we have refrained from commenting on any innovator specifically or any company other than us specifically. But there are public domain reports where the ones that you cited have actually made public communications, that certain SKUs and certain products will be withdrawn to certain markets, particularly in the U.S. by the end of this calendar year. And until stocks last, they will continue to make supply. So that was the reference that I'm making. And we've also seen that in the past, it's not one. We've seen both the large insulin manufacturers who make such comments. And they are probably they are driven by their priorities and focus. So we wouldn't want to comment on that. But it does present us with two situations. One is, we are in a position to provide that requirement for patients who are looking for this life-saving drug. And we have always been willing to step in when such an opportunity arises. So we are very conscious of the humanitarian aspect as well and the business opportunity as well. And we have made the investments. You know that we are making investments to double our

capacity in our drug product line in Malaysia. We have increased our drug substance manufacturing, which should come online shortly in the coming years. And we have tied up with Civica, who's a local United States manufacturer, so that we can even localize manufacturing closer to patients. So, we really see this, I wouldn't want to comment on short-term blips in realizations, but I certainly see this as a long-term sustainable growth opportunity where there's very limited to none in terms of competition.

**Kiran Mazumdar Shaw:** I would also like to add to that, Nitin, that we are seeing this rising demand just not in North America, but also across the world. I think even if you look at our partner, commercialization partner in India, I think that demand has also increased significantly. So I think the insurance story worldwide, I think all of you just focus on one market, but the insulin story worldwide is really, really a very interesting one for us. Emerging markets, I can tell you that demand is only rising, and there are very, very few insulin players in the world to really cater to this rising demand. So we are very excited with what the insulin story has to offer us.

**Nitin Agarwal:** **Just sticking on that, hypothetically, while given the some of the way, some of these positive trends are playing out in the insulin market, while we are doubling our capacity in Malaysia at this point of time, do we actually, at some point in time, foresee a situation that we need to go in for some more capacity additions in this plant? Or this is, this capacity enhancement will be enough for us to fit whatever that you have in mind for the next foreseeable future?**

**Kiran Mazumdar Shaw:** We are taking all the necessary steps for addressing this market, this large market opportunity in various ways. Not just through our own capacities, but also through partnerships and other networks that we are developing.

**Nitin Agarwal:** **And secondly, on the denosumab, when do we see our approval sort of coming through in the U.S.? And secondly, how do you see this the dynamics in this market, given the fact that probably, is a little bit of a late entry here?**

**Shreehas Tambe:** So, two things, Nitin, again here, we've indicated in the past that we will have the approval before the end of this calendar year. And we are tracking well to that date in the U.S. So we see that approval imminent. And once we see that, we'll have both these products coming in. Again, the opportunity continues to be still very strong in terms of how we will get into the market. There are a couple of players like you seem to have indicated that whether there will be an opportunity for us. Let me give you a sense that there are two products here. One is a Part D product, and the other one is a Part B product, given that there are two brands, Prolia and XGEVA. And they are operated very differently. So one is impacted a little bit by time and also in how the archetype operates, which is a Part D product. But the other one is really played to our oncology franchise strength, and we feel very good about it. Timing may not necessarily be a big difference in how we eventually realize success out of this asset.



- Nitin Agarwal:** And last one, Kedar, in the presentation, you talked about the like-to-like margins for the biosimilar is 24% versus the 26% that you reported. What would be the adjustment be of 2-odd %?
- Kedar Upadhye:** Yes, Nitin, these are all the items below Opex, R&D and gross margin. So that includes Forex, that includes the derivative accounting that we do, and that includes other income and expenses. So you should take 24% on a normalized basis for the quarter.
- Nitin Agarwal:** And Kedar, as we have mentioned a few times in the past, as the operating leverage begins to kick in this business, what are the typical sustainable margins that we can hit in the business going forward?
- Kedar Upadhye:** Yes. So typically, we have awarded giving guidance, Nitin, on the margins going forward. But as the new launches kick in and the operating leverage plays out, that improvement will reflect in the numbers going forward. But we don't want to guide specifically at this stage.
- Nitin Agarwal:** So what I meant is from a range or does it become like a 20%, 25% margin business? Or is that a 25%, 30% margin business on a more sustainable basis? Is there a way to characterize the inherent profitability of the business?
- Kedar Upadhye:** Yes, yes, directionally, I think improvement is what will kick in, but we don't specifically guide for any range, Nitin. But you are right, directionally, I think you should see improvement in gross margins, because of new launches and the Opex as a percentage of revenue.
- Saurabh Paliwal:** That was our last question, ladies and gentlemen, for this call. We thank you very much for joining today and hope to see you in next quarter. Have a good day.

-Ends-

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