



# Meta morphosis

Biocon 5.0

## **Biocon Limited Q4 & FY23 Earnings Conference Call Transcript**

*May 24, 2023*

## Speakers and Participants from Biocon Limited and Biocon Biologics Limited

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- ✦ **Dr. Kiran Mazumdar-Shaw** – Executive Chairperson, Biocon Limited
- ✦ **Mr. Siddharth Mittal** – CEO & Managing Director, Biocon Limited
- ✦ **Mr. Indranil Sen** – Chief Financial Officer, Biocon Limited
- ✦ **Mr. Shreehas Tambe** – Chief Executive Officer & Managing Director, Biocon Biologics Limited
- ✦ **Mr. M.B. Chinappa** – Chief Financial Officer, Biocon Biologics Limited
- ✦ **Mr. Abhijit Zutshi** – Commercial Head - Global Generics, Biocon Limited
- ✦ **Mr. Nehal Vora** – Commercial Head - Global API, Biocon Limited
- ✦ **Mr. Susheel Umesh** – Chief Commercial Officer – Emerging Markets, Biocon Biologics Limited
- ✦ **Mr. Matthew Erick** – Chief Commercial Officer – Advanced Markets, Biocon Biologics Limited
- ✦ **Mr. Sibaji Biswas** – Chief Financial Officer, Syngene International
- ✦ **Mr. Saurabh Paliwal** – Head - Investor Relations, Biocon Limited

## External Participants during Q&A session

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- ✦ **Cyndrella Carvalho** – JM Financial
- ✦ **Damayanti Kerai** – HSBC Securities
- ✦ **Harith Ahamed** – Spark Capital
- ✦ **Neha Manpuria** – Bank of America Securities
- ✦ **Nithya Balasubramanian** – Sanford Bernstein
- ✦ **Nitin Agarwal** – DAM Capital
- ✦ **Prakash Agarwal** – Axis Capital
- ✦ **Ishita Jain** – Ashika Group
- ✦ **Sandeep Joshi** – Individual Investor
- ✦ **Shyam Srinivasan** - Goldman Sachs
- ✦ **Surya Patra** – Phillip Capital
- ✦ **Tushar Manudhane** – Motilal Oswal Securities

## Prepared Remarks Session

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### **Saurabh Paliwal:**

Good morning, everyone. I'm Saurabh Paliwal from Biocon Investor Relations team, and I would like to welcome you today for the fourth quarter and full year ended March 31, 2023, earnings conference call. I would like to indicate that all participants are in the listen-only mode, and you'll get an opportunity to ask questions once the opening remarks conclude.

Should you have any questions, please select the raise hand option under the reactions tab on your Zoom application. During the Q&A session, we will call out your name, unmute your line, and enable you to ask a question. When asking a question, please begin with your name and your organization.

Please note that the chat box has been disabled for this conference call, but you can raise any technical concerns by sending us an email at [investor.relations@biocon.com](mailto:investor.relations@biocon.com). I would like to also bring to your attention that this conference call is being recorded. The recording will be made available on our website within a day, and the transcript will be made available subsequently.

Today, to discuss the company's business performance and outlook, we have Dr. Kiran Mazumdar-Shaw, our Executive Chairperson; Mr. Siddharth Mittal, CEO and Managing Director of Biocon Limited, along with senior management colleagues across our business segments, including Generics, Biosimilars, and Research Services.

Now, I would like to allude to the safe harbor related to this conference call. Comments made during this 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 future results, performance, or achievements to differ significantly from what is expressed or implied by such forward-looking statements. At the end of this call, if you need any further information or clarifications, please feel free to reach out to us. With that, I would like to turn the call over to our Chairperson for her opening remarks. Over to you, Kiran.

### **Dr. Kiran Mazumdar-Shaw:**

Thank you, Saurabh. Good morning, everyone.

**Let me start with a high-level summary for FY23.** Biocon has delivered a total revenue of ₹11,550 crores, a growth of 38% over FY22. All business segments contributed to the growth with operating revenues in Biosimilars growing 61% to ₹5,584 crores, Research Services by 23% to ₹3,193 crores and Generics by 13% to ₹2,637 crores.

The year gone by saw the completion of the landmark acquisition of Viatrix' biosimilars business which has contributed to the year's growth. In fact, Q4 reflects the full contribution of the Viatrix acquisition. This strategic investment, we believe, will accelerate our journey to global leadership as a fully integrated biosimilars player.

Syngene delivered a strong performance led by its manufacturing services business, which includes the signing of a 10-year biologics manufacturing agreement with Zoetis, expected to be worth around US\$500 million over the contract period.

The Generics business continued its geographic expansion initiatives with strategic partnerships across markets. FY23 marked the launch of products in a few ex-US geographies such as the UK and other emerging markets. And this coupled with a strong performance in the base business contributed to the segment delivering 13% year-on-year growth. Investments in R&D and Capex towards a pipeline of complex products including peptides and oncology molecules are expected to play out positively in the coming years.

Sustainability is integral to Biocon's business purpose. The company continues to develop a progressive agenda for its ESG practices in alignment with stakeholder expectations as well as of course the company's objectives. Our efforts continue to receive global recognition reflected by our improving scores from leading global sustainability indexes. Biocon improved its score in the Dow Jones Sustainability Index over 2021 from 45 to 52 and based on this performance, we were inducted into the S&P DJSI's prestigious annual sustainability yearbook under the industry mover category. Biocon was also awarded a Silver Medal by EcoVadis for its sustainability accomplishments.

It has certainly been a transformative year for the Biocon Group. All three business segments are at an inflection point and poised for significant growth in the years ahead.

**Let me now come to the Viatris biosimilar business acquisition.**

The integration of the Viatris biosimilars business is progressing well. Viatris continues to provide commercial and other transition services to Biocon Biologics as part of a transition services agreement. We remain on track to integrate a major part of the acquired biosimilars business, region-wise, in a phased manner during FY24.

**Net Debt reduction** - As far as net debt reduction is concerned, we continue to work towards reducing our net debt. As of December '22, Biocon had a consolidated net debt of US\$1.9 billion. Since then, net debt has been reduced through the following events. US\$270 million was brought in through the stake sale in Syngene, US\$130 million investment by Kotak, US\$150 million conversion of loan in BPL to equity in BBL by Serum, and US\$98 million investment by Edelweiss. Post these investments, the net debt has been reduced by US\$650 million to a level of US\$1.25 billion excluding, of course, structured investments.

Whilst the present debt level can be comfortably serviced, we plan to raise additional equity at the BBL level during FY24 to provide us flexibility for any business development opportunities.

Now coming to the financial highlights, first for Quarter Four and then the Full-year FY '23.

**Let me start with the Q4 numbers.**

At the group level, total revenues for the quarter was up 59% year-on-year to ₹3,929 crores.

The Biosimilars segment revenue more than doubled on the back of the acquisition of Viatris' biosimilars business, with Q4 reflecting the first full quarter of consolidation. Research services grew 31% while generics remained flat. The total revenue also included ₹109 crores of the stake dilution gain in Bicara, pursuant to their Series B fundraise.

Core EBITDA grew by 56% to ₹1,260 crores, representing continued healthy core operating margins of 35%.

R&D spend stood at ₹342 crores, which is an increase of ₹152 crores for the same period last fiscal, and it corresponds to 12% of revenues ex-Syngene.

EBITDA for the quarter was up 75% to ₹1,152 crores versus ₹659 crores in the same period last year. EBITDA margins stood at 29% as compared to 27% for the same period last year.

Depreciation, amortization, and interest increased by ₹389 crores over last year and this is primarily related to the biosimilars business acquisition cost.

Consequently, profit before tax and exceptional items stood at ₹500 crores up 30% year-on-year.

Net profit for the quarter excluding exceptional items stood at ₹335 crores versus ₹262 crores in Q4 FY22 up 28% year-on-year. It must be highlighted here that there is an impact of higher minority interest due to stake dilution of

Biocon shareholding in both Biocon Biologics and Syngene in the consolidated results.

### **Now coming to full-year numbers**

Total revenue for FY23 was up 38% to ₹11,550 crores.

Revenue from operations in Biosimilars, Research Services and Generics were up 61%, 23% and 13% respectively. The total revenue includes ₹217 crores of stake dilution gain in Bicara pursuant to their fund raise during the year.

Core EBITDA was up 43% to ₹3,807 crores, representing core operating margins of 34% versus 32% last year.

Now I come to R&D spends for the full year, which were at ₹1,119 crores. A big jump over ₹524 crores last fiscal, representing 14% of revenues exceeding. We also recorded a Forex loss of ₹160 crores in FY23 as compared to a gain of ₹58 crores during FY22.

EBITDA for the year was up 32% at ₹2,888 crores versus ₹2,183 crores in the same period last fiscal, with EBITDA margins at 25%.

Profit before tax and exceptional items stood at ₹1,189 crores, which is up 9% year-on-year. The growth in PBT is not commensurate with growth in EBITDA due to additional depreciation, amortization and interest charges primarily related to the biosimilars business acquisition cost.

Consequently, net profit for the year before exceptional items stood at ₹787 crores versus ₹722 crores in FY22 which is still up 9% year-on-year.

For the full year FY '23, there were exceptional items amounting to ₹324 crores net of tax and minority interest as compared to ₹74 crores last fiscal. These include deal related expenses of the Viatrix transaction and a MAT credit balance charge as Biocon decided to adopt the new tax regime of 25%. As a result, net profit stood at ₹463 crores.

Let me now turn to the segmental business performance during the quarter.

### **Let me start with Generics.**

The Generics segment reported an operating revenue of ₹717 crores for the quarter, similar to Q4 last fiscal. Profit before tax stood at ₹75 crores. For the full-year, the Generics segment recorded an operating revenue of ₹2,637 crores, delivering a growth of 13% year-on-year, which is in line with our guidance. Profit before tax stood at ₹264 crores with PBT margin at 10%, in line with last year.

Now coming to the key highlights for the Generics business.

- Q4 performance was driven by API immunosuppressant sales, as well as growth in the base business of generic formulation products in the US, as well as certain new product launches.
- Margins were lower compared to previous year, mainly due to price erosion in our base business products, particularly Statins.
- During the quarter, we secured four product approvals, one each in the US and EU, and two in emerging markets.
- On the regulatory front, our API manufacturing facility in Bengaluru underwent an EU GMP inspection in February with no critical or major observations. And most recently, last week, the US FDA concluded a pre-approval inspection for site 3 located at Hyderabad, Telangana with no observations.

On a full year basis, the business recovered from a muted performance in FY22.

- Growth during the year came from API sales, again from immunosuppressants and specialty APIs, as well as generic formulations, where a higher volume market share of products launched in FY22 contributed to revenue growth.
- During the fiscal, we had 32 filings and received 19 approvals for our generic formulation products across US, EU, UK, and emerging markets.
- We continue to focus on the enhancement of our manufacturing capacities and capabilities throughout the year. Our facility in Vizag for immunosuppressants and peptide facility in Bengaluru were commissioned during FY23, with validation batches at both sides expected to be completed by the first half of FY24. We are also investing in a new injectables facility, as well as expanding our largest scale peptide, synthetic, and non-immunosuppressant API manufacturing capabilities.
- To reduce costs and development timelines, various cost improvement initiatives and projects were undertaken and the benefits of these are expected to accrue in the quarters ahead.

In summary, FY23 has been a good year for the Generics business, backed by cost improvement initiatives, strategic partnerships, and product approvals.

**Now coming to the biggest segment in our consolidated financials, which is Biosimilars.**

Q4 is the first full quarter with consolidated financials from our base and acquired Biosimilars business, representing the new reference point for Biocon Biologics as a fully integrated enterprise. Biocon Biologics recorded revenues of ₹2,102 crores for Q4, ending the year on \$1 billion dollar trajectory as per our guidance.

Core EBITDA, which excludes R&D, forex, licensing income and MTM on financial instruments was at ₹742 crores with margins at 39%, demonstrating continued healthy profitability post consolidation of the acquired business.

EBITDA was at ₹573 crores with a margin of 27%.

Depreciation, amortization, and interest pertaining to the acquisition impacted the quarter's profit before tax, which stood at ₹152 crores, which is up 5% year-on-year.

Moving to the full year performance, Biocon Biologics recorded revenues of ₹5,584 crores in FY23, a year-on-year growth of 61%.

Core EBITDA for the year was at ₹2,216 crores, up 68%.

Net R&D spend for the year was at 16%, which is higher than our guidance of 12% on account of the closing timelines of the Viatrix transaction. I might remind you that we concluded this deal at the end of November. We had expected to conclude it a little earlier, but this has impacted the R&D spend in terms of percentage of revenues. The R&D spend we expect will normalize to around 12% in the coming quarters.

Subsequently, EBITDA for the year stood at ₹1,338 crores, which is a 32% year-on-year growth. And profit before tax and exceptional items was at ₹403 crores, which factors in acquisition-related amortization and interest costs, which actually amount to ₹379 crores.

Let me also share some highlights, starting with our vaccines' collaboration with Serum.

We have restructured our original equity structure with Serum under the strategic alliance announced in September 2021. As for the new arrangement, BBL will have access to 100 million doses of vaccines annually, together with distribution rights to Serum's vaccines globally, without any assured revenues and EBITDA. BBL will no longer be issuing the 15% stake to Serum, thereby increasing Biocon's stake in BBL. Serum will now have an aggregate equity

investment of US\$300 million in BBL.

Moving on to business performance.

- We continue to see a strong performance of our biosimilars globally.
- There were more than 35 launches in FY23, increasing the depth and breadth of our reach.
- In the US, Fulphila or Pegfilgrastim achieved a 14% market share, growing from 11% in December. Ogivri continues to maintain its 10% market share, and our biosimilar insulin Glargine's market share has improved to 12% in-line with the new prescription trends or the NRx's trends observed in the prior quarter.
- There is a strong interest in the upcoming launch of Hulio backed with its performance in Europe, which will be a key growth driver in FY24. In Europe, Fulphila, Ogivri and Hulio continue to experience improvement in performance. For instance, in France, each of these products have more than 10% market share. Our Canada franchise continues to be robust with Ogivri having a 35% market share. Hulio, which was recently launched in Canada has already attained a market share of 6%.
- We continue to see strong demand in demand in our emerging markets business driven by a growing portfolio coverage and several new launches. Through our partners we have won tenders for Glargine in Mexico, Trastuzumab in Belarus, and Bevacizumab in Algeria.
- On the regulatory front, our new B3 mAbs facility received a certificate of GMP compliance for our biosimilar Bevacizumab from Europe's Health Products Regulatory Authority. We have responded to the CRL for our biosimilar insulin Aspart wherein the US FDA had accepted our CAPA plan pertaining to the Malaysia facility and expect this to be followed by a site inspection. We are in discussion with the US FDA on our CAPA plan submitted for biosimilar Bevacizumab.
- We continue to progress our pipeline with biosimilar Denosumab, Ustekinumab and Pertuzumab and we are on track to complete the studies for Ustekinumab and Denosumab by the end of 2023 and 2024 respectively.

In summary, FY '23 has been a transformational year for Biocon Biologics driven by the acquisition of Viatrix' biosimilar business. This has enabled us to create a unique, fully integrated biosimilars enterprise with clear growth catalysts. The focus in FY24 will be on integration, transition, and execution in the commercial arena.

### **Coming to Novels.**

I will now provide you with an update on the novels business starting with Itolizumab which continues to make progress.

Patient enrollment has ramped up with 70 clinical sites operationalized as a part of the ongoing pivotal phase III EQUATOR study of Itolizumab in patients with acute graft versus host disease. The Phase 1b clinical study for Lupus Nephritis also remains on track. Equillum expects to report top-line data from the EQUALISE study on Lupus Nephritis in the first half of 2024 and remains on track for the interim review of Phase 3 equator study later in 2024.

Coming to Bicara Therapeutics, its lead candidate BCA101 continues to make good progress in Phase 1/1b development in head and neck cancer. And based on the promising data generated thus far, Bicara completed an oversubscribed US\$108 million Series B financing, which will help to advance this asset. As mentioned earlier, fundraises during the year resulted in a step-up gain recorded in Biocon's consolidated P&L statement.

Biocon's stake in Bicara currently stands at 38%. It is expected to reduce to a little over 23% post receipt of the full amount from the Series B financing in FY24.

### **Coming to Research Services.**

Syngene ended the year on a strong note with positive performance across all four divisions. In fact, it was the strongest

quarter ever for Syngene.

Revenue from the operations grew 31% to ₹994 crores over the corresponding quarter last year and reported revenues crossed ₹1,000 crores for the first time. Profit before tax was at ₹231 crores, up 29%.

Strong performance in the fourth quarter added to performance over the course of the year and ensured that Syngene delivered full-year results ahead of its upgraded guidance. In fact, it delivered the highest absolute year-on-year increase in revenue and EBITDA in the last five years.

Operating revenues were ₹3,193 crores in FY23, a growth of 23% over last year, while reported EBITDA was up 18% to ₹1,005 crores with EBITDA margins at 31%. Profit before tax was up 15% to ₹594 crores.

For the quarter, the research services business, discovery services and dedicated centers delivered sustained good performance and in the manufacturing services, this quarter also saw the start of manufacturing of drug substance at commercial scale for Zoetis, which added to the strong year-on-year growth for Syngene.

To conclude, I am pleased to announce that the Board of Directors have recommended for approval by the shareholders a final dividend of ₹1.50 per share, representing 30% of the face value of each share for the financial year 2023.

I would like to conclude by saying that all business segments in Biocon are well-positioned to grow in FY24. We expect a mid-teen growth trajectory for the Generics business driven by enhanced capacities in our API business, volume growth in our base business, and new launches in generic formulations in the US and other geographies.

With the Viatris transaction concluded in FY23, Biocon Biologics is also well positioned with clear growth drivers in place. The upcoming launch of Adalimumab in the US and the anticipated approvals and launches of Aspart and Bevacizumab should help us to build upon the US\$1 billion revenue run rate on which we have concluded FY23. Syngene sees the healthy demand for its services continuing in FY24 with the start of commercial manufacturing in Biologics spurring the growth momentum.

And with this, I would like to open the floor to questions.

## Q&A Session

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**Saurabh Paliwal:** Thank you, Kiran. We will wait for a few moments before we start the Q&A session. I'll request all participants to please limit the questions to two per person to allow everyone in the line to get a chance to ask a question. The first question is from Cyndrella Carvalho from JMFL. Please go ahead.

**Cyndrella Carvalho:** Thanks for the question. So, congratulations on consolidating the entire Viatris. How should we see any synergies do you see from this transaction as we go ahead? Would you like to highlight on the balance sheet size? You said that you have reduced the net debt from December level, but what is the plan for FY24? Could you help us understand what would be the further debt reduction that we are looking at? On the R&D side, you also highlighted that number should look more close to 12%. Just to clarify, is it ex-Syngene we are looking at? Or is this overall sales that this number should look closer to 12%? These are my questions at this point in time. I have more questions. I'll join back in a queue.



**Kiran Mazumdar-Shaw:** So, let me answer your second question and I'll turn over your other questions to both Chinappa and Shreehas. As far as the 12% R&D spend is concerned, obviously the large part of R&D is attributable to Biocon Biologics. And as we said, we would like to be at a 12% of revenue level. As you heard, this fiscal, we've been much higher than that. It's been at 16%. So, we would like to reduce that level. Both Shreehas and Chinappa to answer that question. So over to you, Shreehas.

**Shreehas P Tambe:** Thanks, Kiran. Cyndrella your question was more about the synergies that we would look at now that we've integrated the Viatris business. Just to bring you back to how we've structured the contract with Viatris, we've of course now started consolidating the revenues and the profits. And you're seeing the first full quarter of revenues and profits flowing in into the Biocon Biologics books. But we've also signed with them a TSA or a transition services agreement through which they provide us services for a period of two years. So, at this point in time, Viatris continues to provide us services and our numbers factor in the charge that Viatris levies on us for the services that it provides, in the geographies that they operate in.

Going forward, like we've said in the past, that we, being an integrated, a fully integrated player, we would be looking to see how we become more nimble and flexible. But at this point in time, that's not what's changed. We've got a fixed charge through the TSA that flows in into our P&L. But, Chini, if you'd like to add something, over to you.

**MB Chinappa:** No, you covered it, Shreehas, thanks. Cyndrella, any follow up to these two questions?

**Cyndrella Carvalho:** **Yeah, I mean, the follow-up is, is there any synergies, as you're saying, that there is a charge with us? So, where do you see this charge going beyond two years? Do you have any, I mean, the numbers that you had earlier shared with us, does that change? And more from a synergy perspective, do you see the market share ramp up giving us, we've seen gross margins being more stable, but do you see any scope of improvement here with Humira launch coming up? Are we prepared for the launch? Are we in the preparation mode already? You can help us understand that.**

**MB Chinappa:** Cyndrella, I'll take the first part of your question and then I'll go to Shreehas. Just to clarify on the charges, Viatris is still running the commercial engine and they cross charge costs at actual towards us. So, it's a cost that currently, they incur and cross-charge us, but once we transition out Viatris, we will be incurring the cost directly on our books.

**Shreehas P Tambe:** And to answer the other part of it, as we look to get past into this year, into the full fiscal, we are looking at, making sure that we take on the Hulio launch. Viatris is right now the marketing authorization holder, but Matt and his team are fully involved in leading that launch. So obviously, we are looking at a very successful launch that we expect in the US. So, we expect things to move forward. But at this point, the important message is, as we've integrated the full quarter revenues you've seen the health of the business is very strong. The core EBITDA margin is at the same levels at 39%, 40% that we've had in the past. So, it reflects the basic health in a very, very strong position.

**Kiran Mazumdar-Shaw:** And we're also seeing some good uptake in some of the market share of key products in the US and other markets.

**Cyndrella Carvalho:** **And on the debt side, if we can have that number for FY24, where do we bring the debt down? Any number?**

**Kiran Mazumdar-Shaw:** I think, we will share this information with you as and when we progress. But at this point in time, I think what we have done thus far is what we can share with you. But we will aim to reduce it further.

**Cyndrella Carvalho:** **Thank you. I'll join back to queue.**

**Saurabh Paliwal:** Thank you, Cyndrella. The next question is from Tushar Manudhane from Motilal Oswal.

**Tushar Manudhane:** **Yeah. Thanks for the opportunity. Just on this licensing income, if you could share further details related to this? Of ₹175 crores?**

**Kiran Mazumdar-Shaw:** Yeah. Shreehas would you like to take this?

**Shreehas P Tambe:** Yeah. Let me respond to that, Tushar. The licensing income is a part of our routine business. As we develop our portfolio, we've seen opportunities where we in-license products and we out-license some of the assets. There are some assets that we see may or may not be synergistic to our portfolio. We see an opportunity to out-license them. We see an opportunity to in-license some, where we see gaps in our portfolio. Now that we are a fully integrated organization with a commercial engine, there are so many more things that we can do. So, these are things that you will see happening during the course of the year. You'll see some in-licensing asset and revenues, and you'll probably see we see some out-licensing happening during the course of the year.

What's happened in this particular quarter is we saw that there was an opportunity for us to out-license a particular asset in our portfolio. And that's something that has flown through, and these will happen as and when we proceed, when we see opportunities to either out-license or in-license products.

**Tushar Manudhane:** **So, from that perspective, the ₹175 crores seem to be not to be taken as a sustainable number, right?**

**Shreehas P Tambe:** It will be as and when the things happen, you will see that as and when things will progress.

**Tushar Manudhane:** **And just to add to this, so if this licensing income while considering that as and when it comes, so the PBT margin excluding this seems to be much lower for biosimilar segments.**

**Kiran Mazumdar-Shaw:** So Tushar, I want to interrupt you right here, please understand that our R&D spend has increased significantly and I keep reminding people that this business has to be looked at the core EBITDA level. Please do not look at isolated numbers because if you can see what we have done, we have actually offset some of this increased R&D spend with this licensing income. So, if you look at it in that context you will see that the core EBITDA margin is what you really need to look at.

**Tushar Manudhane:** **And considering the vaccine or Serum deal going away but at the same time Adalimumab launch happening. So, if you could refresh in terms of Biologics' sales for FY24.**

**Kiran Mazumdar-Shaw:** Yes. I did indicate that we were exiting this fiscal at a US\$1 billion trajectory and we believe that we will build on this US\$1 billion trajectory in FY24 and like you point it out yes the Serum income will not be available to us this fiscal and we will look to building momentum on the US\$1 billion trajectory that we have exited out.

**Tushar Manudhane:** **And just lastly on this new debentures which we have raised to the tune of ₹800 crores, so would there be any provisioning on account of this in P&L and at what rate, if so?**

**Kiran Mazumdar-Shaw:** Chinappa, would you like to take this?

**MB Chinappa:** Tushar, hi, good morning. So, yes, the fund raise from Edelweiss is like a quasi-equity. It is a loan but to be repaid to the sale of BBL shares. They would carry an accounting charge but no cash interest cost.

**Tushar Manudhane:** **So, what would be that? So, why you do not consider cash, but the accounting charge would be how much on ₹800 crores?**

**MB Chinappa:** It would be linked to the fair value movement of the BBL shares but for modeling you could take 12%.

**Tushar Manudhane:** **Fair. Thank you. Thank you. That's it for me.**

**Saurabh Paliwal:** Thank you, Tushar. The next question is from Prakash Agarwal from Axis Capital. Prakash.

**Prakash Agarwal:** **Good morning and congratulations on good operating performance. First question, trying to understand the outlook better on the upcoming product, Adali. So, if I see Amgen's performance, I mean, the first six months, it's been a very slow start on that molecule. So how should we look for us, like modeling in for Fiscal '24 and '25? Is it going to be a slow start and then ramps up or we are better prepared if you could help on that? And secondly, you mentioned uptake in key products. I mean, if I see, Trastu and the other products, so it seems to be stabilizing and do you expect them to improve and include the Glargine outlook that will be helpful.**

**Kiran Mazumdar-Shaw:** Matt, you might want to take these questions.

**Matthew Erick:** Yeah. Sure. Thanks. And thanks for the question. I think from a standpoint as we're looking at this, the opportunity still remains very large. As we think about our Hulio product and the timing of this launch, I see that from the channels that we have in regard to the payer channel, we see a lot of inquiry about our Hulio product. We see a lot of interest in our product from specialty pharmacy and we also remember we're very well positioned and have been talking to key prescribers about Biocom Biologics, not particularly about our product because of the settlement date. But there's a tremendous amount of interest

as these new products are coming to market. And I think what we're seeing is a steady state from the payers in waiting. And this is why you're seeing the slower uptake with Amgen. And also, I think, if it was the other way, the size of the opportunity would be much smaller. We feel very confident in our four-channel strategy from payers to our prescribers to the specialty pharmacies and then the end patient. As we look at our position with our portfolio, our patient assist programs are top-notch. Our product from a standpoint of our auto injector, there's a lot of excitement about our product. And I think when we go forward and start being able to see the recognition at the time of launch, which will occur July 1, you'll see a tremendous amount of interest with our Hulo product as we progress. So, I'm happy that the market is still large, and we have this opportunity from the payer perspective, and then also from a prescriber perspective. And then we'll be able to compete as the market evolves, either on the high rebate side or on the low side from a WAC standpoint, because we will have our Hulo branded product and we'll have the authorized, that would be the Adalimumab. So, we're able to play in all channels and we're in a good position.

**Prakash Agarwal:** **Well. That's great to know. And if you could just give some color on if there could be uptake in the existing large product, the three products we have in the market in the US?**

**Matthew Erick:** I'm sorry. Could you repeat that question? I couldn't hear you very well.

**Prakash Agarwal:** **Could you give us some outlook on the market share on the three products, Trastu, Pegfil, as well as Glargine?**

**Matthew Erick:** Oh, yes, certainly. So let me talk about this from a franchise perspective. When we look at our Pegfilgrastim, and our Tras, as well as our Bevacizumab from a therapeutic area, we see tremendous amount of growth.

In the first time in the US on the Peg and Tras, we're over 10% in market share. Particularly on the Pegfilgrastim, we've crossed that 14% mark. And I think this is attributed to our franchise with our selling team and understanding of ASP and being good stewards of balancing our rebates with the payer, but also understanding how physicians are looked to be incentivized for the work that they do. And then we're seeing tremendous uptick in our insulin Glargine, as you've seen with the market share, as well as the new Rx's and we continue to be optimistic about continue to add new customers with our insulin Glargine because of a lot of interaction that we're getting today with current customers.

When you think about the franchise though of Tras and Peg across all advanced markets, remember from Trastuzumab, we have over 35% in Canada. In Australia, Germany, and Italy, we are approaching 15% to 20% market share. So, we have a great franchise and the opportunity to continue to grow those not only in North America, but also in our European as well as our JANZ opportunities.

**Prakash Agarwal:** **Okay. So, you do expect some improvement in the market share versus stability?**

- Matthew Erick:** Yeah, I think that what I would say from market share, we've seen continued improvement in our insulin Glargine or Semglee and continuous improvement in our market share with Pegfilgrastim. We see a steady state in the US and other places on our Trastuzumab, but that's where we're seeing the growth in our Peg as well as our insulin Glargine.
- Prakash Agarwal:** **Perfect. That helps. And second question is on the cost side. So, we did fairly well in stabilizing the staff cost. So, is there any one-off there and also outlook on the interest cost? So, you mentioned about trying to reduce the debt, but these are quasi-equity. So while accounting interest would still be there for the quasi equity that we have taken from Kotak and Edelweiss. So, one is on the staff cost and the second is on the interest cost outlook for Fiscal '24. Thank you.**
- MB Chinappa:** Hi Prakash. I'll take that. So, staff cost is about 10% of revenues. We see it in in that range. Interest cost has been higher than what we had previously expected, let's say, at the beginning of last year and that's tracking the increase in interest rates. It's roughly 50% more than where we wanted to be. That should largely get corrected through the additional fund raise that Kiran had just said.
- Prakash Agarwal:** **Can you repeat that, sir? How will it reduce?**
- MB Chinappa:** Through the equity fund raise, equity fund infusion into BBL
- Prakash Agarwal:** **Okay, which is expected in Fiscal '24**
- MB Chinappa:** Yes
- Prakash Agarwal:** **And it would also convert the quasi-equity into equity so that accounting interest will also not be there and you will raise additional fund in the company. Is that right?**
- MB Chinappa:** Yes, but we'll clarify this closer to the fund raise, when we announce it.
- Prakash Agarwal:** **Okay, got it. And staff cost, you said 10%**
- Prakash Agarwal:** **No, so this quarter you were 15% and for the year you were 19.5%. So, I don't know. So, you're talking about BBL level, I was talking more from company level, sir.**
- MB Chinappa:** Apologies. Sorry, I was just referring to BBL.
- Siddharth Mittal:** I think Prakash, this quarter, if you look at ₹529 crores which was the staff cost. Of course, this is time for the annual increments. So, we will see increments come in quarter one. Apart from that, Chini or Shreehas maybe you can just talk about the incremental absolute staff cost from BBL perspective as the transition happens in FY24.
- MB Chinappa:** Yeah, I mean, it's really on the consol revenues, BBL is at above ₹188 crores for the quarter, which is a 9%, but you see this at the 10% range for BBL.
- Prakash Agarwal:** **Got it. Thank you. All the best.**
- Saurabh Paliwal:** Thank you, Prakash. The next question is from Damayanti Kerai from HSBC

- Damayanti Kerai:** Hi, thank you for the opportunity. Coming back to cost. Actually, I'm not clear on the operating cost movement since the Viatris integration. So, staff, if you look at the consol level, it remains like flat, more or less, compared to the December quarter, despite the fact that last quarter only had one month of Viatris cost, right? So, if you can clarify that, and also wanted to understand the TSA cost, which will continue for two years. But right now, I believe it's not part of operating expense, and we are booking as professional expert fee. So, if you can clarify on that part also, please.
- MB Chinappa:** Damyanti, Hi. I'll just clarify on it, from the BBL perspective. One we will just go on the TSA cross-charge. So, there are two components in the TSA cross-charge. One is a reimbursement of expenses at actuals. So, they're incurring the SG&A, as they're carrying their employees and other contracts on their books, and they cross-charge us. Then there is an additional, for a year, charge of ₹44 million per year, which is a TSA fee that they charge. That's been announced along with the deal. That cost, there's a fair value of that, that gets charged to the P&L, and the balance goes into purchase consideration. So that really is covers for the overheads. Once we absorb the business, we would have, we would incur those overheads directly on our own.
- Damayanti Kerai:** **Just to clarify once, right now like this cost is getting reimbursed by Viatris and after two years, once it's part of Biocon, it will be coming into your P&L, which is right now not flowing into the numbers.**
- MB Chinappa:** That's right. On TSA exit, we would incur the cost directly. During the TSA period, they incur the cost and cross-charge it to us.
- Damayanti Kerai:** **So, the exceptional which we are booking, that include both this cost reimbursement as well as the exit fee, if you can also –**
- MB Chinappa:** Exception that we booked, include both. And we don't really see any savings coming there as we transition out of Viatris on to BBL.
- Damayanti Kerai:** **Okay. So, any cost synergies which we are looking are looking from this portfolio will likely happen once everything comes into your book and then you see pick up on the top-line etc. to see the better.**
- Kiran Mazumdar-Shaw:** Yes.
- Damayanti Kerai:** **Okay. And then my second question is on ma'am mentioned there are plans to further raise equity for BBL in FY24. So right now, what is parent's take in BBL and how where you would like to settle it down finally?**
- Kiran Mazumdar-Shaw:** I think Chini, I think the question is what is the Biocon stake in Biocon Biologics at the moment? I think and where could we be expected to finally land.
- MB Chinappa:** So right now, Biocon stake is 70%, Damayanti, and if you raise additional 10%, you'll get diluted accordingly.

- Kiran Mazumdar-Shaw:** But as you know, Damayanti, it all depends on the value at which you fundraise. So it could be maximum 10%, but much lower than that is what we're aiming.
- Damayanti Kerai:** **Okay. So up to 10% stake dilution we can see, but obviously it depends as and when things happen.**
- Kiran Mazumdar-Shaw:** And the valuation you get.
- Damayanti Kerai:** **Okay, and my last question is clarity on your net debt. The current position which you have given is excluding the structured asset, as mentioned in the presentation. So just to clarify that Goldman Sachs investment is not included here, right?**
- MB Chinappa:** So, at the consol level, no. We have taken out Goldman Sachs and Kotak for the purpose of net debt calculations.
- Damayanti Kerai:** **So, Edelweiss is part of that?**
- MB Chinappa:** Edelweiss is come in only in the May. So, it's not reflected in here.
- Damayanti Kerai:** **Okay. I have more questions. I'll get back in the queue. Thank you.**
- Saurabh Paliwal:** Thanks, Damayanti. The next question is from Harith Ahamed from Avendus Spark. Please go ahead.
- Harith Ahamed:** **Hi. Good morning. Thanks for the opportunity. In your press release, you mentioned a tentative approval for Lenalidomide capsules. So, it will be helpful if you can give some details around launch timelines. Just trying to understand if it's a FY24 opportunity for us or FY25? Some color would be helpful.**
- Siddharth Mittal:** It's confidential settlement terms with Celgene, so we cannot disclose the dates. But it's not imminent. Let me just say that it's not definitely in FY24.
- Harith Ahamed:** **Okay, my second question is on Aflibercept. We have a deferred consideration that's due for this product. Can you refresh on the exact amount and when the payment is due? And any comment again on updated launch timelines and whether we'll have an exclusivity post our launch for this particular asset?**
- Shreehas P Tambe:** Chini, why don't you talk about the amounts and I can take the second question.
- MB Chinappa:** Yeah, Harith, the consideration that the deferred consideration is US\$175 million payable in FY25. Okay.
- Shreehas P Tambe:** On the question related, Harith, to the launch, you know, at this point in time, when we acquired the asset from Viartis, we are the first to file. We are currently in a litigation with the originator, Regeneron. So that litigation is currently ongoing. Wouldn't be fair on our part to talk about the launch dates at this point in time. But we will update you as things go in the process of the litigation.
- Harith Ahamed:** **Okay. And last one is on insulin pricing. We've seen a lot of developments in recent months around insulin pricing in the US. The major innovator brands have seen a significant price reduction on their list prices. So, does this in any way impact**

**pricing for our Glargine product now? And when we think about our future insulin launches, do these developments have any kind of an impact on our pricing?**

**Kiran Mazumdar-Shaw:** Matt you might want to take it.

**Matthew Erick:** Currently what we're seeing remember some of these don't go into effect until 1/1. So right now, of FY24. Right now, we don't see a lot in changing in our model. We certainly are taking a look at it, but we're well positioned in regards to our cost structure and well positioned in the market to be able to play with in both the channels, meaning the rebate channels with the payer and then on the lower side, the low WAC channel, so it's pretty much in line with what we're seeing right now, and we don't anticipate a lot of change, but I do want to keep remember we're well positioned and this growth in our market share, and the opportunity really says a lot about our franchise, and particularly in the US on how we are able to play and adjust. And I think it says a lot about our platform, our manufacturing as well as how we're vertically integrated. So well in line with our expectations and we see continued growth as I said, with our market share uptake as well as the new Rx's and interest from customers within the US.

**Harith Ahamed:** **Thank you. That's all from my side. Thanks for taking my questions.**

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

**Shyam Srinivasan:** **Hi, good morning, and thank you for taking my question. Just the first one on the biosimilar overall revenue, ₹2,100 crores, like roughly making US\$250 million. Talked about the billion-dollar run rate annualized. Can you split this revenue into your top products and maybe it's a request going forward as well that from a disclosure perspective could give us what the top three, four products are and how these are trending. But if you could on this call at least, maybe rank order and how should we look, or should we look at that particular revenue pile?**

**Kiran Mazumdar-Shaw:** Well, there are very few products. So, all of them are key products for us. And I don't think we would be able to give you granular data on each product because there are multiple markets, multiple regions, and it would be very difficult for us to share with you that kind of data. But we've heard what you've said, and we'll try and see how we can give you some indicators going forward.

**Shyam Srinivasan:** **Mrs. Kiran, just maybe getting the rank order also is helpful. So, which are the largest products? Say, is it insulin Glargine? Is it Adali, Europe? You know, you've talked about the Europe market share. So, any sense that we could get, I'm just adding a follow-up here on what are the learnings from Europe, Hulo which will help us gain share. Are the numbers at 18.5% for Germany or 10% in France? Is that the numbers we need to kind of extrapolate in US or it would be a different ballgame?**

**Kiran Mazumdar-Shaw:** I think you have to wait for the business to come into our hands. You have to also wait for the market to actually start shaping up because these are very, very early signals. I don't think we're the kind of company who wants to forecast things without really



understanding very comprehensively what we're talking about. So please bear with us for some time this are early days of our acquisition. We would like to really do a good job of presenting the real business prospects, but please bear with us for a while till we actually integrate the business fully.

**Shyam Srinivasan:** **All right. That's helpful. Second question is on the status of the plants and the pending applications because of plant compliance issues. If you could help us update and is there any refresh timelines around at the Beva or insulin Aspart please?**

**Kiran Mazumdar-Shaw:** Like I said in terms of compliance, all our facilities are fully compliant with EU-GMP and others. We've got all the approvals that we had applied to EMA. Now the only two pending approvals that we are waiting for is of course, biosimilar Aspart from our Malaysia facility and the Bevacizumab from the Bangalore facility. Now as you know we have already submitted the CAPA plan to the US FDA for Aspart which they have accepted. We are hoping that we will get an inspection soon. We are in the process of providing the CAPA plan to USFDA for Bevacizumab from Bangalore. Again, we hope to be inspected thereafter. So hopefully in FY '24, we are expecting to be inspected and approved. That is our hope. We are in a very high state of preparedness. We have taken all the steps that are required to ensure that we are in a state of readiness and preparedness from a US FDA point of view.

**Shyam Srinivasan:** **That is helpful. My last question is on the mid-teen guidance for the Generics business. Siddharth, maybe if you could help us understand, you said Generics Revlimid is also not there. So, what are some of the drivers? Is it more on API? Is it linked to the capacity that we have added? Thank you.**

**Siddharth Mittal:** Yes. So, Shyam, it's a combination of both the new capacities that we have added. We will also have our immunosuppressants and peptides facility commission, qualified in FY24 and some of the additional capacity enhancements we had done last year. So, we will see a full year impact of those capacities in the coming fiscal. Apart from that, generic formulations as we've got additional contracts on our base business in the US, which will lead to the growth in FY24 plus some of the new launches in FY24. So, combination of these three would drive the growth to that mid-teens level next year.

**Shyam Srinivasan:** **And what is your, what are you penciling in for base business erosion? Is it different versus '23 versus '24? Has it seen an improvement; you think?**

**Siddharth Mittal:** The pricing part is similar. We have not really seen any significant change. So, both on our API as well as formulations business, the price erosion would be anywhere between 7% to 10%.

**Shyam Srinivasan:** **Got it. Helpful. All the best. Thank you.**

**Saurabh Paliwal:** Thank you, Shyam. We'll take the next question from Surya Patra from Phillip Capital. Please go ahead.

**Surya Patra:** Thanks for this opportunity. First clarification, about the licensing income and the ₹109 crores kind of a stake sale gain. Whether these are two different things, or this ₹109 crores of stake sale gain is part of the licensing income, if you can just first clarify that.

**Siddharth Mittal:** Let me clarify that. Both are very different, Surya. Bicara had done fundraise of \$108 million, which led to the step up of the investment that Biocon has. That led to the one-time gain. Licensing income, of course, as Shreehas had mentioned, is business transaction. And it was considered in the other income under the licensing line. So that you can see in the factsheet as ₹175 crores as licensing income.

**Surya Patra:** Okay. So, sir then just on the licensing, this is one of the highest ever licensing number that we have seen. So, is it possible to kind of indicate what asset that is possibly bringing in this kind of income? And since now that we are progressing with our pipeline and all that, so any visibility on this licensing front and how focused and serious about this revenue stream?

**Kiran Mazumdar-Shaw:** I might remind you that we've had much higher licensing deal in the past. So, it's not correct to say that this is the highest licensing deal.

**Surya Patra:** Yeah. So basically, in the recent past, ma'am.

**Kiran Mazumdar-Shaw:** Yeah. But I'm just saying that this is part and parcel of our business, and we keep reprioritizing our pipeline and please understand that as I mentioned earlier on, this is to calibrate the R&D spends, which as you know we would like to maintain at a 12% level of revenue. So, when we look at these opportunities and see the ability for us to out license certain assets, we will also calibrate it with in-licensing certain assets, like Aflibercept is a very important in-licensing opportunity for us. So, I think you have to view this business very differently. You will have opportunities to out-license, you will have opportunities to in-license, but overall, we would like to calibrate our R&D spends at a 12% level, by and large.

**Siddharth Mittal:** And even in the past, we have mentioned licensing income is lumpy. So, you really cannot predict or put a trend on what it would be.

**Surya Patra:** So, in the sense, just continuing on the Bicara, whether the charges relating to Bicara would meaningfully come down for the '24 or how should we think so?

**Siddharth Mittal:** Yeah. So right now, we consolidate 35%. I think once the Bicara raises the remaining \$70 million, which is expected sometime this quarter, Biocon would be down to ~23%. So, we will be consolidating only ~23% of their R&D expenses. So, it would keep coming down. At some point in time, Bicara will also look at raising Series C funding.

**Kiran Mazumdar-Shaw:** I think it will be fluctuating because it depends at the value at which they raise their Series C funding. So, I think it's very difficult for us to project, but I hope you have also appreciated the value creation opportunity that the Biocon Group has created through this very, very interesting asset.

**Surya Patra:** Sure. My other question is on the benefit of this integration. See, in fact, obviously we have successfully completed and integrated the, or in the process of integrating fully the business of this Viatris biosimilars. So sure, like on the revenue side and let's say on the EBITDA side, we have seen progression because of the integration, but because of the multiple divestments and the kind of finance cost, capital cost, what we have witnessed, so that has suppressed the overall earnings contribution by the acquisition.

**Kiran Mazumdar-Shaw:** Again, Surya, I would like you to focus on the business fundamentals, okay? So, my business fundamentals are about revenue and core EBITDA

**Surya Patra:** Yeah.

**Kiran Mazumdar-Shaw:** I keep trying to remind you that R&D is a very integral part of this business. And under normal circumstances, R&D should be a Capex rather than an expense. But unfortunately, accounting systems call, require us to treat it as an expense. So, I would like you to look at it in that context. You know, our pipeline is our lifeline and as we continue to deliver on this pipeline, we actually can surge the growth prospects of our business in the coming years. Now, in the meantime, of course, we are also trying to see how we calibrate our R&D spends and contain them as much as possible. So, I think we've actually demonstrated to you this quarter what is possible in terms of operating performance and core EBITDA performance. Now, of course, because we made that acquisition very recently, there are going to be charges and accounting treatments of some of the quasi-equity that we have taken to reduce debt. So, I think if you look at it holistically, it's a very, very good business with huge growth potential. And I think that's the way I would look at this whole business.

**Surya Patra:** Sure. So, my last question on this.

**Kiran Mazumdar-Shaw:** Not just looking at the PAT, you know what I mean?

**Surya Patra:** Yeah. Sure. My last question is on Syngene. So, the commentary in the press release indicates about 1,000 kind of job additions. So, this is for the FY '24 that we're talking about or anything.

**Kiran Mazumdar-Shaw:** Sibaji, if you can answer that question.

**Sibaji Biswas:** Yes, I will. So, if you can please repeat what 1,000 you said?

**Surya Patra:** So, 1,000 more job additions that has been mentioned in the question in the press release. So, is it for FY '24 or it is that you have been talking for the recent past?

**Sibaji Biswas:** So, this is about the recent past. We added thousand jobs in FY23, but we are an expanding company. So, we'll continue to expand jobs as we expand our both research and development and manufacturing businesses.

**Surya Patra:** Sure. Okay. Yeah. That is it. Thank you.

**Saurabh Paliwal:** Thank you, Surya. We'll take the next question from Neha Manpuria from Bank of America.

**Neha Manpuria:** Thanks for taking my question. My first question is on the core margins. As we go ahead into next year, with the commentary that you've given on improving, sharing some of our products and new launches possibly, how should we look at the core margins? Is there scope for improvement from the high 39% odd level that we are seeing, or give and take this should be the level that we continue?

**Kiran Mazumdar-Shaw:** I think we have guided for mid-30%s to 40% margins. And I think a 39% to 40% is a very, very strong margin that we think we can find.

**Shreehas P Tambe:** We've guided, sorry, to add to what Kiran said, we had said mid-30s, mid to high 30s, and we've been able to continuously deliver above that. I think that's really where the range is.

**Neha Manpuria:** Okay, so more in the 35% to 40% range rather than the 39% that we have done this quarter?

**Kiran Mazumdar-Shaw:** Well, 35% to 40% is the range we've given. So, anything in that range, I think is a good performance.

**Neha Manpuria:** Shreehas, is it fair to assume that as we see new launches coming through and probably even existing products ramp up, there is some operating leverage that could come through with the TSA charge, etc. and therefore, there's hope for improvement in margins?

**Shreehas P Tambe:** Like Kiran said earlier on, Neha, these are things, early days in the acquisition and we are still in the TSA period for a while. So, unless we get past it, wouldn't be fair for us to comment on how things will move. But we certainly expect things to get better and hopefully we should be in a higher, in a better operating performance range. But we will state that as we get closer to those things.

**Neha Manpuria:** Understood. And Kiran ma'am, on Biocon's stake in Syngene, what is the comfortable level that we are okay to stay, hold in terms of Syngene's stake?

**Kiran Mazumdar-Shaw:** So, we've already indicated we do not plan to reduce below this level which is at a roughly 55% level. I think we will stay; we will maintain it at this level. We do not need to divest further.

**Neha Manpuria:** Got it. Thank you so much, ma'am.

**Saurabh Paliwal:** Thanks Neha. We'll take the next question from Ishita Jain from Ashika Group.

**Ishita Jain:** Hi, thanks and congrats on being on the US\$1 billion trajectory for BBL My first question is on Semglee. We have a US market share you mentioned of 12%. Can you provide some color on how interchangeability helped in this journey? And would the market share look any different without both the interchangeability and the exclusivity?

**Kiran Mazumdar-Shaw:** Matt, do you want to take this question?

**Matthew Erick:** I'll take it and Shreehas, please dive in here. We look at it from a standpoint, not just interchangeability, but how's the product performed throughout the market. Interchangeability on this particular product definitely gives us extra opportunities to talk about, but it's really the franchise of the product itself. And this is the power that we have in regard to the Semglee, the insulin Glargine also the power that we've acquired from Viatrix in understanding how market access works, as well as all the different influencers in the value chain and how do we position our products. So, the more opportunities we have between interchangeability or existing products, it really helps us within formulary design. And I think this is why you're seeing the success that we're having, rather it be from an interchangeability standpoint with the payers or a straight up more market access that you would see where it's more formulary design with the payers, we are well positioned in both channels.

**Shreehas P Tambe:** Just to add to what Matt said, if you really look at it, stepping back from it, the interchangeability is just a US specific phenomenon. And the real piece, even when FDA approved Semglee as the first ever insulin, which they had approved as an interchangeable, they said it was a landmark moment overall. That was because they had to break this myth about whether biosimilars can be interchangeably used. And I think to that extent, Semglee or our insulin Glargine, was that watershed moment in the entire biosimilars industry. And it's paved the way. So, it's taken away that whole myth that you cannot use a biosimilar interchangeably. And that's really helped us gain that market share. Suddenly it's broken that barrier for anyone to have any apprehension of whether a biosimilar would be as effective. And I think that's really paved the way. You've seen after that several other products getting approved and now if you see biosimilars have got over 80% acceptance in the launches that we've seen in the US. So, it's really helped, and we see this getting better as we get more products into the US.

**Kiran Mazumdar-Shaw:** But to your point, I don't think it is absolutely imperative to get an interchangeability label to succeed in the market.

**Ishita Jain:** **Got it, thank you. My next question is, you have given the guidance for percentage of revenue that will be R&D spend. What part of that would be earmarked for the generics segment?**

**Siddharth Mittal:** So, generics R&D will be around 10% of segment revenues.

**Kiran Mazumdar-Shaw:** No, I think she's asking about the total R&D spend in the group, how much of it is contributed by generics. I would say the large part of the spend would be by biosimilars.

**Siddharth Mittal:** See, generics R&D spend last year was roughly ₹220 crores for the full year and will be closer to ₹300 crores next year.

**Ishita Jain:** **Understood. Thanks. And just a final question. I'm not sure if you have already mentioned, but do we have an overall timeline on Itolizumab, which is our novel biologic, and what is our expectation from this opportunity?**

**Siddharth Mittal:** Well, the clinical trial is ongoing for acute graft-versus-host disease, which is the lead indication, it's a global Phase 3 trial is going on, and Equillum, I think, had indicated that

they expect to complete trial in CY24, end CY24, and then do a BLA filing in CY25. And of course, the Lupus is getting into a Phase 2. We also have an India Phase 2 trial for Ulcerative Colitis which is going on. And in terms of expectations, of course, the Equillum had given an option agreement to the Japanese company Ono to license this asset. Ono is expected to exercise that right by end of this calendar year, after which the commercialization in the US and Canada would be done by Ono. We do not expect a commercialization in the near term. As I mentioned, the filing is expected somewhere in CY25, followed by a review process. It's under a fast track review by the FDA. So, the launch definitely is not until CY26 at the earliest. And we will have supplies which will be done by us as well as we'll get royalties and milestone payments once the asset is commercialized in the US.

**Ishita Jain:** **Will this be a partnered asset?**

**Siddharth Mittal:** It's already partnered. Right. Equillum is a partner for US, Canada, Australia and New Zealand. We still retain full rights on Europe, which we will license out at a later date.

**Ishita Jain:** **Understood. Thank you and all the best.**

**Saurabh Paliwal:** Thank you, Ishita. Next question is from Nithya Balasubramanian from Bernstein.

**Nithya Balasubramanian:** **Yes, thank you. First question is on Glargine. So, we didn't really see the needle move much in terms of higher number of covered lives in 2024. Please correct me if I'm wrong. So, it seems like you're capitalizing on the payer wins you had last year. And now come 2025, Lantus is expected to lower their list price quite significantly on the innovator product. Can we expect this to be a meaningful opportunity for Biocon, given that their ability to rebate at a lower WAC level will be much lesser than before?**

**Matthew Erick:** I'll take that, Shreehas, and then please chime in. So, I want to make sure I totally understand your question here. Come in FY25, the changing of the WACs of the other three companies, I think there remains an interesting opportunity in covered lives. When you think about the payers, how they look at their portfolio, it's just not always the low WAC strategy. It's an important one for key customers that they have within their portfolio that has covered lives, but there's still a lot of customers on the other side in which we're talking to every one of the payers of looking at opportunities as this market is changing of having more shots on goal in regards to getting payer coverage, especially as we're seeing this market start to switch. So, I think you're going to see this play out. And also, to remind you, remember some of the things that you're seeing in the data, IQVIA data or their sort of lives, some of it's not totally reported. When you think about closed door pharmacies, things like that. And this is another opportunity for us. So, just covered lives is something definitely, but we're looking more in regard to positioning our insulin Glargine, Semglee with the payers as we continue through this year and the following year, but also maintaining the lower WAC opportunity. And thinking about Biocon's platform, where we make this product, we're in a good situation, I believe, to play in the US on both the rebated side as well as the low WAC, where you're seeing some of these

pricing components that are being indicated from the other diabetes company. But I'll stop there, Shreehas, anything to add?

**Shreehas P Tambe:** I think you covered it comprehensively, Matt. My only comment would be the financial years that were mentioned. I think we probably were talking about, Nithya, fiscal '23 was your commentary, and what we've responded to is what happened in the year went by and fiscal '24 is where we are currently, and that's what Matt's talked about. So just correcting for fiscal '25, so.

**Nithya Balasubramanian:** **Yeah, I think I was talking calendar year. I'm sorry, I'm just going to follow up because I don't really get an answer here. When Lantus lowers its WAC price, their ability to compete on the rebating channel comes off. They will not be able to give the same level of rebating to the peers. Do you see that as a significantly important opportunity when that happens? Because you can play both.**

**Shreehas P Tambe** Let me respond to that so we get a straight answer to that. If you look at how we priced our insulin Glargine in the US, and I will not right now comment on the competitive play because a lot of that is also to do with the US., the way the US overall system and the market is structured, and how the compensations are passed on back from CMS. So I think there's a little bit of that to the action that competitors have taken. But our insulin has been priced always with the high WAC and the low WAC strategy, which allows you to play on both segments, which allows us to be in the commercial space with that higher rebate opportunity that you talked about, Nithya. And also, those with direct purchases of the like the hospitals or the veteran affairs where you have the lower WAC product. And we've been always very competitive. So, we do not see a challenge like Matt said of the lowering of the prices because we've always been amongst the lower price products in the US and quite competitive at that. It does place us in a good position with the payers given that everyone else has probably moved to a lower WAC position and we would have that opportunity. But we really leave it to the buyer and the channel that is procuring product from us to make that decision. But we've been basically pricing it in such a way that every stakeholder in the US market has an opportunity and we have an offering for all these channels. I don't know if that gives you clarity, but we're happy to elaborate if you need later.

**Nithya Balasubramanian:** **Thank you, Shreehas. Quick one on Ustekinumab. We now know that the market formation is in early 2025. You had indicated earlier that your development is slightly behind, and you'd probably be in the second wave. Can you help us understand when do you expect to participate in that market? And I have one more on margins, if you'll allow me.**

**Shreehas P Tambe:** Yeah, just to respond quickly on Ustekinumab and we've seen the 1-1-25 settlement date that's there. We've said in the past that our products are ready to file end of '23. We're on track with that. I wouldn't speculate at this point how it places that, but clearly, I think there were discussions about an earlier market formation date. Now I think there's more clarity on that. I think there's more clarity on where market formation is, which certainly gives us

an opportunity to play in that space and brings more clarity on when the market is really going to open up. So, it's not '24, but it's more '25.

**Nithya Balasubramanian:** **Understood. Thank you. A quick one on margins. I think we were, there was an earlier question about whether the 39% can move up. I actually have a different question, which is that as you're building your commercial infrastructure to support both the Adalimumab as well as maybe Aflibercept, will we see those numbers actually slide down and to what extent?**

**Shreehas P Tambe:** I think we've always said, Nithya, that we will be in that mid to high teens, sorry, mid to high 30s. And that's what Kiran was also referring to, 35% to 40% is where we see ourselves. We've continued to perform in that range even after we fully integrated the full quarter business from Viartis. As you know, the Hulio launch, the Adalimumab launch in the US is something that Viartis is leading and in the numbers as we pay the TSA fee that we talked about earlier in the call. And we expect things to be in that space. But as we fit out, stand up the business in the US and other markets, you will see us in that range of mid to high 30s is our expectation.

**Nithya Balasubramanian:** **Got it. Thank you so much.**

**Saurabh Paliwal:** Thank you, Nithya. We have a follow-up from Cyndrella. Please go ahead.

**Cyndrella Carvalho:** **Yeah. Thanks for taking the follow-up. On the rh-insulin, can you share the timeline for the approval?**

**Shreehas P Tambe:** As said before Cyndrella, the rh-insulin is not one product. We've got three products and multiple presentations. There's the R, the N, which is for the NPH, and the mix, which is the 70-30. We are developing all these products. And at this point in time, we had filed the R formulation, which is the soluble one. We've received the CRL, which we've talked about in the past. So, we are at this point in time working with the agency to see what is the best way forward in bringing in the other two products, the NPH and the 70-30 to the US market? We are waiting for their views on Aspart, and then we will be in a position to take the RHI product and a decision on that, which we will share with you shortly.

**Cyndrella Carvalho:** **On Aspart, we shared that we'll have an inspection, right, somewhere in Q1 FY24 right? So, is there any TAD along with it or how should we read that? And would that lead to missing the formulary cycle with interchangeability?**

**Shreehas P Tambe:** Yeah, so, at this point in time, what we had said is we've responded to the CRL, the agency has accepted the CAPA plan, and they've said that an inspection is needed for them to approve us. There is an indication that the agency will inspect us in Malaysia. We are trying to get clarity whether that will cover both Glargine and Aspart as we get on past this year. So, we should have full clarity on that, on whether they will cover Aspart and Glargine both, and then we should be in a position to do that. We are quite optimistic that we should be able to get both these products covered in the inspection and should be able to be in time for the contracting cycle. There is a lot of interest, as we've said, given that Aspart, when approved, will be the first biosimilar insulin Aspart rapid acting analog



in the US and the customers were really looking forward to us getting that approval and launching it in the US.

**Cyndrella Carvalho:** **CRL is not pending anything on the study side or anything, right? It is just for the plant inspection. Is that understanding, correct?**

**Shreehas P Tambe:** That's accurate.

**Cyndrella Carvalho:** **Okay. One more question. And this is how should we look at our BBL top-line guidance for FY24, given that now we have Serum out. So, what is the number range that we should be looking at? And would you be able to share on BBL, what is our ROW and reg market? And if we can start getting the split between US, Europe and ROW, if that is in future which we can incorporate?**

**Shreehas P Tambe:** I think first off, I think let me respond to your first question on the FY24 piece. We talked about when we left the last earnings call, Kiran had guided about the quarter run rate being at a US\$1 billion as we exit Fiscal '23. And I think that's what we've delivered on. So, we're building off that base of a US\$1 billion in revenue. We certainly have a lot of upsides coming up. We just talked about at Adalimumab a few minutes ago. There is certainly a big upside coming up with that is the way we see it. It's a big opportunity for sure. We are looking at Aspart and Bevacizumab getting approved through the course of the year. Now we could fit this out and put that up together and see where that leads us to. But at this point, it's best to wait for these approvals to come through and the launch to play out before we can give more guidance and as we get closer there. We also know very clearly that the vaccine integration of the numbers won't happen, and we had said that would be about 300 to 350. So those clearly won't be happening. So, if you look at the math, it's clearly upwards from a billion. As we progress through the year, we'll see how far that can go and how much we will achieve. But clearly, it's a build up from here, Cyndrella, towards where we want to be.

**Cyndrella Carvalho:** **Just a clarification, will Q1 reflect our preparedness for launch for Adi?**

**Shreehas P Tambe:** And just to understand your question, what does reflect mean?

**Cyndrella Carvalho:** **Our preparedness, I mean the launch quantities, and all should start seeing it from the Q1 results?**

**Kiran Mazumdar-Shaw:** I think you should realize that the launch itself is after Q1. It's on July 1st.

**Cyndrella Carvalho:** **Yeah. So, I'm asking if we will be seeing some preparedness.**

**Kiran Mazumdar-Shaw:** But how can you look at Q1?

**Shreehas P Tambe:** So, what we've got right now is, it's in the public domain that we have a settlement date where July 1 is our launch date. And given that now we will start accruing revenues only post-secondary sales, I think the supplies to the channel stocks is when you can actually do that only starting Q2 is when you will start seeing it. You effectively won't see that in June 1, but you will see a lot of preparation which is going on right now where the teams

are getting ready for the launch. But we can't really divulge more than that because of the terms of the agreement that we've got with that.

**Cyndrella Carvalho:** **Thanks. That's appreciated. And can we give the break-up on reg and non-reg for BBL?**

**Shreehas P Tambe:** Sorry, again, my apologies.

**Cyndrella Carvalho:** **Regulated market and non-regulated market share. The split, do you want to call out the split? The way we used to call it.**

**Shreehas P Tambe:** Yeah, maybe the advanced market and emerging market is that I can paraphrase that. And then maybe Chini, you can respond to that.

**MB Chinappa:** Cyndrella, yes. It's about 70-30, 70 developed and advanced markets, 30 emerging markets.

**Cyndrella Carvalho:** **Thank you so much for all this clarification.**

**Saurabh Paliwal:** Thank you, Cyndrella. We have the next question from Sandeep Joshi, an Individual Investor.

**Sandeep Joshi:** **Sorry, can you hear me now?**

**Shreehas P Tambe:** Yes.

**Sandeep Joshi:** **Okay, thanks for taking my question. Just two of them. One is on the Serum deal. It was mentioned at the beginning that the equity would be taken back. Can you explain for the US\$300 million that you are getting from Serum, what is the consideration that they get back?**

**Kiran Mazumdar-Shaw:** So, let me try and start with answering your question by saying that the original strategic alliance deal, if you recall, was about issuing Serum 15% equity in return for assured revenues and EBITDA pertaining to 100 million doses of vaccines. And thereafter, of course, Serum infused an additional US\$150 million and gave us a loan of US\$150 million towards our Viatrix acquisition. As you know, we were expecting certain court approvals for completing this deal, the original deal, which didn't come through. So, the two companies decided to withdraw from this alliance and instead convert the US\$150 million loan into equity, thereby giving Serum a US\$300 million equity into BBL at an average valuation of US\$6 billion. I think this entails them to about 5% equity stake in the company. And the original 15% is no longer required to be issued.

**Sandeep Joshi:** **Thanks for the clarification. Is would that be considered pure equity, or would this be quasi-equity?**

**Kiran Mazumdar-Shaw:** It's pure equity.

**Sandeep Joshi:** **So, we would take this as a 5% equity being taken by Serum.**

**Kiran Mazumdar-Shaw:** Yeah, so \$300 million would be pure equity.

**Sandeep Joshi:** Okay, thank you. And the other question is on the additional borrowing. If we look at the P&L and add back the tax, it looks like you had a cash flow of over ₹700 crores on the quarter. And I'm just trying to understand, what would be the driver to raise additional equity? Because on an annualized basis, you seem to be generating over ₹2,500 crores in cash.

**Kiran Mazumdar-Shaw:** I don't know whether either Chini or Siddharth wants to take this question.

**MB Chinappa:** So, the intent to raise additional equity is to lower the net debt, but there is definitely no concern on cash flow and servicing of debt. We have strong cash flows, as you pointed out, and we can easily service the debt. I think it's an overall improvement in the net debt position, which we'd like to bring down.

**Sandeep Joshi:** Okay. So, this would not impact the debt load, the new ₹800 crores that was mentioned to be raised?

**MB Chinappa:** The ₹800 crores that we just raised from Edelweiss, that's a quasi-equity. I think it is to be repaid to the sale of BBL shares and doesn't have a cash interest charge on it. Not really following your questions, Sandeep, and the audio is not the best. Maybe you want to take this offline.

**Sandeep Joshi:** Okay. Thank you very much. Thanks for your response.

**Saurabh Paliwal:** Yes. Thanks, Sandeep. We'll take the follow from Surya.

**Surya Patra:** Yeah, thanks for this opportunity. Just a last clarity. So, in fact, since we would be approaching a contracting cycle for the subsequent period for most of our products, as well as for the Adalimumab. So, given the facility or the pending observations at our plants, whether it has impacted our contracting capability with the customers either in the recent period or for Adalimumab?

**Kiran Mazumdar-Shaw:** Let me answer that question by saying that Adalimumab is not impacted at all because it is not from the facilities that I mentioned earlier on.

**Surya Patra:** Yes.

**Kiran Mazumdar-Shaw:** Okay. As far as our facilities are concerned, we expect to be inspected and we hope to clear these current queries at the next inspection.

**Surya Patra:** Okay. So basically, my question was that okay, since the sustained supply of the materials that is the key for procurement by the customers, so whether it has impacted our volume flow in the recent period and whether we are likely to see improvement on that with the clarity that we might see for our facilities from the regulators in the subsequent period.

**Kiran Mazumdar-Shaw:** So, to answer your question, none of our current supplies are impacted by any of these CRLs or pre-approval inspections. And obviously, we are hoping to clear the pre-approval inspections which will only add to our supply ability for these other products, which is Bevacizumab and Aspart.

- Surya Patra:** Okay. And just on the PAI approval for the Telangana facility, is it possible to say what was that product or for which API product that we are?
- Siddharth Mittal:** There were multiple filings in the US, ANDA filings, which triggered the PAI, one of them was Copaxone.
- Surya Patra:** Sure sir. Yeah. Thank you.
- Saurabh Paliwal:** Thank you Surya. We'll take the last question for today from Nitin Agarwal from DAM Capital.
- Nitin Agarwal:** So, Chini, we said Biocon now owns 70% in BBL. So, if you can give us a broad sense of the cap table for BBL right now.
- Saurabh Paliwal:** Chini you need to unmute please.
- MB Chinappa:** Thanks. Hi, Nitin. Yeah, that's on a fully diluted basis after taking into account stake dilution in favor of both Edel and Kotak. That's clarification one. I think the next largest shareholder would be Viatrix with close to 15% stake. We have Serum close to 5% and other shareholders largely representing the balance.
- Nitin Agarwal:** So, this takes into account, I just want to rephrase, both Kotak and Edelweiss conversion as into equity is what, that takes us to 70%.
- MB Chinappa:** That takes it to 70%, yes. That's a fully diluted basis, assuming dilution for GS, Kotak, Edel etc. Viatrix is more closer to 14%.
- Nitin Agarwal:** Okay. Thanks. And secondly, Chini, in the press release, we talk about the core EBITDA and the net EBITDA. Can you just explain how you sort of, what you include in core EBITDA and what is it that is subtracted to arrive at the net EBITDA number for the Biologics business?
- MB Chinappa:** So, core EBITDA truly reflects the operating performance and that excludes R&D cost, we exclude licensing income, we exclude FX gains or losses and any MTM movement. So, these are the exclusions that we don't take into account when we calculate the core EBITDA. EBITDA is calculated after all these items.
- Nitin Agarwal:** So, the ₹742 crores that we reported in the quarter on ₹2,100 crores of revenues did not include the licensing income?
- Kiran Mazumdar-Shaw:** No.
- MB Chinappa:** Yes, doesn't include the licensing income.
- Nitin Agarwal:** Okay. That gets netted off. When you're computing the net EBITDA number is when we take the licensing income, and we net off the R&D from there.
- Kiran Mazumdar-Shaw:** Yeah.
- Nitin Agarwal:** Okay. Thank you.

**Saurabh Paliwal:**

Thank you, Nitin. This was the last question for today's call. I thank everyone for joining us today. If you have any follow ups, please do get in touch with us. Thank you very much and you can hang up now.

- Ends -

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