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BIO/SECL/SP/2024-25/71

August 19, 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 Q1 FY25

This is further to our earlier letter dated August 10, 2024, regarding presentation and video recording of Q1 FY25 Earnings Call held on August 09, 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 said information on record.

Thanking You,

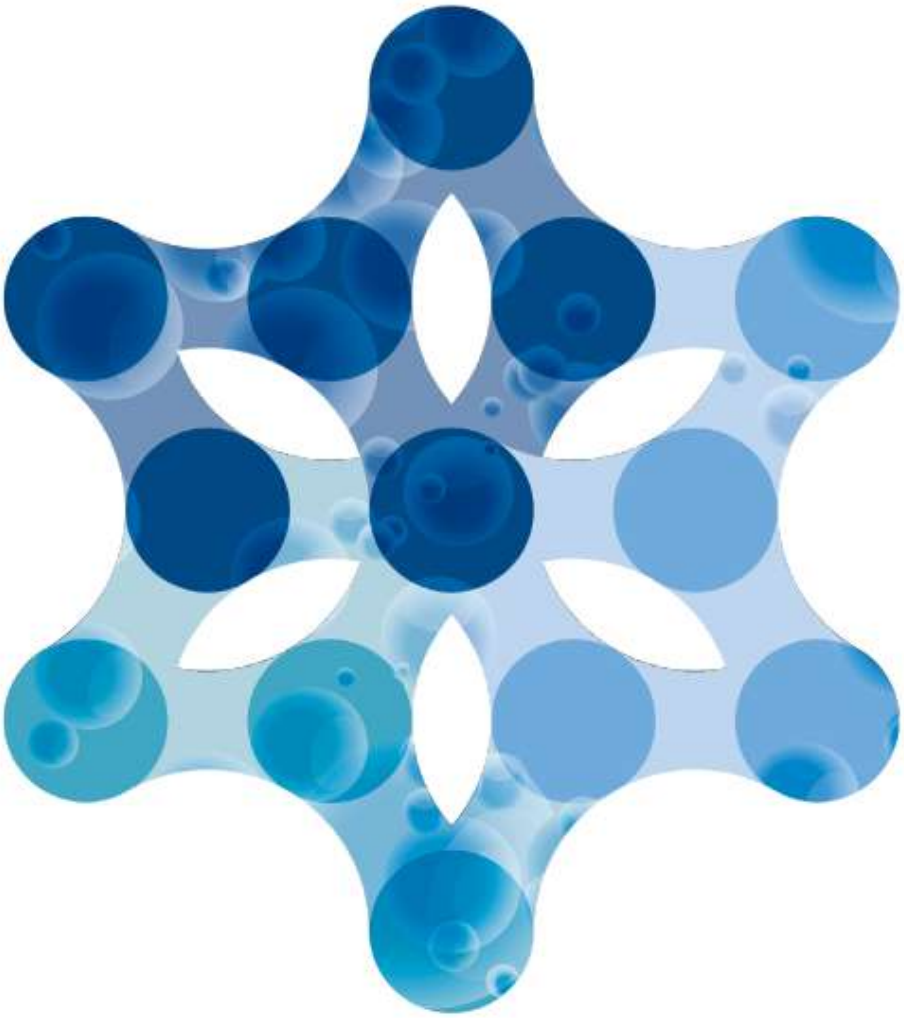
Yours faithfully,

For **Biocon Limited**

MAYANK VERMA
Digitally signed by MAYANK VERMA
Date: 2024.08.19 17:16:06 +05'30'

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

Encl.: as above



The **Multiplier** Effect

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Biocon Limited Q1 FY25 Earnings Conference Call Transcript

Aug 9, 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. Sibaji Biswas** – Chief Financial Officer & Executive Director, Syngene International 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. Saurabh Paliwal** – *Head - Investor Relations, Biocon Limited*

External Participants during Q&A session

- **Amey Chalke** – *JM Financial Institutional Securities Pvt. Ltd.*
- **Tushar Manudhane** – *Motilal Oswal Financial Services Limited*
- **Neha Manpuria** – *Bank of America Securities India Limited*
- **Surya Narayan Patra** – *Phillip Capital (India) Private Limited*
- **Manoj Bahety** – *Carnelian Asset Management & Advisors Private Limited*
- **Kunal Randeria** – *Axis Capital Limited*
- **Ashish Thavkar** – *JM Financial Asset Management Private Limited*
- **Jamsheed K** – *Individual Investor*
- **Rahul Jeewani** – *IIFL Securities Limited*
- **Dhaval Bhalodia** – *Individual Investor*

Prepared Remarks Session

Saurabh Paliwal:

Good morning, 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 first 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 to ask questions after the opening remarks conclude. Should you need to ask a question, please select the raise hand option under 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 at investor.relations@biocon.com

I would like to bring to your 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 that, 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 morning, everyone. Before presenting the results in detail, I would like to start with some opening remarks. As you will see and hear, on a reported basis, the comparable or year-on-year first quarter group financial performance has come in very strongly, with total revenue up 30%, EBITDA up 117%, and PBT up over 500%. This performance has been driven by the impact of the Eris Lifesciences business transfer consummated in the quarter. After adjusting for the Eris transaction, underlying group financial performance, while relatively subdued, has come in line with our expectations and our previous guidance. And this is reflecting a mix of headwinds and tailwinds across our businesses. The highlight was the Biosimilars business, which has delivered a strong like-for-like operating revenue growth, which has offset degrowth in the Generics business and in Syngene. In line with our previous guidance, we expect the quarter 1 trends to continue into quarter 2 before we see a transition toward accelerating growth across the businesses through the second half of the fiscal year and into next year.

Financial Highlights – Q1 FY25

I will now move on to present the financial highlights for the quarter.

At the group level, **Total Revenue** was INR 4,567 crores, a growth of 30% year-on-year and 15% on a sequential basis. This included proceeds amounting to INR 1,057 crores from the strategic business transfer agreement with Eris Lifesciences, which is classified as other income. **Revenue from operations**, which excludes income from the Eris transaction was INR 3,433 crores, largely flat as compared to last year. As I have just said, this reflects a balance of performance across the segments where Biosimilars revenue from operations grew 11% on a like-for-like basis while Research Services and Generics saw declines of 2% and 6%, respectively.

Group core EBITDA for the quarter stood at INR 903 crores, down 4% year-on-year and representing a core operating margin of 26%. Quarterly R&D investment spend stood at INR 228 crores corresponding to 9% of revenues, excluding Syngene. Reported EBITDA for the quarter stood at INR 1,755 crores, up 117% year-on-year with a margin of 38%. Adjusting for the income from the Eris transaction, EBITDA for the quarter was INR 698 crores with an EBITDA margin of 20%. Profit before tax and exceptional items stood at INR 1,114 crores versus INR 184 crores last year. Adjusted for the Eris transaction flow through, PBT for the quarter stands at INR 57 crores. Reported Net Profit for the quarter was INR 660 crores while adjusted Net Profit stands at INR 19 crores.

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

Generics Business

Revenue from operations in Generics was INR 659 crores, a degrowth of 6% year-on-year. Core EBITDA for the quarter was INR 123 crores with a margin of 18%. R&D spend at INR 64 crores, and representing 10% of segment revenues, was up by INR 10 crores from the same period last year, reflecting continued investment in our strategic peptide and injectable portfolios. EBITDA for the quarter stood at INR 59 crores with a margin of 9%, reflecting lower sales, price erosion and the increase in R&D investments seen during the quarter. Profit before tax stood at INR 17 crores, with a PBT margin of 3%. Overall, while the performance for the quarter was muted, it was in line with our expectations, reflecting the anticipated pricing and demand challenges across our API and formulations base business.

Moving to the business updates, let me start with **business development**. And here, our preparations for entry into the GLP market opportunities are continuing to build momentum, and we were very pleased to sign an exclusive licensing and supply agreement with Handok, a leading specialty pharmaceutical company in South Korea for the commercialization of our Synthetic Liraglutide for the treatment of chronic weight management. This is consistent with our commercial strategy of expanding our global footprint beyond our direct presence in the United States into other important geographies, including the U.K., Europe, Latin America, Asia, and Australia, either through a direct presence or working with strong local strategic partners.

On the **regulatory front**, there has been significant activity and progress. With 17 market filings, including 2 ANDAs in the United States, and we have received 3 approvals including our first generic injectable drug product approval for Micafungin in the United States.

In June, the U.S. FDA conducted GMP and PAI inspections at 2 of our API facilities, Site 5 and the new Site 6, both located in Vizag. These inspections resulted in the FDA citing 4 and 3 observations, respectively, which were procedural in nature. The company responded to the agency's observations within the stipulated timelines for both inspections, and I am happy to report that earlier this week, the FDA issued an establishment inspection report for Site 5 and classified the inspection as 'VAI' or Voluntary Action Indicated. We now await agency feedback for Site 6. In June, the Brazilian Health Agency, ANVISA, conducted a regulatory audit of our oral solid dose facility in Bengaluru, which concluded with no major or critical observations.

Looking ahead for the Generics business and consistent with previous guidance, we expect the second quarter to continue to be relatively muted with performance then building in the second half of the fiscal led by new generic formulation launches across multiple markets. Importantly, this includes the launch of our Liraglutide formulations for diabetes and obesity, both in the U.K. and in other markets where preparations are well underway. Our extensive GLP portfolio led by Liraglutide will be the major growth driver for Generics' in the coming years and has strong synergies and complementarity with our global Insulin business in our Biosimilars vertical, providing Biocon a unique positioning in addressing the strategic diabetes and obesity global market opportunities ahead.

Biosimilars Business

Let me now move on to our Biosimilars vertical. While our focus in fiscal 2024 was on ensuring business continuity and preserving value during the transition phase post-acquisition, our focus in FY25 has now shifted to consolidation and leveraging our unique vertically integrated model to drive profitable growth. And I am pleased to say we began the year on a positive note with a robust 11% like-for-like growth in Q1 and achieved several key regulatory milestones.

In the United States, we continue to see strong demand across our product range. In our oncology franchise, Fulphila, our biosimilar Pegfilgrastim and Ogivri, our biosimilar Trastuzumab, continue to hold strong market shares of 20% and 19%, respectively, with several market access agreements coming into effect and increased pull-through at the physician level from our marketing team. Our Semglee and Insulin Glargine franchise serving the diabetes market segment also holds mid-teens shares on the back of strong formulary coverage, including a large managed care network. The U.S. insulin landscape continues to evolve dynamically, and we believe we are very well positioned with our extensive heritage and expertise in insulins to exploit and capitalize on the emerging opportunities.

In Europe, our market shares have remained stable at the regional level with some strong performances in several key markets. Hulio, our biosimilar Adalimumab is the market leader in Germany and on the oncology front, our Ogivri, Fulphila and Abevmy (biosimilar bBevacizumab) products have captured double-digit market shares in key markets such as France and Italy. We are also making good progress on our business expansion strategy in Europe with new launches and tender wins at national and hospital level in markets such as the United Kingdom and Italy.

Our Emerging Markets business reported a strong performance on the back of higher sales of our biosimilar Bevacizumab, recombinant Insulin and Etanercept. During the quarter, we expanded the depth and breadth of our reach through 12 new product market launches.

Now coming to the **financials** for the first quarter of fiscal 2025, Biosimilars revenue from operations was INR 2,083 crores, up 11% on a like-for-like basis, adjusting for revenues in Q1 fiscal 2024 from the branded formulations unit in India. Revenue from operations does not include the income from the Eris agreement, which is booked as other income.

This growth translated into a core EBITDA of INR 614 crores with a margin of 30% and an EBITDA of INR 474 crores or 23%, reflecting the strong underlying profitability of the core business. We continue to invest in our pipeline with R&D spends at 8% of revenue to drive the mid and long-term growth of the business. Profit before tax is INR 1,065 crores, including the gain from the Eris agreement.

Moving on to **regulatory updates**, there have been significant activity and progress. The U.S. FDA-approved Yesafili, our biosimilar Aflibercept as the first interchangeable biosimilar, which marks our entry into Ophthalmology, a new and exciting therapeutic area. Our biosimilar Denosumab global clinical trial has met the required endpoints, and we are currently on track to submit regulatory filings later this year.

The European Medicines Agency (EMA) has renewed its Good Manufacturing Practice (GMP) Certificates of Compliance for both our Bengaluru and Malaysia sites. We have also received EMA approval to manufacture our biosimilar Bevacizumab at our new monoclonal antibodies drug substance facility in Bengaluru. The same facility has also received GMP certification from the Therapeutic Goods Administration (TGA), Australia.

The U.S. FDA recently concluded a combined GMP and Pre-Licensing Inspection at our facilities at Biocon Park Bengaluru, in July 2024, spanning 6 manufacturing units and the associated quality labs and warehouses. The 10 observations noted in the Form-483 were procedural in nature. There were no observations related to data integrity or on quality oversight at any of the facilities and no repeat observations were noted by the agency during inspection. We will submit a comprehensive, Corrective, and Preventative Action (CAPA) plan to the agency within the stipulated time frame and are confident of addressing these observations expeditiously. We do not expect the outcome of these inspections to impact the supplies of our commercial products.

Syngene

Finally, coming to Syngene. In Syngene, we saw Revenue from operations for the quarter down marginally over last year at INR 790 crores. Reported EBITDA was down 20% to INR 188 crores with an EBITDA margin at 23%. Profit before tax at INR 69 crores was down 44% from last year. Overall, Syngene's first quarter performance is in line with its guidance and commentary given in its Q4 fiscal results presentation.

The Dedicated Centres reported steady performance while there were continued growth momentum in biologics manufacturing, driven by both commercial as well as clinical scale projects.

Performance in Discovery Services was impacted by the dip seen in U.S. Biotech funding that has impacted the sector over the last 2 years. However, green shoots are now on the horizon as the value of funding to U.S. biotech saw remarked increase in the first half of calendar 2024, which will generally flow into outsourcing demand with a lag of a few quarters. Requests for proposals are up 50% year-on-year with the first quarter of fiscal 2025 being the best first quarter for RFPs for Syngene in 4 years. This quarter also saw the start of several pilot projects from pharma

companies. Successful delivery of these projects is expected to build a foundation for larger scale future collaborations, and Syngene expects to win its fair share of these pilot projects.

Increased visits by companies exploring outsourcing options beyond China, add to the positive future outlook and provides long-term tailwinds for Syngene. The repurposing of the Biologics Manufacturing facility acquired from Stelis Biopharma remains on track for completion of qualification and facility modifications in the second half of fiscal 2025.

So, **to conclude**, overall, the underlying operational group performance delivery in the first quarter while largely flat has reflected the balance of a strong Biosimilars performance, offsetting transitory degrowth in Generics and in Syngene. This is consistent with our earlier stated guidance and is in line with our expectations. Performance in the second quarter is expected to largely mirror that seen in the first quarter. In the second half of the year, and as previously guided, we expect to see a transition to accelerated growth underpinned by continued traction in Biosimilars, new product launches in Generics, and Syngene being in a strong position to capitalize on the emerging trends in its business to hit its guidance range for the year, and with momentum expected to build in the second half.

I would now like to conclude my opening remarks and open the floor to questions.

Q&A Session

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

Amey Chalke: **The first question I have is on the Biosimilars. I agree that we are increasing market share quarter-on-quarter in the existing products in the U.S. But should we assume the similar improvement happening on the value of these products? Basically, how is the pricing tracking in these Biosimilars so vis-a-vis the market share gains?**

Peter Bains: Thank you for the question, Amey. I am going to ask Shreehas to lead the response for that question, please.

Shreehas Tambe: Thanks, Peter. Thanks, Amey, for the question. I think the good part is that the Biosimilars opportunity that we are seeing overall in all markets, whether it is North America, Europe or in Emerging Markets, seems to be very strong. It has shown strong growth for all our products in all geographies.

And if you specifically ask on the pricing front, we are looking at a more stable pricing across regions. In the U.S., we have seen that Biosimilars have held on to their price, particularly those in the oncology space for over 5 years and this will continue to hold value. So, there is, of course, a competitive dynamic, which will play out. But we expect a much more stable pricing regimen than the other markets that are there. We expects this to be a very stable market overall, Amey.

Amey Chalke: **Should we assume the value gain in these products correspondingly the market share gain, which is happening in these products, basically. Should we assume that sales to be increasing?**

Shreehas Tambe: Yes. I think the way you would expect is that their competitive dynamics will play out across markets as products matures. But we really feel that given the increased market shares there will be a growth in the products and the revenues. Pricing will, of course, erode over time. So that the expectation that we should all have of any market for any product, but it is gradual price decline. And market share should be a good indicator of product acceptance and performance.

Amey Chalke: **Sure. So, a second question I have is on the Hulio, basically our expectation was in FY 2025, the market landscape will move towards generic. If you can give some colour on the market development here in the Humira biosimilar market.**

Shreehas Tambe: Peter, if I can just go into this and then I will have Matt join me as well for this answer. Amey, if you go back to the commentary that we had shared on how we see this market evolving, we have said it's a 3-stage evolution, where we have said calendar 2023 is when the market opens up, which is when everyone got in. 2024 is when we set the market, and that was calendar 2024 is when we said market will start to see traction towards Biosimilars, and 2025 is when the opportunity really opens up from a calendar year perspective. What we are seeing right now in the U.S. is that you are seeing Biosimilars starting to take market share, although still a large part of the market is with the originator, but we clearly see that it will move in the direction that we have guided in the past. I would like, Matt, of course, to add more colour to this in terms of how it shaped in 2024, and how we see this evolving in 2025. So Matt, would you like to please comment on?

Mattew Erick: Sure. Thank you, Shreehas. So, a little more colour around this is that we are starting to see the Biosimilars, you can see this starting to take off. But it is relatively just with 1 large U.S. payer, and that large U.S. payer is primarily using their private label, which is very publicly what's going on. The other 2 large U.S. payers currently still have Humira on their formulary. As Shreehas stated, we do see this as a second half of FY 2025 opening up, and we are in a position right now of bidding these products. And we feel that we have got a great opportunity as we look towards the second half in meeting our expectations that we've laid out.

Amey Chalke: **If I can add the supplementary question. So, assuming that the Humira will get developed in the second half, is there any change in our guidance for this year, considering if there is any delay on the new product launches?**

Shreehas Tambe: Amey, we have not provided any guidance on the numbers at this point to my knowledge. And the way we see this is that given that for Adalimumab, we are in a very good position that we are integrated, we have a history of commercializing this product since 2018. I would like to point you towards our leading market share position in Europe where we have successfully had this product in the market for a very, very long time. So, we believe

that this will play out in our favour as the market in the U.S. matures, and we see this market consolidating over a period of time.

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

Tushar Manudhane: **Sir, with respect to this inspection at Bengaluru, while the response has been submitted, can you share the timeline for implementation of the measures?**

Peter Bains: Thank you, Tushar. Let me again give that to Shreehas to perhaps get someone from his team to reply.

Shreehas Tambe: Tushar, thanks for your question. As Peter explained in his opening comments, we did have the inspection from the agency last month. And we are in the process of responding to the agency with a very comprehensive CAPA plan and that is within the stipulated timelines. So, once we have done that, we should be in a position to outline next steps.

Tushar Manudhane: **Any broad timeline you would want to share to implement this and how is the approvals of the product will be subject to the implementation of the CAPA?**

Shreehas Tambe: Like every inspection, once the inspection is done, the company is expected to provide a response to the observations. These observations are what the inspectors note during their time at the facility. We have noted those observations, and we will be responding to this. The agency typically reviews this in a time frame, but there is no guidance that they have in terms of when they will revert back to us. We expect them to come back typically in the 60 to 90-day time frame, but there is no real time frame that is defined for this. So, it would be incorrect to comment on behalf of the agency.

Tushar Manudhane: **And progress on the Malaysia side from a compliance point of view?**

Shreehas Tambe: On the Malaysia side, we have responded to the observations that the agency had made, and we will be looking forward to them scheduling an inspection for us to move forward on that.

Tushar Manudhane: **Effectively that would also as a timeline, 3 to 5 months can be considering the inspection timeline for Malaysia side?**

Shreehas Tambe: Tushar, it would be hard to comment on behalf of the agency when they would come or whether they would need an inspection once they have concluded on the Bengaluru inspection. So, I wouldn't draw right now a timeline on it. But I can tell you that we are in constant conversation with the agency, and we will provide them with whatever is required for them to assess the readiness of the site to supply new products. I should also point out to you that we continue to supply large amounts of products to the United States from this site and all other regulatory agencies, including EMA, most recently, have approved our facilities in Malaysia and in India.

Tushar Manudhane: **And just lastly on the Generic Liraglutide and considering the business prospects for Biocon Generics, how do we see like what kind of scale up can we expect if you could quantify, let's say, second half FY 2025, we expect this business to scale up. And if you could also elaborate on the Liraglutide opportunity per se.**

Peter Bains: Thank you, Tushar. Sid, perhaps you could address that question.

Siddharth Mittal: Sure. Tushar, I think as we have indicated earlier, and Peter mentioned in his opening comments that we have various markets where we have done the filings, we expect approval from European authority in later part of this fiscal. We have already got a launch coming up in the U.K. through our partner, Zentiva as well as under our own label. And there are various other markets, which, where we expect to launch the product during this fiscal year.GLP-1 franchise is a very important part of our growth story. For next couple of years, as you know, there is a huge opportunity in GLP-1 space, both in diabetes and obesity management, and we are very well placed in capturing the benefits of this large opportunity. In terms of specific numbers or guidance in terms of what the growth is, I think it will be a bit difficult for us to give that. But definitely, the first half will continue to be muted as we have seen in first quarter. But second half, we will see significant growth over first half. For the overall year, we still expect like a high single-digit kind of growth levels for the business.

Peter Bains: Tushar, if I may, then just add in a little bit on top of that to amplify something I said in my opening remarks. Obviously, the GLP peptide opportunity is the strategic growth driver for Generics in the coming years and will play into a huge market opportunity being formed by the innovators over the coming years and decade. I think it is important for me just to emphasize here, this is an area of very, very strong group complementarity and synergies as the peptides where we are scaling for global market opportunity complements and has many synergies with the global insulin franchise that we have built in the Biosimilars. And quite clearly, as we look at this opportunity in both diabetes and obesity, we see Biocon being very uniquely positioned with its heritage position in insulin and its leading position in the generic peptides business to look at leveraging the synergies, these complementarities, these convergences to drive a unique opportunity here for the group.

Tushar Manudhane: **Just one more on this. As far as API capacity is concerned, do we have sufficient capacity to cater at least for next couple of years or would we need further investment for Liraglutide API?**

Siddharth Mittal: We do have initial set of capacities that we had created, and we are expanding those capacities, which will be sufficient for the next couple of years. But of course, the big drug, which is Semaglutide goes off patent beyond 2030 in many of the large developed markets. And for that, we will, of course, add on more capacities over a period of time. But the volume of business that we are targeting over the next 5 years, we will have capacities by end of this year.

Saurabh Paliwal: The next question from Neha Manpuria from Bank of America.

Neha Manpuria: **Just to understand the BBL business a little bit more on a quarter-over-quarter basis. There seems to be a sharp decline. I am assuming a large part of this is because of the divestment. So, if you could just give us some colour in terms of how much of that decline that we are seeing quarter-on-quarter because of the India business divestment versus, let's say, underlying business trends?**

Shreehas Tambe: Neha, thanks for pointing it out. Kedar, please feel free to jump in on that. I think Neha as Peter outlined in his opening comments, the quarter-on-quarter decline, which you are seeing is, one is to adjust for the branded formulation business, which is a discontinued business that we have seen, and that's a clear change that the baseline is different. The other piece, of course, is that you will see a cyclical nature in terms of how tenders will open up over the different emerging markets. And we will see a strong growth usually in the quarter 4 before you get into quarter 1. So that is what you are seeing. But I do want to point you towards the performance of the business over the comparable quarter in fiscal 2024. And there, you can see that there's a very strong growth in the product performance. And that is a 19% increase over the product performance and market share that has driven it. So, if you look at how the products have performed in the market, there's a very strong uptick. The cyclical nature of this will mean that between quarters you will have movements where quarter 4 could be higher than quarter 1, particularly in emerging markets. But in North America, you see a steady performance across borders, and you will see some minor movements in Europe, where also there are large dependencies on tender timing.

The chronic therapy areas that we operate in actually allows us a natural buffer and a hedge towards some of this, but the tender opening cycles in different markets will cause some of these differences and lumpiness between quarters. Otherwise, we see this moving in the right trajectory.

Neha Manpuria: **And so, is it fair to assume, Shreehas, that the emerging market piece should continue to grow mid-teens, high teens? It's just a matter of the tender phasing between quarters. But the underlying growth is still in line with the trends that we are seeing for the biosimilar business overall**.

Shreehas Tambe: Yes. We have seen a strong uptick across markets. It's not just that we have seen growth in North America. And the Emerging Markets is a growth area for us, Neha. So, it is quarter-on-quarter sequentially, you might see that there is some movement between quarters because of, as I said, when tenders open and when supplies begin. But otherwise, on an annualized basis, you will see that across markets our performances will be pretty strong.

Neha Manpuria: **Understood. And my second question is on Aflibercept. Now we have the U.S. FDA approval, obviously, the lower quarter litigation didn't go our way. What are the timelines that we need to monitor this for the appeals for this one? And therefore, does the timeline of launch based on how you are thinking about the appeal?**

Shreehas Tambe: Yes. And bAflibercept is an important asset that you draw attention to. It is an exciting asset. It has over USD 10 billion of sales globally in innovator revenue. So, it's clearly a very exciting asset. We have a first-to-file status. We have a first-to-approval status as an interchangeable bAflibercept. We feel very good about it. We have already secured approval for this product in Canada, in the U.K., in Europe and now most recently in the U.S. as well. We are in a good place, scientifically, and in the ability to begin supplies. We recently also announced that in Canada, we will be supplying product come July of next

year, which will be the first in that market. We are, of course, in litigation with the innovator in the United States. And as things progress there, we will be able to talk more about it. But given that we are in a litigation right now, Neha, it would not be appropriate to comment on this. I know you made a comment on how the litigation in the district court played out. There were 3 patents that were litigated. 2 were ruled in our favour. One wasn't ruled in our favour, which, of course, we will take up appropriately so that we can get to the patients as soon as that is behind us, and we are working on that.

Neha Manpuria: **And one last question, if I can squeeze in. What is the net debt position in this quarter for BBL as well as the consolidated entity? And if you could give us some colour on likely repayments in the next year?**

Shreehas Tambe: Kedar, would you like to take that question?

Kedar Upadhye: Yes, sure. Neha, the net debt for BBL is about USD 1.2 billion. You would see a sequential improvement because of working capital efficiencies, which have come in this quarter. And Saurabh, can sort of clarify the net debt at the group level. But at BBL, it is about USD 1.2 billion plus, with some incremental efficiency in this quarter.

With respect to the repayments, there is a schedule of repayment that we have agreed. We are also thinking about ways to optimize both the repayment time lines and the interest rates as well. We are thinking about various options to get that sorted up.

Peter Bains: Neha, let me just add on to that to build on what Kedar said. We have obviously been comfortably servicing our debt position to date. We have made clear that we are looking to reduce it. We have taken action last year reducing acquisition debt by USD 250 million. It is a clear management priority that we will look to continue to reduce that debt level. And we have a wide range of options available to do that, and I am sure we will take further action during the year.

Neha Manpuria: **Saurabh if I can get the net debt number on the consol level, please?**

Saurabh Paliwal: Yes. So net debt at the consol level will be about USD 1.1 billion plus when adjusted for structured investments and optionally convertible debentures linked to equity conversion in Biocon Biologics.

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

Surya Patra: **My first question is on the Aflibercept. You have discussed about the potential U.S. opportunity and all particularly the commercial benefit can flow in Europe first. Could you share what is your competitive positioning there considering the multiple approval already? And when do you think that benefit can start flowing in for us?**

Peter Bains: Shreehas, again, I think if you could take that.

Shreehas Tambe: Thanks, Surya, for that question. Just a couple of clarifications. I would not speculate which market will open up first other than the fact that for Canada we have a very clear market entry date, and we are the first to enter there. We also do not think, Surya that,

there are multiple other players who have got approval. I am sure there are multiple players developing the asset. Given that the ticket size is large, we expect competition to be there. We believe we are very well placed given our advantage in terms of the timing and our position in the market, given that we are present in the market as a fully integrated player. We believe that we should be able to provide an option to patients sooner and in a much more efficient manner than has been available so far.

Surya Patra: **And sir, just an extension to this, is the 1-year exclusivity opportunity because it is an interchangeable one in the U.S. that will be ensured to us given the 2 other players have also got the approval for U.S.**

Shreehas Tambe: I think the interchangeability approval in the exclusive part that you talk about, Surya, is something that is exclusivity to claim interchangeability. It is not like an exclusivity to commercialize the product like you have in a 505(b)(2) or ANDA kind of an exclusivity where you have the ability to supply the market exclusively. I think this is more of your ability to claim interchangeability on an exclusive basis. So yes, we will have that for a period of 12 months. And once we have got the product to the market, we will look to explore that.

Surya Patra: **Sir, my second question is on Adalimumab. In fact, 2 points that I wanted to clarify here. First is that, given the kind of contract that we have signed and that is what we have indicated. So based on this, is there a possibility to share that, okay, what are the kind of volume share that we could be thinking about, let's say, for FY 2025 or FY 2026, whichever way that you can possibly share that. That is one.**

And secondly, the interesting development that happened during this quarter relating to adalimumab that one of your competing peers in the adalimumab has exited out of the opportunity by selling all their rights just for USD 40 million. So, whether it is a worrisome factor for the entire Biosimilars opportunity, and in the U.S. market, the way things are happening about the progression of the Biosimilars and all that. If you can share your view on these 2 aspects relating to adalimumab, then that would be useful, sir.

Shreehas Tambe: I think both great questions, Surya. Let me respond to that. The first is, we have not given guidance in terms of our projections in the past and we continue to stay with this. It is not advisable to give guidance on market shares. We will let you know as market evolves and we will see how that progresses. I will refrain from commenting on market shares.

The second question that you talked about, which was regarding a particular player exit the market by monetizing that asset and moving on. I think this is in line with the commentary that we had shared in the past that we do not see this market as 8, 9, 10-player market for a long time. We expect this market to consolidate, and we expect those players those will have the ability to endure over a period of time, which requires you to be fully integrated. The ability to be in control of your development, your manufacturing, and your ability to supply the market through a strong commercial force, I think that is really what will allow you the ability to be in the market for long. And we believe Biocon

Biologics has that now post the integration of the business that we acquired from Viatris. We believe we are in this for long. So, Surya, that is what we see happening. And we look at this as what was along expected lines.

Surya Patra: **Sure, sir. Just one clarification from Kedar. The staff cost this quarter is meaningfully up. Is it entirely because of the field force responsibility or the kind of marketing responsibility that you have taken up from Viatris from last quarter, it is entirely because of that? And hence, this is the kind of run rate going ahead per quarter?**

Kedar Upadhye: Yes, Surya, you're right. I think the staff cost was expected to go up to reflect the full quarter effect of the colleagues who have come over from Viatris. So that was expected, and that is in line with plan. You could see a similar reverse switch, in other expenses. That has come down. In fact, if you would have noticed in quarter 3 and quarter 4, the spend run rate was touching USD 110 million for Biologics. That has come down to USD 90 million as we had planned. Staff cost was expected to go up, and it has gone up to reflect the full quarter effect of mainly colleagues who have come over to us. But overall, costs are down by 10% compared to the peak.

Surya Patra: **Okay. On the margin front, we have seen a sharp decline this quarter, maybe it could be just a quarter-specific one, but this is the lowest ever quarter margin over the last 5 years. How would you address this, Kedar?**

Kedar Upadhye: Which margin you are referring to, Surya? Is it consol BBL PAT margin, EBITDA margin, which margin you are referring to, please so that we can answer your question.

Surya Patra: **I was looking at the EBITDA margin without factoring the Eris transaction.**

Kedar Upadhye: Yes. The EBITDA margin is about 23%, and that is consistent with what we reported last year as well. So, core EBITDA is healthy at 30%. EBITDA is at 23%. And you cannot compare the margins for the last 5 years because before FY 2023, business was different. So, the revenue scale was different, and the nature of business was different. We are in line with what we had expected, and we will work through in terms of improvement through revenue and cost levers. But those are not comparable, last 5 years margins are not comparable to what we are reporting this quarter.

Saurabh Paliwal: We will take the next question from Manoj Bahety from Carnelian Capital.

Manoj Bahety: **I have just one question for Kedar. If you can highlight maybe as capital raising options, which we are considering and any timelines around that to deleverage our balance sheet. And what is the plan to deleverage our balance sheet in next 1, 2 years?**

Kedar Upadhye: So, Manoj, I will make a first attempt and I will request Peter from a group standpoint to sort of clarify as well. As you can expect that a company of this scale and company of this capital structure will have several avenues at our disposal to conduct financing activities. And those activities help us improve our costs of financing, appropriate capital structure and maturities and all that. I think you should expect us, like any other company in our

situation would do to be active on that front. But it's going to be difficult for us to give you specifics unless those are officially approved by board and position to be announced. So, I will pause there, and maybe, Peter, you can.

Peter Bains: Thank you, Kedar. Let me build on that. Thank you, Manoj. And as I said earlier, I mean, clearly, we have been comfortably servicing the debt for the last 2 years related to the acquisition. We continue to be comfortable to do that. We have clearly stated now that several times that debt is obviously a management priority and that we are taking action, and we will continue to take action to manage and reduce that. We took action last year, as I said earlier, with a USD 250 million reduction on the acquisition debt. And we continue to look at ways to manage and reduce the debt. We will be taking further action this year. But as Kedar has said, we will advise you as and when those opportunities mature.

Saurabh Paliwal: We will take your next question from Kunal Randeria.

Kunal Randeria: **Sir, on this aflibercept interchangeable exclusivity that you are vying for, would it be a shared one or an exclusive one?**

Shreehas Tambe: So, Kunal, the bAflibercept exclusivity is already granted on approval. It is not something that we are applying for now. And that exclusivity is also part of what the guidance provides for. And it becomes only post commercialization. So right now, it is not a relevant point. But given that we are the first interchangeable approved biosimilar, yes, you will certainly look at this when you get the commercialization.

Kunal Randeria: **Sure. When you do commercialize it, it will be just you having the interchangeable exclusivity, right?**

Shreehas Tambe: We were approved on the same day with another firm, which got an approval along with us. We will have to see how that plays out, and we will keep posted on that.

Kunal Randeria: **Sure. And sir, just on Liraglutide potential, should we sort of assume or believe that the potential is bigger in markets outside of the U.S.?**

Peter Bains: Sid, would you take that one?

Siddharth Mittal: Well, I would not necessarily say it's bigger outside of U.S. U.S. is also a big market. Of course, there is a shift of patients from Liraglutide to Semaglutide in the U.S. But that said, there are patients, large number of patients who continue to take Liraglutide in the U.S. But the way I look at other markets, especially the MOW markets, there is a huge market expansion potential available when you have a generic Liraglutide, which will be launched by our partners. And because the Semaglutide, which is where most of the patients have moved of course, priced at a very high level compared to Liraglutide. And monthly treatment cost, what a generic drug will offer will expand the market. We definitely are working with our partners in various markets, the large MOW markets, to see how there could be an expansion. And Europe continues to be an attractive market for Liraglutide as well. I would say it will be a very evenly distributed numbers in the U.S., Europe and in Most of the World.

Kunal Randeria: **And just one more, if I can squeeze in. Just one clarification. Is the Stelara launch a contingent on your plant clearance by Feb 2025?**

Shreehas Tambe: I think it requires the FDA approval before you can launch.

Kunal Randeria: **Okay. So, let me ask this way, is the FDA approval withheld because of the plant issues?**

Shreehas Tambe: No. Nothing is withheld right now.

Saurabh Paliwal: We will take the next question from Ashish Thavkar from JM Financial.

Ashish Thavkar: **Sir, are there any timelines to deleverage balance sheet? Because I guess it's eating a lot of the management's bandwidth. Are you putting any certain timelines as to when do you want to deleverage the balance sheet?**

Peter Bains: Ashish, thank you for that. Again, I will amplify that we are looking at this as a priority. We intend to take action this year, but I cannot be specific on timelines.

Ashish Thavkar: **And understandably, obviously, we now have Biosimilars, the Generics business, the API one. At any point in time, would you want to share some of the business elements is that also on your cards the go-forward strategy?**

Peter Bains: I think we feel that there are strong opportunities in both the Biosimilars and the Generics business, and there are no plans in that we are looking at to do any divestments.

Ashish Thavkar: **And lastly, on Eylea, the injunction that we have, any timelines that you are sharing with the investors?**

Shreehas Tambe: We have shared, Ashish, the timelines that we will be looking to launch this in Canada mid-next year. We have already talked about that. We just discussed that there is an ongoing litigation in the United States. And we will see how it works in Europe and other parts of the world.

Saurabh Paliwal: The next question is from Jamsheed K.

Jamsheed K: **I would like to know about the Ustekinumab timeline. In the previous quarter you have already mentioned the submission in the U.S. So can you please provide light on the U.S. and EU timeline?**

Peter Bains: Shreehas, would you take that one?

Shreehas Tambe: Thanks, Peter. Jamsheed, thanks for the question. We had indicated that we have made a submission to the U.S. FDA and to the European authorities already for this product and this product is under review with the agencies. Once it is approved, we have also been able to negotiate a risk-free launch date and agreed settlement date with the innovator for Stelara in the United States, and we will be amongst the first wave of companies launching this early next year in the last quarter of this fiscal once we've got the product approval. So that's the status on bUstekinumab, Jamsheed.

Saurabh Paliwal: We'll take the next question from Rahul Jeewani from IIFL Securities.

Rahul Jeewani: **Sir, if I am not wrong, there is a deferred consideration, which is payable to Viatris this year related to the deal and our option to in-license Eylea. I think that consideration which is payable to Viatris is around USD 335 million. So how are we looking to fund that? And given that, how are you looking at your debt at the BBL level by the end of this year?**

Peter Bains: I will start and Kedar, Shreehas, you can add in. I think the first payment that you referred to has already been made. And the second payment that you are referring to, we will address when it is due. So, no issues, no problems there. And with regard to the debt in BBL, I think we have addressed that several times to other questions that it is clearly a priority. We intend, as we did last year, to reduce further. We are exploring a number of options. And as and when those mature, we will advise. And other than that, we can't give any more detail, be more specific on what option and what timeline, but we will address that, and I think resolve both the any payments due and work to reduce the debt further during the year.

Rahul Jeewani: **Sure, sir. So essentially, the debt at the BBL level, which we have right now is USD 1.2 billion. That is after taking into account the first payment, which we have already made to Viatris?**

Peter Bains: Yes, it would be.

Saurabh Paliwal: The next question is from Dhaval Bhalodia, an individual investor.

Dhaval Bhalodia: **I had a question regarding mainly for the U.S. biosimilar sector. As Peter mentioned, some with major PBM and specialty pharmacy forming their own subsidiary to market their own biosimilar and capturing the significant markets share with product like the Humira biosimilar. And in the future, while that maybe happen and potentially applying the same strategy for the future product as well. And the remaining major PBM player, I think they are doing the strategic tie up with other pharma. So how Biocon plan to capture a profitable market share for this future biosimilar product because most of like Stelara, Hulio, they're most of like the retail specialty product.**

Siddharth Mittal: Shreehas, I think that's one for you and perhaps, Matt.

Shreehas Tambe: Dhaval, thanks for your question. It is a very valid one, given what we have seen. Matt, maybe you can also join me in responding to this. So, what you are basically asking here is what we saw in case of Humira where we saw one of the PBMs work through a channel, which was more like a captive to white label or private label or product, which then they can source, and that's been gaining market share. That is certainly one of the things that PBMs have used to capture more share of the pie, that is an activity that we have seen, Dhaval. And that is something that can happen in the market. We are watching this closely. Not every product will, of course, go through that route, and that is not necessarily a practice that we expect to see happening across every product, but it is something that we are seeing PBMs trying to do to protect a larger share of the pie and get a larger piece of the business. But I'll let Matt talk to you more about this. Matt, over to you.

Matthew Erick: Thank you, Shreehas. Some other key things, as Shreehas said, it is not just the commercial environment. There is also a U.S. government business that is not part of any private pay. There are also closed-door networks that we are familiar with. There is also the hospital channel. There are quite a few other channels in which we can play in. Certainly, as Biocon, we are competing aggressively in these private labels. As you know, there is only one that's been really established. We are seeing some foothold taking part in maybe another PBM establishing one, which we are in conversations with, but then the third largest is still remaining as a traditional PBM. So once those private payers go with one, the others open up because we have not seen overlap across. There's still opportunity for us in all the Part D programs that are out there.

Saurabh Paliwal: Ladies and gentlemen, that was the last question for the day. Thank you all for joining today's investor call. And if there are any subsequent questions or clarification needed, please do get in touch with us. With that, have a good day, and goodbye.

-Ends-

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