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November 07, 2024

To, The Secretary **BSE Limited** Department of Corporate Services Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai – 400 001	To, The Secretary **National Stock Exchange of India Limited** Corporate Communication Department Exchange Plaza, Bandra Kurla Complex Mumbai – 400 050
Scrip Code- 532523	**Scrip Symbol- BIOCON**

Dear Sir/Madam,

Subject: Transcript of Earnings Call Q2 FY25

This is further to our earlier letter dated October 30, 2024, regarding the presentation of Q2 FY25 Earnings Call held on October 30, 2024, please find enclosed herewith the Transcript of the Earnings Call.

The same is also available on the website of the Company at https://www.biocon.com/investor-relations/financial-information/earning-call-transcripts/.

Kindly take the above information on record.

Thanking You,

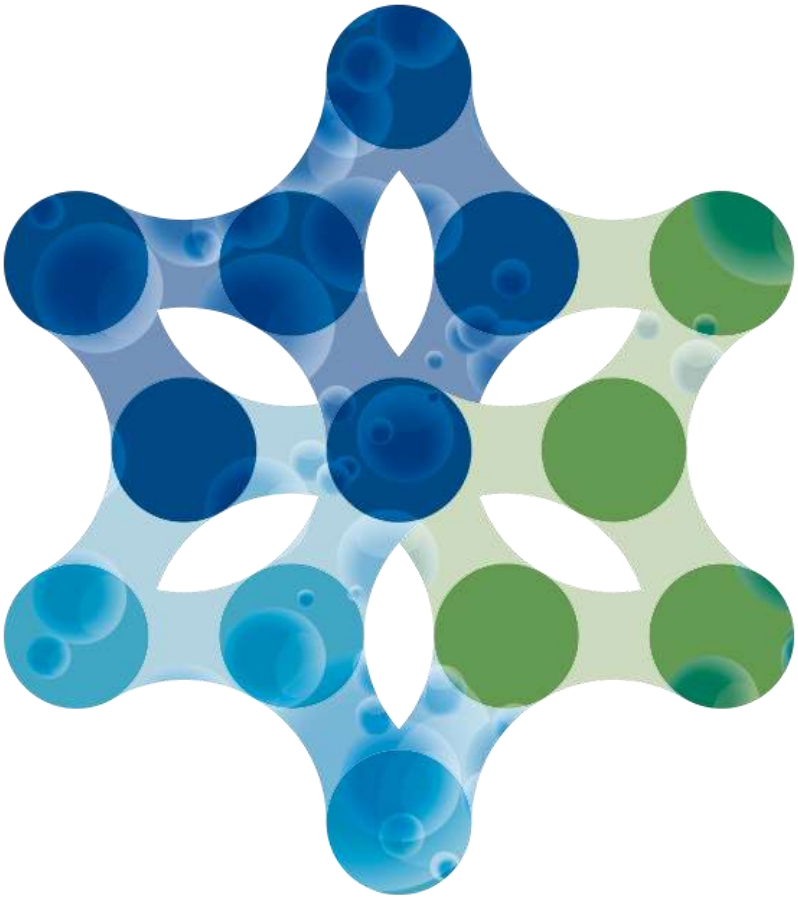
Yours faithfully,

For **Biocon Limited**

MAYAN K VERMA
Digitally signed by MAYANK VERMA
Date: 2024.11.07 21:04:58 +05'30'

Mayank Verma
Company Secretary & Compliance Officer
Membership No.: ACS 18776

Encl.: as above



Relentless Pursuit.

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Biocon Limited Q2 FY25 Earnings Conference Call Transcript

Oct 30th, 2024

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. 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. Sibaji Biswas** – *Chief Financial Officer & Executive Director, Syngene International Limited*
- **Mr. Saurabh Paliwal** – *Head - Investor Relations, Biocon Limited*

External Participants during Q&A session

- **Harith Ahamed** – *Spark Institutional Equities Private Limited*
- **Surya Patra** – *Phillip Capital (India) Private Limited*
- **Neha Manpuria** – *Bank of America Securities India Limited*
- **Palak Shah** – *Entrust Family Office*
- **Amey Chalke** – *JM Financial Institutional Securities Private Limited*
- **Jamsheed K** – *Individual Investor*
- **Niraj Jain** – *Individual Investor*
- **Naman Bagrecha** – *IIFL Securities Limited*
- **Tushar Manudhane** – *Motilal Oswal Financial Services Limited*
- **Yash Darak** – *RSPN Ventures Private Limited*
- **Kapil Aggarwal** – *Daksh & Associates*
- **Rumel Dahiya** – *Individual Investor*
- **Harshit Dhoot** – *Dymon Asia Capital*

Prepared Remarks Session

Saurabh Paliwal:

Good evening, everyone. I am Saurabh Paliwal from Biocon's Investor Relations team, and I would like to welcome you to Biocon's earnings call for the second quarter of fiscal year 2025.

I would like to indicate that 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. Should you need to ask a question please select the raise hand option in the reaction tab of the Zoom application. We will call out your name and unmute your line to enable you to ask a question. While asking a question please begin with your name and organization. Please note that the chat box is disabled but you can raise any technical issues by sending us an email to investor.relations@biocon.com

I would like to bring to your attention 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.

Moving to discuss the company's business performance during this quarter and future outlook, we have on this call, our Group CEO, Mr. Peter Bains; Mr. Siddharth Mittal, CEO and MD of Biocon Limited; Mr. Shreehas Tambe, CEO and MD of Biocon Biologics Limited, along with other senior management colleagues across our business segments.

Before we begin, 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. After the end of this call, if you need any further information or clarifications, please reach out to the investor relations team.

With this, I would like to turn the call over to our Group CEO, Mr. Peter Bains, for his opening remarks. Over to you, Peter.

Peter Bains:

Thank you, Saurabh, and good evening, everyone. Can I begin by wishing a very happy Diwali to you all and to your families. We appreciate you taking time out to join us today during this festive time in India.

Ahead of presenting the results in detail, I would like to start with some high-level remarks, led by reported operating revenue growth of 4%, but up 8% on a like-for-like basis after adjusting for revenues from the Indian branded formulation unit in Q2 FY24. The overall Biocon Group performance in Q2 FY25 has come in line with our expectations. While the Biosimilars business reported healthy double-digit growth, overall performance has remained relatively muted due to continued pressures in the Generic business and a marginal decline in Syngene's revenues.

We maintain our outlook for a transition to accelerating growth in the second half of the fiscal year, with Syngene returning to growth-maintained momentum in our Biosimilars business and a recovery in Generics in the latter part of the second half, driven by the launch of our first GLP-1 Generic in the U.K. A clear highlight for the quarter has been the highly successful refinancing of the long-term debt by Biocon Biologics through a bond

issue and a new syndicated loan facility on improved terms. I will expand on this later when discussing the Biosimilars business performance.

Let me now move on to present the financial highlights for the quarter.

Financial Highlights – Q2FY25

At the group level, T**otal revenue** was INR 3,623 crore, a flat performance year-on-year and a degrowth of 21% quarter-over-quarter on a reported basis. However, Total revenue grew 7% year-on-year and 3% sequentially on an adjusted like-for-like basis, after excluding revenues from the divested BFI business and one time income from Bicara in Q2 FY24 and onetime income from the Eris transaction in Q1 FY25.

Revenue from operations was INR 3,590 crores, up 8% year-on-year and an adjusted basis 5% sequentially. As mentioned in my opening remarks, this reflects a balance of performance at the segment level where Biosimilars revenue from operations grew 19% on an adjusted basis, 11% reported, while Research Services and Generics saw year-on-year declines of 2% and 8%, respectively. On a sequential basis, both Research Services and Biosimilars recorded operating revenue growth with Syngene growing 13% and Biologics growing 5% while Generics declined by 5%.

Group Core EBITDA for the quarter stood at INR 992 crores, down 10% from last year and representing a core operating margin of 28%. Quarterly R&D investment spend stood at INR 200 crore corresponding to 17% of revenues, excluding Syngene. Reported EBITDA for the quarter stood at INR 718 crores with a margin of 20%. Profit before tax and exceptional items stood at INR 72 crores versus INR 238 crores last year, and reported net loss for the quarter was INR 16 crore on a higher tax basis, geographical split in profits and minority interest. Adjusting for exceptional items, the loss stands at INR 13 crores.

Let me now turn to the business segment highlights and start with Generics.

Generics Business

Revenue from operations was INR 624 crores, a decline of 8% year-on-year and 5% sequentially as a result of maintained demand and pricing challenges and a planned facility shutdown. Core EBITDA for the quarter was INR 98 crores with a margin of 15%. R&D spends at INR 67 crores, representing 11% of segment revenues was up by INR 14 crores for the same period last year, reflecting continued investment in our strategic peptide portfolio as well as other complex molecules. EBITDA for the quarter stood at INR 36 crores with a margin of 6%, reflecting lower core EBITDA and increased R&D investments seen during the quarter. Profit before tax for the quarter was a loss of INR 9 crores.

Moving now to the business update. Let me start with **business development**. And here, our preparations and mobilization to address the global GLP market opportunity continue to build and we were pleased to sign licensing agreements with 2 leading pharmaceutical companies in the Middle East and Brazil, respectively, for the commercialization of our GLP-1 products in these important regions. A key win during the quarter was securing a tender to supply Everolimus tablets in a MoW market with supplies expected to commence this quarter.

On the **regulatory front**, there has been significant activity in progress with 7 market filings, including 1 ANDA in the U.S. And we also received 6 approvals, including 2 ANDAs in the U.S. for Sacubitril and Valsartan tablets and Daptomycin for injection, respectively.

In September, the U.S. FDA conducted GMP inspections at 2 of our API facilities, site 1 and 2, both located in Bengaluru, these inspections resulted in the agency citing 3 and 4 observations, respectively. The company has responded to the observations with CAPA plans within the stipulated timelines for both inspections and we await agency feedback. Earlier in June this year, our API sites in Vizag, sites 5 and 6 were inspected by the FDA. Both inspections have been successfully closed with the receipt of establishment inspection reports on both sites. While performance for the quarter has been muted, it is nonetheless consistent with our expectations and previous guidance and reflects the balance of continued pressure on our existing business, phasing of new products and maintained investment in R&D to support pipeline delivery, and of course, especially for our Peptides and our other complex products across both API and formulations.

Looking ahead, we expect recovery in the Generics in the second half of the fiscal year, and we expect this performance to build over the 2 quarters driven by new launches, including the launch of Liraglutide in the U.K. in Q3FY25 as well as injectables such as Micafungin and Daptomycin in the United States. We also expect sales to benefit from the impact of ongoing Cost Improvement Programs (CIPs).

Biosimilars

Moving now to our Biosimilars vertical, where I am pleased to report that Biocon Biologics continues to make good progress as it consolidates the acquired Viatris business and has delivered strong year-on-year growth as well as achieving several key milestones in the quarter.

In the United States, we continue to deliver strong performance across our product portfolio. Our Oncology franchise comprising a Ogivri, Biosimilar Trastuzumab and Fulphila, Biosimilar Pegfilgrastim is witnessing robust demand that we have reported marked year-on-year market share increases, with Ogivri increasing to 18% from 11% and Fulphila rising to 21% from 15%. Our Semglee and Insulin Glargine franchise shares continue to be in the mid- to high teens, including closed-door pharmacy networks and government business.

In Europe, market shares have remained largely stable at a regional level with Germany and France continuing to drive value. Strong growth across key markets and products has allowed us to expand patient access. Hulio, our Biosimilar Adalimumab has maintained its market-leading position in Germany with an 18% share, and we hold an 11% share in France. The company has also made significant strides in expanding its footprint with double-digit growth in the U.K. and the Mediterranean cluster, which includes the U.K., Italy, and Spain as well as partner-led markets. We are also seeing positive traction in our JANZ region, as promoting and marketing activities have transitioned to our commercial partner in Japan during the quarter.

On the emerging markets front, Biocon Biologics continues to expand the depth and breadth of its patient reach and has secured market-leading shares in several major countries for example, 74% for Trastuzumab and 86% for Bevacizumab in South Africa. We have seen strong demand for our insulin franchise, especially in Mexico and for Adalimumab and Etanercept in Saudi Arabia. We also had 15 new launches this quarter in the AFMET and LATAM regions including Bevacizumab and Pegfilgrastim in Saudi Arabia. These new launches will be a key driver of growth

going forward. And we've also seen an uptick in market shares across our self-led markets which are a strategic priority for us.

Now coming to the **financials** for the quarter. Biosimilar Revenue from operations was INR 2,182 crores, up 11% on a reported basis, but 19% on a like-for-like basis, adjusting for revenues in Q2 FY24 from the Branded Formulations unit in India. This growth translated into a Core EBITDA of INR 691 crores, growing 5% year-on-year and with a healthy margin of 32%. Reported EBITDA was INR 469 crores, which grew 4% and delivered a margin of 21%. Adjusting for the Forex impact of the appreciation of the Japanese yen against the U.S. dollar, EBITDA was INR 550 crore with a margin of 25%, reflecting the strong underlying profitability of the core business. We continue to invest in our pipeline with R&D spend at 6% of revenue to drive our mid- and long-term growth ambitions.

As mentioned in my opening remarks, a key highlight during the quarter was the successful refinancing by Biocon Biologics of the USD 1.1 billion or INR 9,347 crores in long-term debt through a combination of a USD 800 million bond issuance and a new syndicated loan facility on improved terms. This strategic financing has significantly strengthened Biocon Biologics midterm financial foundations and will help improve its liquidity profile, provide enhanced financial flexibility, and improve the opportunity to reinvest cash from operations into the business to drive growth.

The bond was listed on the Singapore Stock Exchange and was the first U.S. dollar-denominated bond issued by any pharmaceutical company in the Asia Pacific region and the largest high-yield debut bond issuance from India over the last decade. The issuance was 3x oversubscribed and witnessed robust participation from marquee global investors, a testament to BBL's investor confidence in its growth potential.

On the **regulatory front**, I am pleased to share that the U.S. FDA has classified Biocon Biologics drug substance facility at Biocon campus (Site 1) in Bengaluru, as a Voluntary Action Initiated or VAI. This inspection was held in February 2024 and pertains to the supplies of rh-insulin drug substance to the United States. The U.S. FDA also conducted GMP inspection at Biocon Biologics insulin manufacturing facility in Malaysia in September 2024. This included several Biologics manufacturing units and supporting infrastructure such as quality labs and warehouses. There were no observations related to data integrity, systemic deficiencies, or quality oversight at any of the units. We have submitted a comprehensive CAPA plan to the agency, and we are confident of addressing these observations expeditiously. We do not expect the outcome of these inspections to impact commercial supplies of existing products.

On regulatory filings, I am pleased to share that the European Medicines Agency, the EMA, has validated our regulatory filing for Denosumab, and we are now on track to complete filings in several other markets later this year. In August, Biocon Biologics, signed a settlement and license agreement with Janssen and J&J that clears the way to commercialize Yesintek, a Biosimilar Ustekinumab in Europe, the United Kingdom, Canada, and Japan upon regulatory approval.

Looking ahead, we remain focused on consolidating the business and leveraging our vertically integrated model and expanding global footprint to drive value for the organization. Our priority is working with the FDA to address their observations at our Bengaluru and Malaysia facilities, which would pave the way for several new launches in the U.S. in the near term. These new launches, coupled with product launches in other geographies, will serve as the key growth catalyst for both revenue and margins.

Research Services

Turning now to Syngene, our Research Services unit.

Syngene's performance for the quarter was broadly flat again, in line with both our expectations and previous guidance. Revenue from operations was down 2% on a year-on-year basis but grew sequentially by 13% to INR 891 crores. Reported EBITDA was down 5% to INR 261 crores with an EBITDA margin of 29%. Profit before tax at INR 137 crores was down 13% from last year. The performance in the second quarter was driven by a return to growth in Research Services, which benefited from multiple pilot projects in Discovery Services for both large and midsized biopharma clients, looking at China alternatives as well as sustained performance from the dedicated centres. There are early positive signs of recovery in Discovery Services with healthy interest from clients and increased request for proposals (RFPs) and on-site visits. Syngene successfully concluded over 60 audits in the first 6 months of the year, representing an increase of 36% as compared to the same period last year.

Syngene continues to add capacity and capabilities in Discovery Services at its Bengaluru and its Hyderabad campuses in areas such as Antibody-Drug Conjugates (ADC), Peptides and Oligonucleotides. In development and manufacturing services, Syngene continued to see good traction in its Biologics business and early-stage process development projects in its small molecules business. Delivery of both the early-stage projects and the pilot projects has been strong, which provides Syngene with now a solid foundation for the future growth. The repurposing of the Biologics manufacturing facility acquired in December last year, remains on track to commence operations in the second half of this fiscal. There are early signs of stabilization and improvement in the early-stage discovery market. There is momentum building from the pilots and with a strong third quarter underway, Syngene remains on track to deliver within its guidance range for the full year.

Novels Business

Turning briefly to Novel Molecules, I am very pleased to report that Bicara Therapeutics, U.S.-based clinical stage biotechnology company in which Biocon has a minority shareholding, successfully closed its initial public offering, its IPO in September this year and raised gross proceeds totalling USD 362 million. On its IPO, Biocon's stake in Bicara was diluted to 10.7%.

I will conclude now by saying that while the group's financial performance for the quarter and the half year has been relatively muted, we reiterate our guidance of a transition to acceleration and growth through the second half of the fiscal year. Business and operational trends are pointing in the right direction in Syngene, Robust momentum is being maintained in Biosimilars and new product launches are coming into line of sight for our Generics business. We are looking forward to an improved second half.

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

Q&A Session

Saurabh Paliwal: Thank you, Peter. We will wait a couple of minutes for the questions que to assemble. We will take the first question from Harith Ahamed from Spark Capital. Please go ahead.

Harith Ahamed: **My first question is on the reported revenues for Biocon Biologics, which is around INR 2,200 crores for the quarter and almost INR 4,300 crores for the first half. Will you be able to give an indication of the breakup of these revenues between U.S., Europe, and other markets?**

Peter Bains: Thank you, Harith. I will pass that over to Shreehas to respond.

Shreehas Tambe: Thanks, Peter. Harith, I appreciate that question. Since you are asking specifically about the comparison of the last quarter to last year quarter and then also about the split between the regions. I will have Kedar respond to that. So, Kedar if could kindly get into that detail.

Kedar Upadhye: Absolutely. So Harith, thanks for your questions. See, you should take roughly – I am giving you rough numbers, about 40%- 41% of the revenues are contributed by North America, about 34% by Europe and JANZ and balance 25% by Emerging markets. So that's a rough split across the regions in quarter 2. And that is sort of playing in a narrow band over various quarters of the current year.

Harith Ahamed: **Okay. And Kedar if you can provide the R&D spends at Biocon Biologics for the quarter. I could find the R&D spend at the consolidated level. But just for Biocon Biologics, if you could share that, that would be helpful.**

Kedar Upadhye: Yes. It is about USD 17 million Harith. That's about INR 140 crores for the quarter in Biocon Biologics.

Harith Ahamed: **Okay. And last one from my side is on the net debt movement quarter-on-quarter. In the first half, we received proceeds from Eris to the tune of around INR 1,100 crores. But despite that, there is an increase in net debt at a consolidated level of around INR 400 crores, I understand there is an outflow related to the deferred consideration to Viatris, but the number I am seeing is around INR 840 crores. So just trying to understand why there is such a high negative free cash flow during the first half.**

And in that context, how should we think about Capex given net debt reduction is a priority, shouldn't we be looking at moderated Capex spends? I see that number at around INR 900 crores in the first half.

Peter Bains: Kedar, do you want to pick that up on Biologics? And Sid maybe you can then pick it up on the Generics side?

Kedar Upadhye: Yes. I mean the Biologics net debt was tracking roughly USD1.3 billion till now. And as of 30th September, it's lower than that by about USD 50 million. So, the Biologics net

debt has improved. And Capex stays in the zone of about USD 90 million to USD 100 million for this year. And half of that is for maintenance Capex, half of that is on expansion for our insulin capacity in Malaysia, which has a strong business case considering the demand and pricing points that we have in all our global markets. So, I think the Capex for us remains at that zone at a predictable zone. But for the group, maybe Siddharth or Peter you can comment. Thank you.

Siddharth Mittal: At the group level, if you look at March 2024, the net debt was USD 1.35 billion, which has gone up to USD 1.4 billion as of September 2024. There is also some reclassification of debt from long term to short term. But of course, that doesn't change the overall number. But I think Kedar did talk about the Capex investments. Same is the case in Generics business where we continue to invest in some of the Capex projects, which are going on to support our investments, especially in the Peptide area. And we, of course, have taken steps such as refinancing the debt, which gives us immediate relief in terms of the cash repayment.

But in the operational cash from all the businesses, what support these investments, and these investments are required to show the growth. So, I think we would see free cash flows starting as you see the businesses grow and the Capex cycles go down.

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

Surya Patra: **My first question is about the regulatory update, what you had been for your Biologics facility in Bengaluru. In your opening remarks, you have mentioned that you were Bengaluru's drug substance facility now got VAI. So is it fair to believe that this paves the way for the approval for Bevacizumab, which has been pending since some time.**

Peter Bains: It is important that we clarify that very clearly. Shreehas, would you like to take that?

Shreehas Tambe: Thanks, Peter, and thanks, Surya, for the question. And I like the way you think. I am hoping that we move in that direction. But as Peter rightly pointed out, it is important to call out how these things have evolved. If you recollect, we had said that we are actively engaging with the agency, and we had met with them earlier in this calendar year. And following that meeting, we have seen inspections at 3 of our sites.

The inspection that occurred in February of this year was the inspection of our campus facility, which makes a recombinant human insulin drug substance for the United States and the outcome that we have just notified today is the outcome of that inspection, which is for the drug substance recombinant human insulin. The other 2 inspections were at different locations. Our site in Biocon Park Bengaluru makes Bevacizumab, the question that you asked. And you're right, that inspection outcome is waited for some time.

We did have that inspection in July, and we are looking forward to the agency giving us the outcome shortly. And this is a good outcome. I would take this the VAI classification of our Biocon Campus site as a good indication that there is confidence that the agency

has in our quality management system. But of course, we'll have to work on seeing how the subsequent outcomes play out, and we will keep you posted.

Surya Patra: **Is it possible to have some sense about the traction in the Biosimilar business, let's say, we have a pipeline of products. We have already Aspart as well as Bevacizumab that has been pending since some time, and now even the Stelara Biosimilar, that is also we have settled for commercialization in the fourth quarter this year. So given that, what kind of traction that one anticipates? Or what are the key catalysts, for your Biosimilar business considering 3-year timeline till FY27 that you do believe?**

Peter Bains: Thank you. Surya, that's a wide-ranging question and one that I think will be very pleased to answer based on the visibility of the pipeline that we have and an outlook in that time frame that would enable us to look at potentially 5 product launches coming up in the near to midterm. And you have picked on some. But Shreehas, perhaps you could expand a little bit more on that in that time frame.

Shreehas Tambe: Thanks, Peter. And Surya, you are absolutely right. You pointed out 3 products that are awaiting approval. That's in the very, very short term. We have a couple of more products in the horizon that you talked about. We are progressing very well. And I think the opportunity ahead of us is very exciting. We do not see any other biosimilar for Aspart at this point in time.

We have said in the past as well that the agency has clearly given an indication that there is no outstanding question on the science or the dossier at this point in time on Aspart. So, once we get past the inspection, we look forward to launching that product and bringing it to those in the United States. But it is important to point out that these products, both the Aspart and Bevacizumab have been approved by all other agencies, and we continue to grow market share for Bevacizumab in Europe.

So, we are very excited about the Oncology franchise in general. And we are looking to add Bevacizumab to our Oncology franchise in the United States as well. Stelara, as you have pointed out, the Biosimilar that we have developed is to be in the first wave of products that we launch in Q4 of this fiscal year. And once we have the FDA outcome, which we are expecting it to be positive, we will be looking to launch that product. And it is a sizable opportunity again. So, these 3 are, I would say, very near term.

Following this are the 2 other products that you just referred to. One would be Denosumab where we announced today in Peter's opening remarks and talked about the fact that EMA has validated our submission. And we should be in a position to be there at the time of market formation. So, I think that is really going to be putting us in a very strong position and driving growth for us in Europe.

Likewise, you have Aflibercept, which we will be looking to launch in mid of next year in Canada, even as we work through the process in the United States. So clearly, over the next 3 or 4 years, like you have outlined just now until '27, we have 5 or more products that are coming on. And let's not forget, there are several more geographies that we will bring these products to. So clearly, a very exciting time ahead for Biocon Biologics.

Surya Patra: **Sure, sir. With your permission, just can I ask 2 more clarifications. One, to Kedar. Kedar, if you can just clarify what is the kind of finance cost for the newly added debt? That is one. And with regards to Bevacizumab in the Europe, what is the target market size in Europe for Bevacizumab? These 2 clarifications I just wanted.**

Kedar Upadhye: Maybe, Shreehas, you can take the Beva question, and then I can answer the finance.

Shreehas Tambe: We will get back to you, Surya, specifically with the market opportunity on Europe specifically, but it is a sizable opportunity, which we will get back to you offline. Maybe we can respond on the finance cost.

Kedar Upadhye: Surya, we have issued the bonds with a 5-year tenure and the coupon is about 6.67% to be paid semi-annually. That is USD 800 million component of the whole USD 1.1 billion refinancing. For the balance, USD 320 million it is linked to SOFR, we have a spread of about 175 basis points. And both these initiatives are lower than what we would have paid on the current acquisition debt.

Surya Patra: **Okay. This finance cost is lower than the earlier one that you mentioned.**

Kedar Upadhye: Yes.

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

Neha Manpuria: **My first question is on the margin for BBL. We have seen a pretty decent improvement in BBL margins quarter-on-quarter, particularly given we have seen a significant market share expansion also. So, is it fair to assume that a lot of this market share expansion has not come at the cost of lower pricing? Could you give us some colour on the margins for BBL and how we should be thinking about full year core margins?**

Kedar Upadhye: Yes. So maybe I can go and then Shreehas you can add.

Kedar Upadhye: Neha, our EBITDA margins have been trending between 22% to 25%, depending upon the product mix and the SG&A pattern in each quarter. In the SG&A, the manning spend for the first 2 quarters is equal to what we spent in quarter 4 of last fiscal, which means the increment impact we have been able to absorb through efficiencies in the manning. That is one.

Outside manning cost, we are lower than the average of the Q2, Q3 and Q4 of last fiscal by more than 15%, which means the integration costs, consulting and many other spends that we have had, we have been able to optimize as we are running the business fully in our hands, right? So, these are the 2 things we have done on the SG&A.

On the gross profit, you are right that we have not seen too much of an impact and you could conclude that the growth has not come at the cost of pricing. And to some extent, whatever price erosion that we had estimated that has played out to that extent, not more. I would leave it there. But as an impact of all of this, the EBITDA margins are trending at that range. And there is no specific guidance that we want to give at this

point of time. But considering the business is stable and the mix of geographies and products stays at the current level, we are likely to sort of operate in that zone.

Neha Manpuria: **Understood Kedar. My second question is on Aflibercept. Given that the outcome of Amgen's patent litigation and a likely launch at risk, how does this impact the market opportunity for us depending obviously on our patent litigation outcome, any thoughts there?**

Peter Bains: Shreehas, will you take that?

Shreehas Tambe: Thanks, Peter. Thanks, Neha. I think clearly, we are watching this space as you are with a lot of interest. And would not want to speculate what a competitor would do and would not. So, at this point in time, we clearly look at some of the developments that are occurring in this space. It is a very attractive, interesting opportunity. It is close to USD 9 plus billion in sales, in innovator sales. There is a very strong position that we brought at this point in time. We have got a mixed judgment at this stage in the District Court level. And we are very confident in moving this with the options that we have got ahead of us. There is obviously going to be other developments that will keep happening around us. But it just tells you that there is a possibility that these things can be worked around and there will be a possibility where there could be an opportunity for all players. And we continue to remain very excited about it in the time ahead.

Neha Manpuria: **Understood. And at the moment, any guidance on timeline of the launch? I know, obviously, the litigation is ongoing, but your sense of what would be the best case.**

Shreehas Tambe: No, we do not have an indication of the timeline at this point in time, Neha. But as things evolve through the courts, we will keep you posted.

Neha Manpuria: **Understood. And, one last question. On Biosimilar for Stelara, Ustekinumab, given what's happened with Humira, one of your peers today commented that they could look at a similar sort of contract like they have done for Humira. Does that make the opportunity for Stelara tough in terms of us being able to get market share when we launched the Biosimilar? Or do you think there are some lessons we have learned from the Humira market formation that could make Stelara a little bit easier for us?**

Shreehas Tambe: Certainly, there are lots of learnings for the Biosimilars industry as well as the regulators and the customers, which is the PBM as well from what's evolved in the U.S. with the Humira Biosimilars. So, there is certainly a lot of learning. We've had our share of learnings as well. We continue to watch this closely, and there will be learnings as well as we go along with new products. We have a very high-quality product and a very strong commercial engine in the United States.

We've been very successful in the medical benefit space, as you can see, when Peter presented in his opening remarks, the market shares that we've got over the course of the last 1 year, where all the products that we brought to the market, both in the medical benefit space and in the pharmacy benefit space, are close to 1/5 and some of them

now trending towards a 1/4 of the market, which is a very sizable gain in terms of market share. So, some of these things will evolve.

Stelara Biosimilars will fall in the same pharmacy benefit space as the Humira Biosimilars. And we will be certainly looking to see how to play that game and how to win there. This will evolve over time, Neha.

Neha Manpuria: **But is it fair to assume that we will probably get better market share than what has happened in Humira as a starting point?**

Shreehas Tambe: That will always be the hope, certainly.

Saurabh Paliwal: We will take the next question from Damayanti Kerai from HSBC.

Damayanti Kerai: **My first question is on Humira Biosimilar, Adalimumab. Some recent industry reports suggest that Biosimilars share in the market has picked up to 20% plus compared to, say, low single-digit market share 6 months back. But that happened mainly on the Cordavis arrangement. So, I just want to understand how market is evolving. What are you hearing from payers, etc.? Because earlier, I understand you mentioned market will open up significantly starting next year and then maybe you will see a much better pickup. But whatever, I guess, market share gain we have seen so far that has gone to Cordavis. So, for a player like Biocon, what are the expectations there in terms of market share gain?**

Peter Bains: Perhaps Matt, you can answer that question for Damayanti?

Matthew Erick: Yes. Thanks for the question around that. Remember, as the timing with these payers in the United States, you're starting to see a progress in regard to Humira now not becoming the sole focus with the payers. So, we're anticipating that as you see the private labellers coming in, like you talked about Cordavis, we are seeing opportunities as we go into the next formulary opportunity where they're discontinuing or not being favourable to Humira. This puts Biocon in a unique position where we have contracts already in place, I don't want to forget that. And Humira is not on there.

We're seeing success where Humira is not part of the formulary and Biocon Biologics is there. We're seeing an uptick, and nice market share when this is happening. So, as we go into CY25 or even in through July of 2025, you are going to start to see the market open up, I believe, more for products like us. And remember, we are multichannel focused. It is not just commercial. There is also the Medicare, Medicaid, so we are seeing payers reaching out directly to us as they come up on their formulary rebids.

And we believe we're well positioned because of how we're established with our current sales force, our partners, and the ability to be able to capture that as we go into our next fiscal year. Thank you for the question.

Damayanti Kerai: **Sure, Matt. And if you can also comment on the pricing aspects. Are prices getting more competitive as market is more moving towards Biosimilars?**

Matthew Erick: I think you will see the market continue to have swings. It depends on the channel. But I believe within the next 12 months, you will see some settling of the pricing. But as you

know, this is a competitive market, and Biocon is well positioned to continue to compete. But I think it is making that point where we are starting to see some settling in the pricing, which will be good as we go forward.

Damayanti Kerai: **Sure. My second question is for Kedar. Kedar, my question is on the working capital status for Biocon Biologics as well as for the consolidated level. I guess, as per the recent releases, we see very little or almost like no progress in terms of receivables, inventory days. Can you comment on it when we can see some improvement coming in there? And also want to understand, was the inventory buildup whatever we have seen, is that mostly related to Viatris deal?**

Kedar Upadhye: That is correct. In fact, we have a plan, Damayanti, to improve the inventory position by about USD 100 million. So, between April 2024 and March 2025 in this fiscal 12 months, the target is to reduce inventory by about USD 100 million to several ways and means. And as the first half has got completed, we are doing good on that front. Inventory position has improved substantially compared to March. And receivable days are tracking at roughly 80 at a company level between all the 3 geographies. And we do not have any write-offs or any issues of that sort. And in fact, net receivables for our U.S. market, if you take account of all chargebacks, rebates, and reductions, are very minimal. So, if you adjust the gross receivables with chargebacks, rebates and other deductions, the net investment that we make in receivables for the U.S. market is very minimal.

So overall, working capital situation, in fact, is healthy. And offline, we can chat, and I can take you through some of the numbers. But between both inventory, receivables and payables, there is significant improvement that we are seeing, and we will continue on this path.

Damayanti Kerai: **Sure. And one last question from my end. Again, I think during the current quarter results, you mentioned you booked around USD 260 million exceptional income, which is related to liquidation of some inventory and then reversal of provision, which you have taken in last fiscal year. Of the remaining provision, how much of that can further see any liquidation? Or what do you think on the provisions which you have already created in there?**

Kedar Upadhye: So, if you recollect last year in December quarter, we had created about USD 28 million of provision under exceptional category because that inventory came during the acquisition. And out of that, about USD 3 million we have liquidated this quarter and underlying activity for packaging, relabelling, moving into other markets, that is on at a very brisk pace. I won't be able to give you one specific number, but we are focused on ensuring that eventually, there are no write-offs, or we don't have to destroy that inventory.

And as you go forward in December or March quarter, you will see some numbers getting booked in the same exceptional line. But focus is there. And as I mentioned, the underlying activity on moving it to different markets with different label, all that is continuing with a specific mini project of its own.

Saurabh Paliwal: We will take the next question from Palak Shah.

Palak Shah: **I wanted to check on the update on liraglutide filing with U.S. FDA.**

Peter Bains: Okay. Liraglutide for the FDA, Sid, can you address that one?

Siddharth Mittal: The liraglutide DMF, since you asked that specific question, the DMF was accepted by the FDA and the ANDA, which was filed for liraglutide is under review. We have made significant progress, and especially in the peptides, the key aspect that the FDA looks at is the API and the API efficiency letter or the DMF efficiency letter is clearly a big win for us, where they have accepted the API impurities and the characterization.
And as far as the drug product is concerned, this product was also filed from Biocon Biologics injectable facility for which, as we have discussed earlier, we are awaiting inspection outcome and the classification. And we expect the approval sometime in the next calendar year. And we are also including another CMO from Bengaluru, where we have taken a batch, and we will be including that site as an alternative site in the file.

Palak Shah: **And also, to Kedar. What is net interest cost reduction from this quarter onwards after the refinancing of the debt?**

Kedar Upadhye: The acquisition debt was variable linked, and the refinance debt is fixed for the bonds portion and variable for the syndicated facility. And as you can see that for the syndicated facility, there is a saving of about 15 basis points. Current loan was SOFR plus 190 to 195. The new one is SOFR plus 175. So, there is a 15 to 20 basis point savings there.

And if you compute the spread over SOFR, the new loan is linked to typically 5-year U.S. treasury. That's how the pricing of the bonds is done because you compare that with the tenure, which is 5 years. So, you can't compare exactly like-to-like, but one should assume that it will be a 20 to 30 basis point saving all in all.

Palak Shah: **Kedar in terms of rupee, that didn't save absolute number from this quarter onwards, is what I'm looking at.**

Kedar Upadhye: Yes. My suggestion, Palak, we should look at December numbers, and we will be able to quantify it better. Because our functional currency is rupee and there is a natural hedge, reported numbers may look different. So maybe from December quarter, we'll be able to track it better, Palak. Yes. But we are looking for reduction. Another thing we have been able to do, Palak is the issuance costs, the debt issuance costs have come down as well from the existing facility versus the new refinancing that we have been able to do.

Saurabh Paliwal: We will take the next question from Amey Chalke.

Amey Chalke: **The first question I have is there have been studies in the U.S. that says that the difference between the interchangeable Biosimilars and the normal Biosimilars or the non-interchangeable ones in terms of clinical outcome is not significantly different. So, if at all U.S. FDA makes this interchangeability redundant going ahead, what kind of market dynamics changes you see going ahead? And will it benefit player like us? Or do you think it would be detrimental considering the entry barriers could be low there?**

Peter Bains: Thank you, Amey. I mean I think the directional answer there can be seen through the lens of Europe. But let me ask Shreehas to pick that up with regard to the focus on the United States.

Shreehas Tambe: Thanks, Peter. Amey, I think that's a very fair question. This is interchangeability is a very U.S.-specific term. And I think that is getting ready to be taken off. We've always been of the view that any Biosimilar as approved should be used interchangeably. We've seen that happen in all globally. In Europe, it's been there forever. It's the case in Japan. It is the case in most of the other countries, except for the United States. And I think there has been an act of the Parliament, there's been an act now on the FDA. So there is obviously a lot of traction that the agency themselves are seeing because they believe that this is no longer a necessity to be used interchangeably. Once it's approved as a Biosimilar, it should be allowed to be used interchangeably. It does create an artificial barrier for Biosimilars and then barriers for affordability to patients and those in the United States, particularly.

So how does it impact us, which is the second question that you've got. And I think that is really a very important thing in terms of companies like Biocon Biologics, which have been at the forefront of developing these products. We've always been for access and expanding access. So, this plays very much to that objective. And we're very well placed to develop them because it doesn't mean that it will reduce the burden in any which way in terms of how the science is developed. What it will take off is the artificial barrier which was created for interchangeability. And I think that is good for the industry, for the patients and also for the company, particularly as well.

Amey Chalke: **Sure. And just basically, our investment for the product will go down, what you mean to say, but that might not have a major impact on the number of players there in the market.**

Shreehas Tambe: No, we do not think so because as I said, again, and I repeat, this is a very U.S.-only phenomena. So, people and companies were developing products anyway globally. There are examples like, for example, in insulin, we have been able to successfully work with them to even remove a clinical trial Phase III, but that has not overnight meant that you have been in a position to have more people trying to develop it because it's not just the clinical development that is what is important. It is also the ability to have the science to develop it through the labs. The clinical capabilities, but also the large manufacturing scale and most importantly, the commercial capabilities to bring it to the market. So, unless you are a fully integrated player and have all the levers, these things are actually going to work towards helping the patients and the industry at large.

Amey Chalke: **Sure. The second question I have is on the Generic side of the business. So Biocon Generic is almost getting around more than USD 300 million kind of sales or at least the quarterly run rate. Over the next 2 to 3 years, what could be the aspirational number here on the revenue side for the Generic side of the business? And apart from peptides, what else are there in the pipeline, which could help us achieve that?**

Peter Bains: Thank you. Amey, I will ask Sid to address that one, please.

Siddharth Mittal: Amey, I think we have given a direction that over the next couple of years, we are looking at mid-teen kind of growth. Of course, peptides being a major contributor within that growth coming from Liraglutide in the near term and Semaglutide opportunity opens up in many markets in CY26. And we're gearing up to file in some of these markets in the next calendar year. Apart from that, we have had many other OSDs, which have either been approved by the FDA and awaiting launch given the patent or the market formation. And third is our base business. As we have indicated that we have been impacted by pricing pressure and hence, volume and the demand. And we are working on cost improvement for many of our base products. And as and when we start realizing the lower cost, and we are going to go back to our customers and build back the volume that we have lost.

A combination of additional volumes with a better cost base on existing products, new launches and OSDs and in a few of the injectables, that we mentioned in the commentary, products such as Daptomycin, Micafungin and third and the most important being Peptides.

Amey Chalke: **Sure. Just last question I have on the Humira Biosimilar for the U.S. Are we thinking of doing a high concentration filing or that is not on the Board?**

Shreehas Tambe: Yes. So that is something that is certainly a part of our development plan, and we will update as things progress.

Saurabh Paliwal: We will take the next question from Jamsheed K. Please go ahead.

Jamsheed K: **Regarding Stelara Biosimilars, I know you have a settlement agreement in the last August regarding the launch in EU, Canada, and U.K. So, at this point of time, can you please provide any launch timelines in the respective territories like EU, Canada, and U.K.**

Peter Bains: Yes. I think I touched on that in the commentary, but Shreehas, you can build on it.

Shreehas Tambe: Launch timelines. Okay. We've been able to secure a launch upon approval timelines on these countries. So as soon as we secure approval, Jamsheed, we will be looking to bring these products to market. So, I think we've been able to negotiate a very good position, and we have already said what our launch date in the United States is going to be.

Jamsheed K: **Okay, one more question. We can see the originator Janssen has already different SKUs like prefilled pen and prefilled Syringes. So, at this point of time, did you have any plan of developing the prefilled pen or some auto-injector devices for the same? I mean Biosimilars?**

Shreehas Tambe: We have always believed in developing whatever is the product that we believe will be the dominant or the large share of the market. To our understanding at this point in time, Stelara in an auto-injector is not a product that they have launched or maybe if they have, then it has a much smaller market share in some markets. But we, of course, have the capability to develop all of it, and we will do that as and when that is needed.

Jamsheed K: **Okay. But one last thing, I know it is very early to ask. If you can provide any rough timeline for the autoinjector device?**

Shreehas Tambe: We will develop this and launch it as needed. We do not necessarily have a restriction on being able to launch the device or not. If we do get a device, we will be in a position to launch it.

Saurabh Paliwal: We will take the next question from Niraj Jain.

Niraj Jain: **My questions are regarding the Pegfilgrastim market. I would like to understand from the management, what are the ASP and competitive trends they see because of the aggressive pricing policy taken by Amgen for Neulasta? And number 2, recently, one of your main competitors have been facing supply chain issues. Has it worked in favour of Biocon that whether we have been able to take some market share because of the issues facing the competitor?**

Peter Bains: Thank you, Niraj. I think I will hand that to Matt to address, please.

Matthew Erick: Yes, sure. Thank you for the question. Just to give you the definition around ASP. As ASP declines for others, it doesn't affect other manufacturers. So, it is the reverse of what you would think in the Part D and the retail side. On the ASP, you control the ASP based on your rebates. And how it is been reimbursed, the ASP matters to the prescriber.

So, you first get contracts with the payers, then the prescribers look at the ASP and the ASP favourability from the prescriber standpoint, because of the way they're reimbursed, the highest one or the one that's the highest or the category in which there's other players on that higher ASP becomes something then that the health care provider would consider more than something that is declining. So, in this market, your ASP is individually to you as the manufacturer. So as others rebate or the ASP declines, it does not affect Biocon. And I think that is why you are seeing a lot of favourability as Peter and Shreehas both explained in regard to our market share, our ASP continues to be a strategic initiative for us and not just lowering it, but understanding the profitability and how it impacts the market.

As it relates to the secondary question, could you repeat that? I didn't quite hear the second part of it.

Niraj Jain: **Yes, sure. One of your main competitors in this market has been facing supply chain issues. So, like my point was that whether it has worked in our favour?**

Matthew Erick: Yes. Look, we are well positioned. Certainly, as other manufacturers have issues, we are here to supply. And certainly, as they continue to report that they are having these issues. We are getting more and more customers reaching out to us. So Biocon is well positioned and ready to fulfil those orders. And certainly, you're seeing our market share tick up. A lot of that is through our strategy. But as the competitor continues to have those issues, we're in a great position to capture more additional share at the right price points. Thank you for the question.

Saurabh Paliwal: We will take the next question from Naman Bagrecha.

Naman Bagrecha: **Just one question for Shreehas. Shreehas, given that our Malaysia facility is not yet cleared by U.S. FDA, have we kind of lost the contracting cycle for Aspart as well for CY '25 and Aspart could now be CY '26 opportunity?**

Shreehas Tambe: At this point in time, we are still looking to see at what time we get that approval. The 2 things to remember, Naman, one, is the contracting cycle as you rightly pointed out, will be in that July to October time frame. So certainly, it is coming towards the end of that time horizon that you look for the subsequent calendar year. But the important piece to remember is that there isn't any other Biosimilar for Aspart at this point in time. So, while it would be true typically for most products where you have options and the payers and PBMs could look for alternatives and they could tie up. Here, it is a very unique situation that would still keep the opportunity available.

It may not be the full year if it is a little delayed. But it does create an opportunity for us to reach out to customers to see if there is an interest and to our understanding at this point, there's a lot of interest in looking at Biosimilar Aspart at whatever time it gets approved. So yes, we continue to remain excited about it. We are actually looking forward to seeing as the approval coming through as soon as possible.

Naman Bagrecha: **Okay. But let's say, today we are in 30th October and the approval comes, in 2 days, given that Malaysia facility also needs to get cleared, but this opportunity will be CY26, right?**

Shreehas Tambe: No. I think what I was saying is that you would do it in '24, July through October'24 for 1-1-25 through December 2025. And given that you are at the end of it, you would probably then miss out if you had competition. But given that Aspart, you don't have any other Biosimilar even if you are outside of that window, you will have some opportunity in 2025 also, assuming you get that approval soon.

Naman Bagrecha: **Can you help me in terms of, let's say, timelines, of what would be your best-case scenario by when can we get the facility cleared and once the facility is cleared, how many weeks or months will it take for us to launch the product?**

Shreehas Tambe: Yes. I mean it is a great question. It is a little bit of an exercise in a hypothetical, Naman, at this time because we can't really speak on behalf of the agency. There are, of course, defined framework in terms of how the agency operates. We have responded to all the observations. As you know, we were given an OAI status earlier this year and the inspection was conducted, so we have responded to that and the CAPAs are with them because they came back for an inspection.

We will look to get a positive outcome out of that inspection like we have just got a VAI status, which is a positive outcome for the India facility, which makes the rhi drug substance. Hoping that we get a similar outcome in Malaysia as well. It would then allow us to respond to the CRL and then get the agency to approve it because that was the only open item that was outstanding at this point. So, it is a little bit of an exercise, as I

said, in the hypothetical, but we would be talking about a few months, not several quarters in the mix if the approval is right.

Naman Bagrecha: **And one question to Sid. If you could provide me the net debt number, I missed in the earlier comments. Net debt for Biocon consol including the structure that we had done. And similarly, the net debt for Biocon Biologics, if you could please?**

Siddharth Mittal: The net debt for the group is ~USD 1.4 billion and in Biologics as of September is USD 1.2 billion.

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

Tushar Manudhane: **I joined late, so maybe these questions have been repeating. Just wanted to understand this as far as Biocon Biologics, the core EBITDA margin has improved, let's say, quarter-over-quarter. So, if you can throw some light there first?**

Peter Bains: Sure, Tushar. We did cover it. But Kedar, maybe you can explain again, please?

Kedar Upadhye: Tushar, it will be difficult to point one specific reason for the improvement in core EBITDA. As you know, core EBITDA is derivative of your geography mix, your product mix, your pricing strategies, your inventory movements, and things like that. So, I think it's still in the zone. It's about 32% like what we highlighted on the slide.

Tushar Manudhane: **And despite improvement in core EBITDA and subsequently reduction in R&D, we see the EBITDA margin still lower quarter-over-quarter. So, the Opex, which has increased, say, quarter-on-quarter, is that the number to look for on an ongoing basis as far as Biocon Biologics.**

Kedar Upadhye: Yes, Tushar. Opex is part of core EBITDA in the sense that core EBITDA reported is after the Opex. So that is not the reason. I think you should adjust the yen-related mark-to-market loss that we had to book this quarter because of a sudden and sharp appreciation in the dollar-yen, which after September has weakened again. So, some of the mark-to-market that we have booked might potentially reverse. But obviously, we would not be able to quantify that now. But if you adjust that, we are at 25% EBITDA, Tushar.

Saurabh Paliwal: We will take the next question from Yash Darak.

Yash Darak: **I missed the average cost of debt for the USD 300 million syndicated loan, if you could just take the same?**

Kedar Upadhye: That is that is about SOFR plus 175 basis points. So, depending upon the average 3 months SOFR, it could vary. But currently, it is around 6.75%.

Yash Darak: **And secondly, if you could just guide on the revenue growth over financial year 2024 total consol revenue, where could we see ourselves at the end of the financial year 2025?**

Peter Bains: Yash, we do not give quantitative guidance in that regard. I will repeat the guidance that we have given, which is that we are looking at a transition to accelerated growth in the

second half. And as I advised in the opening remarks, that is coming from restored growth in Syngene behind the momentum that we are seeing in Discovery and Research Services and large molecule manufacturing. And we have seen the really good momentum in the Biologics business, led by the market share gains in the United States with the key products. And as Sid has explained, we have line of sight now of liraglutide launch in the United Kingdom and some other injectable formulations before the end of the year, which will underpin a turnaround and a return to growth in the Generics business. We are looking at a year of 2 halves, where the first half was relatively muted, notwithstanding the biologic's performance, which has held up very strongly. But looking with all 3 now cylinders of the engine to pick up over the course of the second half of the year.

Saurabh Paliwal: We will take the next question from Kapil Agarwal.

Kapil Agarwal: **This is regarding that is there any plan to raise equity by diluting stake in Syngene or BBL to repay the debt?**

Peter Bains: Kapil, I think as we have said, reducing the debt is a priority. We have taken measures to restructure the debt, but we would also indicate that we are going to look to reduce it. And we have many levers to explore on that. We are. And I think you can expect to see us act before the end of the fiscal, but we will determine which instrument, which opportunity we use as we progress through the year.

Kapil Agarwal: **And one more question regarding that there is some clause for Viatris, we can say that there will be some IPO for BBL. Any timeline or when we can expect the IPO of BBL, something. Any we can say guidance over on it?**

Peter Bains: Kapil, I will make a comment, but I invite Shreehas also to comment. An IPO clearly remains an option for the BBL business. But the timing of that will be when it's right and that will be a combination of many factors, the market factor, the business momentum and so forth. It is clearly something that we have as an option, and it is clearly something that we will be tracking, but we will only do it when the circumstances are right to achieve a very successful IPO.

Saurabh Paliwal: We will take a follow-up question from Surya Patra.

Surya Patra: **My first question here is about the R&D spend. We have seen both for BBL as well as for Biocon, we have seen a kind of a meaningful reduction on a sequential basis as well as Y-o-Y on the R&D spend side. So now at this level of INR 200 crores, it is around 7% of the ex Syngene revenues. Is this is the kind of a run rate that one should think going ahead, given the kind of margin pressure that we are witnessing? Or and at this level, whether our developmental projects can be easily managed and covered with this kind of spend rate?**

Peter Bains: Shreehas. I think that is aimed largely at Biologics, maybe you can address that.

Shreehas Tambe: Thanks, Peter. I think, Surya, the spend that you see at Biocon Biologics level, we would term that as an investment in R&D is we need to look at it as a spend that is in the range. We had said at the beginning of the year as well that it would be in that 7% to 9%

of revenues. And so, we are tracking probably towards the lower bound, but we are very much in the range that we had guided for. And we intend to stay there on a full year basis.

On a quarterly basis, you would see some variance depending on which stage of development, the R&D programs are in. But other than that, we don't see any major change on that aspect. And since I have you back on the line, we looked up the numbers on the European opportunity for Bevacizumab, that is about USD 1.2 billion as reported by independent databases.

Peter Bains: Surya, let me also just add a point of emphasis to Shreehas's response. It is important to understand that R&D spend is not a constant. It reflects the investment behind assets at different phases of their development and not all phases carry the same cost. So, it is perfectly natural for R&D spend to move within a range as you build and evolve and progress your pipeline. So as Shreehas said, we would expect our R&D spend in Biologics to work within that kind of a range, 7% to 9%.

Surya Patra: **Sure. Yes. My second question and last question is about the Generic small molecule business. So here, in fact, when we have been only focusing more about APIs. We have been seeing a kind of decent margins there. Of late, we have seen a kind of a moderation there. While we are anticipating a kind of mid-teens growth led by various initiatives that we are taking. So how should we think about the profitability and the margin trending, let's say, over the next 1- or 2-year period? In fact, we are now having integrated operation, both API as well as formulation in the market like U.S. and all. Despite that, the profitability or the margin profile has squeezed in the recent period. Any outlook or sense on this would be helpful.**

Siddharth Mittal: Surya, of course, profitability has been impacted by the pricing pressure as we have indicated in the past and also during the quarter. As you can see that the majority of our revenues are coming from U.S., unlike many other competing companies, where it is well spread out to other geographical parts of the world, including India, which is a branded business with high margins. But we are quite dependent on the U.S. at this time. And that's why we keep emphasizing on our regional expansion that over a period of time, we would have revenues come from other parts of the world.

Now coming back to U.S., yes, we continue to see pricing pressure, both on our formulation business as well as API, which are being sold to the U.S. customers who are also facing pressure. Now we do expect as I addressed earlier, some of the cost improvement plan, the benefits of these starting to realize, which will not only allow us to regain some of the lost business, but also improve the profitability on the existing products, plus the new launches, of course, it is all finally dependent on the competition that the products that we launch, if it is highly competitive, the margins are going to be probably on an average similar level as current margins.

But if we do have less competition for some of the molecules that we are going to launch, then we could see a margin improvement. But directionally, the revenue growth that I indicated will come with better margins, but it will be difficult to quantify that what those margins would be, given the still many variables out there.

Surya Patra: **Okay. Sir, just one more question about your earlier response to the similar point that you have indicated about cost optimization program for the Peptide products, which will benefit. What is the kind of competitive situation that you are anticipating here? And secondly, on the new Tacrolimus facility, what is the update and what is the kind of a ramp-up, when the real ramp-up that one should anticipate and expect?**

Siddharth Mittal: We just got approval from the European regulators sometime back, we also got the EIR from FDA. And we are currently maxed out in Bengaluru as far as the Tacrolimus is concerned. We would be catering to additional volume from Vizag. We are talking to various customers. We have also secured new customer contracts where once the customers ANDAs are updated, we will start supplying products. And Tacrolimus is not the only product. There will be other immunosuppressants which will be manufactured in Vizag. So that is all part of the mid-teen kind of growth, which I indicated, it is all factored in there. Of course, nothing in the near term because we just got the EIR, and our customers are updating their ANDAs. So, for meaningful revenues to start, it would be more end of next half or more in FY26.

As far as the competitive landscape is concerned, the market is still forming up. We are looking at few approvals, which are already in the public domain in Europe. There is only one approval other than the authorized Generic in the U.S. So, I think it will be quite speculative for me to say how things would be because there is still some time for the launch, especially in the European countries, and we will have to see how the market pans out there.

Saurabh Paliwal: Thank you, Surya. We are coming towards the end of the call. I will request the balance participants, which are 2, to please keep the questions short. We will take next question from Rumel Dahiya.

Rumel Dahiya: **The management would very kindly agree that Biocon has been probably one of the greatest wealth destroyers over the last 5 years for the investors. When do you think the investors can expect improved profitability and some kind of a relief from this continued poor financial performance from the company.**

Peter Bains: Obviously, we would not agree with you. We have been investing behind building what we believe can become very globally competitive businesses. Syngene has already established that credential with the acquisition of Viatris and the consolidation of that business. We are in the top 5 in the Monoclonal antibodies. And the Generic business, while small, has achieved very significant market shares in its chosen areas.

Of course, we understand the financial pressures that we are under, and we are working on that. And of course, we keep in mind our investors and the desire that we have to give them a very competitive return on that investment. Of course, we realize we have much more to do to deliver on that. But I want to assure you that we are all working to that end.

Saurabh Paliwal: Thank you, Peter. We will take the last question of the day from Harshit Dhoot.

Harshit Dhoot: **Just a couple of questions. First is, what's going wrong with the plants, the Bengaluru and Malaysia. Bengaluru is stuck from last 3, 4 years; Malaysia from last 4, 5 years. What is exactly going wrong from the regulatory front here?**

Peter Bains: Harshit, I think I'll start. But again, Shreehas, you can add, I'm sure more detail. Well, clearly, what's not right at the moment is the 2 CRLs, and we've given quite extensive explanations of the characterization of those, the responses that we've put in and the work we are doing with the United States FDA to progress that to a satisfactory conclusion. But I think it would be proper to say there is a lot that is still right in those facilities. I mean we have comprehensive approvals from many other agencies and have had over very many years. I think it would be improper to say that there's something fundamentally wrong. There are challenges that we are working to overcome in those, but we see them as surmountable challenges that we are working on and behind that we are reassured that the quality of those facilities has been approved by many other recognized global health agencies.

Shreehas, you may want to build on that.

Shreehas Tambe: No, Peter, I think you summarized it well. And Harshit, I think Peter's response is quite holistic. There are several agencies around the world who continue to improve the facility. There is a lot of confidence in the quality management system overall. And even for the United States, we continue to supply product from these very facilities as the market shares that we talked about, these come from the very facilities that we are discussing.

I agree with Peter when he says that there's nothing fundamentally off here. We have never had any of these systemic noncompliance issues. But the fact is we only acknowledged that we have to get over the hump, and we are working very hard to do that. We met with the agency. We had a very transparent conversation with them. And you are seeing that there have been inspections which have followed, which had stopped post-COVID. And we've been able to accelerate that.

We will have to work with them collaboratively, which we are doing. And we believe that we will find success. We believe the first one with VAI classification for the India Campus site for the recombinant human insulin drug substance is a good beginning, a good start. It brings in some confidence. And we're looking forward to seeing how we can build on that. But we will continue to work with the agency. We are confident that success will eventually be ours sooner than later.

Harshit Dhoot: **Shreehas, every year, we get some convincing argument from the management regarding the clearance of the plants. But we know that we are getting approvals from other agencies, but main opportunity lies in U.S. FDA, right? It's a long time. So how should we get the confidence here?**

Shreehas Tambe: U.S. is a large opportunity in a large market. But Europe is a large opportunity in a large market, too. And so, I would not discount the others. That is not to say that the U.S. is not important, and we continue to work on it. Our revenue split, which Kedar explained to you is more or less evenly split with U.S. being at 40%. The other 2 geographies that roughly 30% each, broadly speaking. But the U.S. is important. And regardless of that, I

think, as I said, Harshit, it is not about every year we hear this. It is more about every inspection, we learn something. Aseptic processing is something that the agency has looked at very differently post-COVID. We are working with them to see how best we can address it. We have brought in global consultants to do that. We have also brought in folks and experts who used to work for the agency at some point in time to see how we can better adapt to that learning. I know it can be frustrating and it can be very difficult sometimes to see how these things evolve. Believe me, it is very frustrating for us as well. But we are committed to this, and we will continue to work with it before making sure that we get to that finish line sooner than later.

Harshit Dhoot: **Yes, because the main story lies for the Biocon Biologics business in these only because anyways, we are still struggling to ramp up the market share in the Humira also. Let's see when we will get the clearance of these plants. And second question is on the Generics part, Siddharth. You said the liraglutide filing, Sacubitril, Valsartan. If I am not wrong, everyone is chasing the liraglutide, right, and probably in every market. So how big this opportunity can be? And the second thing for the Sacubitril, Valsartan, are you manufacturing API on our own? Or are we buying it from someone else?**

Siddharth Mittal: So let me answer the second one first. Yes, we are manufacturing the API on our own and as also the formulation. We, of course, by the intermediates separately from our KSM vendors, including Valsartan, which we buy. Coming to your first point, liraglutide is still a global USD 3 billion opportunity. Of course, there is a huge shift of patients to Semaglutide, which is almost now between USD 40 billion and USD 50 billion opportunity.

As far as Lira is concerned, what you see today is not what we believe is the true representative of the demand because it is not fully serviced given the focus has moved to Semaglutide, and we definitely see with Generics coming in an opportunity to expand the volume at the right price. And as far as what you said that everybody is chasing this market, but very few have been able to get the approval. I think Peter did allude to the fact that we've got our success was seen when we were the first company to get the approval for Generic liraglutide in the U.K., and that was the first liraglutide approved as Generic product anywhere in any major market. And I also mentioned that we got our DMF sufficiency letter in the U.S., which was again the first company to receive so. There have been many other filers in the U.S. who had filed way ahead of us and they have not been able to achieve this landmark.

We definitely think we are very well positioned. We are also one of the very few vertically integrated companies on the peptides, we do our API, both recombinant route and synthetic route. We do our own formulation. And we, of course, have vendors who have designed different devices for us. So, we are very well positioned to capture the opportunity. But again, I think the whole investment in peptide is what we should look at broadly because this is USD 3 billion small, but in the years to come, there are many, many more attractive opportunities which open up.

Saurabh Paliwal: Thank you, Harshit. That was the last question for this call. Thank you all for joining us today. If you have any further questions or any clarifications, please do get in touch with us. With this, I would like to wish a very happy Diwali to you all and to your families, and we will see you next quarter. Have a good night.

Peter Bains: Happy Diwali everyone.

-Ends-

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