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February 16, 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 Q3 FY24

This is further to our earlier letter dated February 9, 2024, regarding presentation and video recording of Q3 FY24 Earnings Call held on February 9, 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: 2024.02.16 22:11:41 +05'30'

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

Encl. as above

Biocon Limited Q3 FY24 Earnings Conference Call Transcript

February 9, 2024

Speakers and Participants from Biocon Limited and Biocon Biologics Limited

- **Mr. Peter Bains** – *Group CEO, 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. Kedar Upadhye** – *Chief Financial Officer, Biocon Biologics Limited*
- **Mrs. Rhonda Duffy** – *Chief Operating Officer, Biocon Biologics Limited*
- **Mr. Abhijit Zutshi** - *Commercial Head - Global Generics, Biocon Limited*
- **Mr. Nehal Vora** - *Commercial Head - Global API, 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*
- **Mr. Nikunj Mall** – *Head - Investor Relations, Biocon Biologics Limited*

External Participants during Q&A session

- **Neha Manpuria** – *BofA Securities India Limited*
- **Damayanti Kerai** – *HSBC Securities and Capital Markets (India) Private Limited*
- **Surya Narayan Patra** – *Phillip Capital (India) Pvt. Ltd.*
- **Shyam Srinivasan** – *Goldman Sachs Group, Inc.*
- **Vipul Kumar Shah** – *Sumangal Investments*
- **Tushar Manudhane** – *Motilal Oswal Securities*
- **Pranav Tendolkar** – *Rare Enterprises*
- **Yash Tanna** – *ithought Advisory*
- **Harith Ahamed** – *Spark Capital Advisors (India) Private Limited*

Prepared Remarks Session

Saurabh Paliwal:

Good morning, everyone. I am Saurabh Paliwal from Biocon Investor Relations team, and I'd like to welcome you all to the Biocon Limited Earnings Call for the Third Quarter FY 2024.

I would like to indicate that all the participants will be in a listen-only mode, and there'll be an opportunity to ask questions after the opening remarks conclude. Should you need to ask a question please select the raise hand option in the reaction tab of the Zoom application. We will call out your name and unmute your line to enable you to ask a question. While asking a question please limit your questions to two and begin with your name and organization.

I would like to bring to your attention that this conference call is being recorded. The recording will be made available on the website within a day, and the transcript will be made available subsequently.

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

Before we begin, I would like to remind everyone of the safe harbor related to today's 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 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 relation team.

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

Peter Bains:

Thank you, Saurabh. Good morning, everybody, and thank you for joining this call. I'll start with a broad overview of the consolidated group financial results, before discussing each of the business units in more detail.

Total group revenue for the quarter was INR 4,519 crores, up 50% year-over-year. This growth was supported by income from divestiture to non-core branded formulation India business units in Biocon Biologics for INR 350 crores and a gain from Biocon stake dilution and Bicara Therapeutics of INR 456 crores. Revenue from operations increased by 34% to INR 3,954 crores, with biosimilars revenue growing 65%, research services growing by 9% and generics declining by 7% year-over-year.

Core EBITDA for the quarter stood at INR 983 crores, reflecting a group core operating margin of 27%. It's important to note here that core EBITDA excludes the impact of asset and stake sales, as I just described, and of course R&D. R&D spend stood at INR 329 crores corresponding to 11% of revenues, excluding Syngene. Group EBITDA for the quarter was up 106% at INR 1,492 crores versus INR 723 crores last year, with an EBITDA margin of 33%. Excluding the 2 nonrecurring items, group EBITDA for the third quarter stands at INR 686 crores, with a margin of 18% as compared to 24% last year.

Depreciation and amortization and interest increased by INR 260 crores, year-over-year to INR 681 crores,

primarily associated with Biosimilar's business acquisition costs.

Consequently, **Profit before tax and exceptional items** stands at INR 787 crores, up 220% from INR 246 crores for last year. Reported net profit for the quarter before exceptional items stands at INR 644 crores as compared to INR 140 crores in the previous year.

I want to note here that we recorded a net exceptional gain during the quarter of INR 16 crores. This is net of tax and minority interest. This exceptional gain comprised of a gain on carrying value of an existing contractual receivable arrangement, which was offset by impairment of intangibles associated with the product in certain territories from some inventory provision and transaction costs related to the Viatris transaction and Stelis facility acquisition. This gain contrasts with a loss of INR 182 crores last year. And consequently, reported net profit after exceptional items now stands at INR 660 crores as compared to a loss of INR 42 crores last year. And finally, as part of our efforts to reduce debt, we have repaid $200 million of biosimilars acquisition-related debt.

Generics business

Let me now turn to the business segment and start with generics. The generics business reported an operating revenue of INR 703 crores, delivering sequential growth of 4%, while declining 7% year-on-year. The business performance for segment reflects the generic formulations component, which is showing consistent and steady growth; and the API business, which is affected by market dynamics of pricing pressure and variable update, resulting in a lumpiness in performance. Core EBITDA for the quarter was INR 154 crores with a margin of 22%. Profit before tax stood at INR 50 crores, representing a PBT margin of 7%.

Moving to the generics business updates. Let me start with product approvals. And here, I'm pleased to report that we've received our first generic product approval in China for Mycophenolate Sodium. This approval paves the way for the entry of our products into this large and strategic market. In addition to this, we have also received 4 product approvals across API and formulations, including 1 approval in the United States, 1 in the U.K. and 2 in Most of the World markets.

Moving on to an update of our manufacturing programs. I'm pleased to report we've made good progress in our investment in new platform capabilities and capacities to underpin future growth. During the quarter, the company's greenfield Immunosuppressants facility in Vizag received a certificate of suitability, or CET, from EDQM, the European regulator. We now expect the facility to be inspected and subsequently qualified for commercial supplies by other major regulators in the next fiscal. These new approvals, as they are received, will help build upon the established scientific and commercial capabilities of Biocon in fermentation products and help address the growing demand for immunosuppressants across global markets.

Also, during the quarter, our peptide API facility in Bangalore successfully completed process validation activities. As the business model of Biocon Generics evolves in the coming years, we expect peptides, and particularly GLPs, to play a major role as a future growth driver. In Hyderabad, process validation of products has begun in our new and modernized synthetic API facility. We approach the close of the current fiscal, the business performance will remain a balance of API business lumpiness underpinned by sustained performance in generic formulations, supported by recent contract wins and upcoming product launches.

Biocon Biologics

Let me now move on to Biocon Biologics. And let me start by providing an update on the integration of the acquired Viatris business. During the quarter, we completed the operational integration in more than 30 European

countries, Japan, Australia and the remaining emerging markets. With this, we have now successfully completed the full transition of the acquired business in about 120 countries, fully 1 year ahead of schedule to become a globally scaled and vertically integrated lab-to-market biosimilar enterprise.

Turning now to the business performance, I'm starting with the United States. In the first quarter, post integration, our products have maintained momentum and showed resilience in the dynamic market environment. Fulphila, our biosimilar Pegfilgrastim, demonstrates continued strength with 80% market share in November; while Ogivri, our biosimilar Trastuzumab, has been resilient with a market share of 12%. Reported market share for our biosimilar, Glargine, continues at 12%. However, these numbers do not capture the uptake for our unbranded Glargine to a closed-door pharmacy network. New wins during the quarter included 3 contracts for Fulphila, including a sole-source contract with a large GPO organization; and 3 contracts for Ogivri, including a large GPO arrangement. We also secured 2 contracts for unbranded biosimilar Adalimumab commencing this month.

Turning to Europe. And here, our products have made steady gains. The quarterly market share of Fulphila has grown to 8% against 5% last year. And Abvemy, our biosimilar Bevacizumab, has grown to 6% against 1% last year.

In emerging markets, the highlight was the launch of Abvemy in Brazil with an originator market opportunity of $175 million. This was a landmark launch, being the first major launch post-completion of the integration of the acquired business.

Now coming to the financials of Biologics. The revenue from operations was INR 2,483 crore, up 65% year-over-year. On a sequential basis, the growth stood at 26%. As mentioned last quarter, we divested 2 non-core branded formulations India business units to Eris Lifesciences, aligning with our global product focus. This has led to an increased operating income for the quarter by INR 350 crores. Excluding revenues from the divestiture, the sequential growth stands at 8%. This translates into a core EBITDA of INR 587 crores with a margin of 28%. This margin is lower than our guidance of mid-30s on account of the series of integration-related expenses and one-off costs. Adjusting for these, core EBITDA margins would be 5% higher. EBITDA margins for the quarter were 29% with R&D investments at 11% of revenues. Profit before tax stands at INR 196 crores. Debt reduction and strengthening of the balance sheet remains a continued focus for the company, and we are pleased to report that during the quarter, we received $220 million from an existing contractual receivable arrangement, $200 million of which we used to reduce our acquisition-related debt. With this paydown, net debt at Biocon Biologics, excluding structured financing instruments, was reduced to $1.2 billion. And overall, at the Biocon group level, net debt now stands at $1.1 billion.

Moving on to Biologics' regulatory updates and following the receipt of marketing authorization for Yesafili, our biosimilar Aflibercept, in the European Union, we have also received marketing authorization from the U.K.'s MHRA in November. In the United States, we have been in litigation with the originator for our biosimilar Aflibercept, where the court issued a mix decision in December'23. And as a next step, we will appeal the West Virginia Court's decision on the 865-formulation patent.

On the clinical front, we have initiated Phase III studies for our biosimilar Pertuzumab, advancing another medium-term catalyst We continue to engage with the FDA and have had progressive discussions regarding our Malaysia OAI status and biosimilar, Aspart BLA. The next step would involve a site inspection in Malaysia, in the near term.

We have received a CRL from the US FDA for our biosimilar Bevacizumab or Abevmy filing as the agency was not able to visit the site for a pre-approval inspection. To reiterate here, the CRL did not identify any outstanding scientific queries on the dossier, and we continue to engage with the agency to facilitate an inspection of the earliest possible opportunity.

In summary, this has been an extraordinarily busy quarter for the Biologics business completing the transition and integration, as well as maintaining robust business continuity. We see strong demand continuing for our products across the markets. The opening of the Adalimumab biosimilar market, along with the regulatory approvals for biosimilar Aspart and Bevacizumab to come will be additional growth drivers. Debt reduction and strengthening of our balance sheet remains a key focus.

Novel Biologics

Let me now move on to an update on our Novel Biologics statement.

And here, Boston-based Bicara Therapeutics successfully closed $165 million Series C financing in December 2023. With this latest close, Bicara has, to date, cumulatively raised $355 million from a syndicate of biotechnology investors. As a result of Bicara's fund raise, Biocon reported a gain of INR 456 crores in the consolidated P&L statement during the quarter, mainly arising from the fair valuation of its holding in line with the Series C financing. Biocon shareholding in Bicara has now reduced to 14%, and as such, Bicara ceases to be an associate company for the Biocon Group.

Syngene

Coming to Syngene. In Syngene, revenue from operations for the quarter was up 9% over last year to INR 854 crores with reported EBITDA up 5% to INR 261 crores with an EBITDA margin of 30%. Profit before tax was INR 142 crores, up 1% over last year. Syngene's performance during the third quarter was affected by reduced funding in the U.S. biotech segment, which impacted demand in its Discovery Services division, while Dedicated Centers and Development and Manufacturing divisions performed well. In manufacturing services, Syngene's long-term biologics manufacturing partnership with Zoetis continued to make good progress. During the quarter, Syngene concluded the acquisition of the multimodal biologics manufacturing facility from Stelis Biopharma. And once operational, the facility will add 20,000 liters of biologics drugs' manufacturing capacity to Syngene's existing capacities. The acquired facility also includes a commercial scale, high-speed fill-finish unit, providing an essential capability to Syngene for drug manufacturing. The facility is expected to be operational in the second half of FY '25, subject to regulatory approvals.

Summary

In summary, the highlight of the quarter has been the completion of the transition and integration of the acquired biosimilars business. The sustained momentum for its product portfolio across markets augurs well as it focuses on improving market penetration for its commercial products, launching new molecules and working to reduce debt. The generics business is making progress on expanding its portfolio and geographic reach as well as strengthening its manufacturing base, both for today and for future growth opportunities.

Syngene continues to perform well, driven by Development and Manufacturing services, and the demand environment and the U.S. biotech segment is expected to recover over the next quarters as the funding environment normalizes. And with that, I'd like to conclude my opening remarks, and now open the floor to questions.

Q&A Session

Saurabh Paliwal: Thank you, Peter. We'll wait for the questions to be assembled. We'll give the first question to Neha Manpuria from Bank of America.

Neha Manpuria: **Thanks, Saurabh. Hi Peter, thanks for the opening remarks, a couple of questions. First, I missed your comment on Aflibercept. The line wasn't very clear at my end. If you could just tell us the next steps that Biocon is looking at in terms of Aflibercept? And could this still be an opportunity for us, given our first, to filing status in the product?**

Peter Bains: Hi Neha, Thank you for the question. Let me ask Shreehas if he'd like to answer that, please.?

Shreehas Tambe: Yes. Thanks, Peter. And Neha, thanks for your question. As you know, at this point, we are evaluating all the options available to us. And certainly, our appeal is one of the options that we are looking at, we are confident about the position that we've got. And as we progress with this, we will update you on the next steps.

Neha Manpuria: **Understood. My second question is on the BBL business. We have seen traction in terms of revenue quarter-on-quarter. You did seem to indicate a lot of contract wins across products. So, is it fair to assume, even though there is still uncertainty on the approval timeline for Aspart and Beva, what should be the traction of the biosimilar revenue? That's number one. And second, when will that start reflecting in terms of margins? Because we have these one-off costs for a while now. When do we start seeing that one-off cost getting sort of annualized and seeing a clean number in BBL going forward?**

Peter Bains: Shreehas, again, will you take that?

Shreehas Tambe: Yes. Thanks, Peter. Neha, I think that's a very fair question. I think what Peter alluded to in his opening comments was we've just come off a very massive global integration 12 months ahead of schedule. So clearly, it's been a huge focus right now to integrate and go from being present in 2 countries to being present in 120 countries or so. So, I think that's been really the focus. And as we've done that, we've made sure that business continuity is the top focus. And that's what you've seen us do. The market share for all products across have continued to be stable or growing, and that's been very important for us. Now coming to your question, which was related to how we see this. I think the new products are awaiting inspection at site. There's been good progress on that. But until then, certainly, we are going to look at growing the business through existing products and that will come from increased market share. So, there is that piece, until we get new approvals, we will have to work through.

One-offs, anywhere, whenever you have this kind of a transition, you do see that. And that is what we are seeing at this point. But the business will see changes as you see new products getting approved. And then like you asked, it moves to that steady state.

Neha Manpuria: **And when do we expect these new approvals, Shreehas? Would it be this second half or FY25, FY26? I mean, what's your sense on when do we eventually see this approval given the long wait already?**

Shreehas Tambe: Yes. No, I wish I had a firmer answer for this. As Peter rightly alluded to earlier, we've made good progress in terms of how we've approached the agency. There are conversations going on and Rhonda can elaborate later in the discussion. She's our Chief Operating Officer. I think at this stage, we are at a point where we are awaiting the FDA to come to our sites and inspect us, and we should be able to move this forward. There is no outstanding question on the science. So, once we get past that and schedule that inspection, Neha, we should be in a better position to answer that question.

Neha Manpuria: **Understood. And sorry, I'm going to squeeze in one more. If I look at the BBL net debt-to-EBITDA, we're tracking over 4x net debt-to-EBITDA. What's the sense of the net debt deduction part that we have for BBL? And what's our comfort level, let's say, 12 months from now?**

Peter Bains: So, Neha, maybe I'll take that one. Clearly, we've identified strengthening the balance sheet, and debt reduction as a priority. As I said earlier, we've reduced that by $200 million in the quarter. It will remain a focus. The levels that we have, we're comfortable, at a BBL level and BL level. But clearly, we'll be working our way to reduce that over the coming quarters.

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

Damayanti Kerai: **My question is again on biosimilars. So, you obviously are seeing good contract wins in some of the key launches. So, I just want to understand the pricing part of these contracts also, whether we are gaining volume, but how is the scenario on the pricing part, because competition definitely has risen in all the products? So that's my first question. And then what kind of discussions you are undergoing currently for Adalimumab, I guess, maybe not for this year, but for future? And what are the key queries which you might be getting from your channel partners and -- which you believe can help you to gain better access there? So that's my first question.**

Peter Bains: Thank you, Damayanti. Again, I'm going to ask Shreehas and Matt to answer those questions.

Shreehas Tambe: Yes. Thanks, Peter. Maybe, Matt, can start that, and then I can add on to this.

Matthew Erick: Sure. Thank you very much. Look, let me explain the U.S. a little bit from a standpoint of what we've actually seen in market share and growth. And I'll explain to you, during this time, the pressures that we're seeing in winning these. But for Fulphila, if you remember, we're at that 19% market share, which is up 12% over the last month. So, we've seen a great run in our market share and with even potentially new players coming into the market; as well as we're seeing Ogivri, we're seeing wins in that opportunity. When it's in the Part B, Part B deflation is much slower because the way in the U.S., it's attributed to the ASP.

So, this business continues to have pricing pressures, which we're seeing it uptake in addition to volume in which we're winning in our Fulphila, in our Ogivri. But our no.1 piece of this is to make sure we're looking at price optimization and not driving this down as we prepare for additional products within our oncology space.

Let me also remind you that on the insulin Glargine side, which is the Part D, we've seen great progress in the market share. As Peter alluded to, even though you're seeing that 12%, a couple of key things there is that closed-door network or pharmacy that attributes additional of about 3% to 4% in the overall growth of our insulin Glargine. The second piece of this is we've had 2 large payer wins that started at the beginning of this year that's going to add additional opportunities within our insulin portfolio. We are also anticipating, in the insulin portfolio, after everyone knows of the WACC reset that we saw by the large insulin players, we're anticipating the pricing of this through the next year to hold pretty steady. As you asked about Adalimumab, we are seeing wins. We're seeing them steadily progress. It's about 10% of the total U.S. lives, and we continue to see this opportunity, primarily in some commercial as well as in Managed Medicaid and Medicaid FFS. And so, these are continuing.

As you know, the bidding cycle is starting, especially for Adalimumab with what has been announced by CVS Health in those aspects. Let me comment too on Europe really quickly, and then I'll turn it over to Shreehas. We've seen nice growth in our Bevacizumab and also continued growth in our Peg as we look at tenders and opportunities in our retail sector. That's adding on to our strong position already with our Adali in Germany as well as in France. So hopefully, that was clear on answering your questions there, but I'll turn it back over to Shreehas for more clarity or any other insights.

Shreehas Tambe: Thanks, Matt. I think that was comprehensive. I'll hand it back to the questioner.

Damayanti Kerai: **My second question is on update on Malaysia plant. So, what are your expectations? And what kind of timeline we should be looking for resolution of issues there? And just another question on Bevacizumab. So, do you think it's still a meaningful opportunity for you to pursue given we are, like, seeing delay in approval and launch there?**

Peter Bains: So, I think perhaps, Rhonda, you can lead on the Malaysia question? And Shreehas, maybe you can pick up the Beva question?

Shreehas Tambe: Yes. Rhonda, go ahead.

Rhonda Duffy: Thank you very much, Peter and Shreehas. Yes. So, the Malaysia facility is -- now we're awaiting reinspection from the FDA. We have been actively engaged with the FDA and discussing with the agency on a number of occasions. We are patiently waiting for them to arrive for the inspection.

Shreehas Tambe: In terms of the Bevacizumab question that you had asked, I think Rhonda can respond to that as well. I think we are in that same position that she just described for Malaysia as well, where we filed everything, we do not see any questions on the science, and we are waiting for the agency to come and inspect us. So that's where we stand at this point.

Damayanti Kerai: **But is it still a meaningful opportunity as for you to pursue it?**

Shreehas Tambe: Yes, certainly. I mean, Aspart in the U.S., we continue to be the in the pole position with the opportunity to be the first interchangeable biosimilar Aspart in the U.S. market, so clearly, we remain excited there. And on Bevacizumab, Matt has, in the past, alluded to the uniqueness of the market. And while there are clear opportunities for those who come in early, there's also opportunity for companies which can come in at a deferred time point given the way the Part B market is structured in the U.S. So yes, I do not see us being -- or let me put it this way, we see us being excited about both these products as well.

Saurabh Paliwal: We'll take the next question Surya Patra, Phillip Capital.

Surya Patra: **My first question is on the BBL performance. So, while we have seen post integration and all that, we have seen a ramp up in the market share for most of the biosimilar that is currently there on the market. But in terms of the revenues, it looks like that, on a like-to-like basis, we have seen a downward trend only. And particularly this quarter, if I adjust for the one-off gains, it looks like it is a loss-making operation, while this is the biggest component of our business. So, my question is that, so till that time that we are not seeing incremental revenue from the newer pipeline, so should you be worried about the performance of BBL in the near term?**

Peter Bains: Let me ask Kedar to pick up on the financials on that first. And maybe Shreehas, you and I can comment once Kedar addressed the core of the question.

Kedar Upadhye: Thanks, Peter. So, Surya, we hear your feedback. See, there are 2 or 3 adjustments you need to make before you compute steady-state PBT margins. Firstly, the gain from sale of brands in the revenue line is INR 350 crores. But if you account for the costs in all the items for that, in the PBT, it's about INR 330 crores. So that's one adjustment you need to make. Secondly, in the SG&A line, you will see a step-up from quarter 2 to quarter 3. What has happened is this quarter, across the countries, we had deployed multiple consulting experts and professional services for IT, for people, defining various SOPs, for regulatory, for customer service, invoicing and collections. So, all of that is a chunky value, which is coming this quarter. So that's almost 5%. So, I mean that is something that one needs to add. And if you see R&D, which is the third one. Please take a quarterly average. This quarter is 12% or 13% of revenue. We don't spend at that rate. So, if you make these adjustments, you will get to something which is a more steady state, and that will give you an appropriate idea as to the margin profile. So that's the right way to look at it, Surya.

Surya Patra: **So just an extension to that, we have also seen that the company, as well as BBL, signing an agreement, which is an equity support agreement, how should one read this? Whether it is indicating any challenge to BBL because of the upfront cost that is involved for the business? Or how should we practically read it?**

Kedar Upadhye: No, in fact, there is no cost to it, Surya. See, these are the letters which are provided by the parent to their subsidiaries. And this kind of comfort letters actually help to enhance the credit profile and negotiate the cost of capital. So, this is quite positive. These are quite common where a parent gives this kind of letters to their subsidiaries.

Surya Patra: **Okay. Just the last one from my side. This is about Adalimumab. See, what we have understood from the various other participants to the opportunity in the U.S., so they are commenting now Adalimumab is an opportunity of calendar '25, because even after signing contracts, nobody is expecting any great kind of a ramp-up for Adalimumab. So, is it fair to believe that this opportunity is getting extended or delayed to CY '25 even for us?**

Peter Bains: Surya, I can start, and Shreehas, please come in and expand. The broad answer to your question is, yes, I mean it's very clear that the market for Adalimumab is not going to open up in a big way in calendar '24 and the expectation is that will happen in a structured fashion in calendar '25. The opportunity perhaps hasn't gone, it's just been shifted in time a little bit. And we are working hard, and Matt can talk about that, and we're making gains and wins in some of the contracts. It's going to be a slow build, not a big bang. And we're going to be building our position from a starting point to build foothold. And then from a foothold, we will build onto that towards a stronghold. So, I think it is going to be a much slower evolution than the market originally anticipated, but I think that's a market phenomenon more widely. Shreehas, do you want to add any other comments?

Shreehas Tambe: Yes, thanks. I think Peter, that was well covered. I'd just add one piece to this, Surya. If you note what we had said, even in the past, that we see the market opening up in '23, but it'll be '24 that you will start seeing some movement. But it's really '25 that you will really see the market opening up. And the reason we had said this is because this is the first Part D product that has lost exclusivity in that sense. And it's a very large asset. So, there is this part of the U.S. market that's still figuring out how this is to be done. So, we see this happening as more commercial payers take the brand off, and then biosimilars see a greater traction. We've seen that happen in Europe where biosimilars have a sizable portion of the market. We've seen that happen in the Part B space in the U.S., where many of the oncology products, you are seeing more than 80% of the market move towards biosimilars. That's not happened with the Part D drug, which is in the immunology space. And we were expecting to see that anyway in '25. But to a greater extent will start showing as more products come into this space. I would just add that to what Peter said. But otherwise, I think Peter's response was quite comprehensive.

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

Shyam Srinivasan: **Just the first one on Semglee and the competitive dynamics around it, right? I think your press release talks about unbranded Glargine along with Semglee at 12%. And then there is, I think, a 3-4 percentage point on top of that. Just correct me if I'm getting those numbers wrong. But I just want to understand, when we look at the pipeline for 2024 calendar year, I think 2 Chinese insulin guys are likely to be in the market. I know they have different front ends like Sandoz, I think, and King-friend, so how do you think about the competitive landscape for Semglee? Is there still upside? Sorry, I missed the opening remarks. Have we signed some more contracts for Semglee, specifically?**

Peter Bains: Thanks for the question. Maybe, Matt, you could pick up on the sort of competitive position and our position. And again Shreehas, pick up as well on any additional asset?

Matthew Erick: Thank you, Peter. To your question, we're continuing to see progress, nice progress with our market access with insulin Glargine. As I mentioned in my opening remarks, we have won and secured 2 large players that started 1/1 of 2024. We watch any competitor's movement or possibility. We remain determined. Diabetes is our franchise. We will be competitive if these folks launch. Remember, in the U.S., we do have significant agreements. Now can these players open them up. Possibly. But it's also timing based on formulary, and they're normally 1 year. So, as you mentioned, these 2 new competitors that could possibly, they're not here today, but we are absolutely planning to move forward. We defend our portfolio in other areas, and we plan on defending our portfolio if any new launches do occur. I do think that being the first to the market in establishing these relationships and the stickiness of our insulin and Semglee in the marketplace holds well for us as we look at these potential new competitors that could be coming into the U.S. market.

Shyam Srinivasan: **And sorry, Matt, this is a clarification. So, how much percentage points should I be on top of the 12% for this closed-door pharmacy?**

Matthew Erick: We're estimating between 16% and 17%, and then as compliance continues to ramp up, but currently, right now between 16% and 17% for our fiscal year as we see these run rates increasing.

Shyam Srinivasan: **Helpful. Just a second question is on the Generics side of things. I think the readout talks about pricing pressure on the API side. If we could get an update on this. I think we had earlier aspirations to grow double digit, but we seem to be struggling. So just an update on Generics, please.**

Peter Bains: Thanks again. Siddharth, can you take that one?

Siddharth Mittal: Yes. So, Shyam, yes, I mean, we are looking at double-digit growth. Unfortunately, in FY '24, that looks unlikely. Our formulations business is doing very well in the U.S. and in other markets, we have started receiving approvals. We have started launching these products, and that's driving a high double-digit growth. But unfortunately, we've had some challenges in the API business, and the pricing pressure in the U.S. and other markets continue to be a challenge. And that, of course, impacts the offtake from our customers. And I think that we believe that this is just temporary because we are working on necessary steps like cost reduction, bringing in more operating efficiencies to be more competitive for some of our synthetic products. And directionally, I do not see any challenge and we should be able to get back to the mid-teen kind of growth level in the next fiscal. And I think I did mention earlier that, of course, there's a lot of focus on peptides, and starting next fiscal year, we should start seeing the revenues of coming in from peptides.

Shyam Srinivasan: **Siddharth, a little confusing here because any formulation company we talk to is talking about U.S. generic being in a sweet spot, like, low single digit. Is our portfolio so dramatically different that we are seeing this price erosion even now in, like, first quarter, calendar 2024.**

Siddharth Mittal: Yes. So, I think what you've heard is, correct, that there is stability in the U.S. market. As I mentioned, that we have also gained market share and new business for our formulations

business, but when it comes to the API, which, of course, API customers have options buying from us versus other competitors, and that's where we are seeing a little bit more stringent competition where there are a lot of capacities, the Indian companies, the Chinese API suppliers have created. And there is a bit of a price war, I would say, between these companies and the generic formulation companies where they are winning the business, they are, of course, passing on pressure or the heat to the API suppliers.

Shyam Srinivasan: **Okay. Just the last question and I'll stop. It's just on the deleveraging plan, again, just going back to an earlier participant. Just trying to understand the acknowledgment that when we reduced the $200 million net debt number, is it an acknowledgment that our current cash flows are slower than anticipated, which is why we have to do these divestments? Is there more that we need to think of shareholding in Syngene? I'm throwing it all in there. But how should we look at the path ahead?**

Peter Bains: Let me start and then Indranil Sen you may want to come in. So, as I said in my opening remarks, I mean, clearly, looking at the balance sheet, it is a focus that you can see that in the last quarter, we've reduced acquisition-related debt in BBL by $200 million. We want to reduce it further, and we will be looking at a range of options. Clearly, cash flow will be one from the operations, and that will be a focal point. But there are other options that we could employ as well. Shyam, it's going to remain a focus. We do look to bring it down. Cash flows from operations would clearly be a preferred way to do it, and then we'll be focusing on that, but there will be others as well.

Saurabh Paliwal: The next question is from Vipul Kumar Shah from Sumangal Investments.

Vipul Kumar Shah: **So, my question is regarding this contractual arrangement of $220 million, I think, in your opening remarks, what is this regarding?**

Peter Bains: Right. This is regarding a contractual receivable arrangement that we had that's matured. And because of the confidential nature of the arrangement, we can't disclose any further details.

Vipul Kumar Shah: **And I want net debt figures, including structural instruments at BBL level. Is it possible?**

Peter Bains: I see. Okay. Indranil, can you address that?

Indranil Sen: Yes. I think the number at BBL level is $1.2 billion. And there could be another $100 million of structured, so around $1.3 billion would be the number. Kedar, I think that's directionally right, right?

Kedar Upadhye: Yes. So, Vipul, we can connect offline. This number is in line with what we disclosed as of date. So, we don't understand what you mean by structured debt. I think let's take it offline. But this $1.2 billion is in line with what is classified on balance sheet as debt.

Vipul Kumar Shah: **My last question is, what should be the cumulative integration cost as it is coming every quarter? So, from the date we acquired the Viatris business, what should be the cumulative total integration costs so that we can have some idea what is going on?**

Kedar Upadhye: So, Vipul, we don't have that number handy with us. As I mentioned, this quarter, by virtue of multiple contractual arrangements for many activities which were important to integrate ahead of time, that number is roughly 5% to revenue of BBL. But cumulative numbers, we don't have it handy. Again, we can take it offline.

Vipul Kumar Shah: **Should I contact offline?**

Kedar Upadhye: Yes, please.

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

Tushar Manudhane: **Sir, just one more clarification on the notes. The impairment of almost INR 380 crores is with respect to which product?**

Kedar Upadhye: I can take that, Peter. So, Tushar, this is with respect to RHI for the U.S. So currently, we have paused this program because we feel pretty excited about the opportunity of Aspart and other analogs. So, since we have paused it, as required under the standards, we have taken this impairment charge. And there have been, as you know, policy pronouncements and things like that. So, I think our prioritization for analogs has required us to take this as required in the accounting, so that's the charge. But Shreehas if you could follow up, please.

Shreehas Tambe: I think, Kedar, you covered it. If there's any clarification, I can provide it.

Tushar Manudhane: **No, so that's fair. And secondly, even the provisioning is also there with respect to a certain product. If you could also comment on which product, are we taking this provision?**

Kedar Upadhye: Tushar, we are not calling out products. This was the inventory, which was acquired as part of the acquisition. And these are not expired products, but our assessment of the pending shelf life and ability to liquidate, again, has required us under the standards to create a provision. So, it's pertaining to the inventory, which was acquired, and this is approaching expiry, but had not yet expired. So, we still have some chance to liquidate. But on a conservative basis, we have provided it in this quarter.

Tushar Manudhane: **Understood, sir. And just lastly, given that certain potential approvals, because of inspections, are getting delayed, but we do have multiple contracts. And at the same time, certain price erosion because of competition. In fact, quarter-over-quarter, if I exclude Eris income, the biosimilar sales have been stable to slightly declining. So given these circumstances, how to think about growth, particularly for biosimilars business over the next 12 to 15 months?**

Peter Bains: Shreehas, I'll give that to you.

Shreehas Tambe: Thanks, Peter. I think the first piece that I would look at here is that going forward, particularly, we see opportunity in the existing products growing through market share.

We've talked, in the earlier part of this call, about awaiting approvals due to the inspection delays. So, while we await that, what we are very focused on is to grow the business through increased market shares. And I think that is what you are seeing at this point,

Tushar, where almost all our products in every geography that you see are gaining market share, so that is one aspect of it. The second aspect that you should see is what Matt talked about earlier is in Europe, where earlier, the business was focused only on a couple of countries with 1 or 2 products. I think the focus will be to see now that we have approval in Europe with 7 of our biologics biosimilars. We would look to see a two-fold strategy there. One is to see if we can penetrate the couple of countries that we are present in with more products. And second is to see if we can widen our reach beyond the 2 countries into at least the big 5 or the EU5.

The only piece I will put there is that our control of the European business is a month old. So, Matt and the European leadership are putting that commercial strategy in place, but that is how we are going to be looking forward to grow the business even as new products come into the forth.

Saurabh Paliwal: And the next question is from Pranav from Rare Enterprises.

Pranav Tendolkar: **Sir, can you just highlight about the debt that we have taken for Viatris? You referred to it that 30% of it is fixed rate, 30% of it is payable and 30% of it is hedged in the last quarterly con call. So, can you just let us know what is the reset time? And has the interest rate actually come to current interest rates? That is one. And also, is interest payments in that actually going to affect our various other research programs? Because if we just remove one-offs and include the expenses that we have incurring in BBL, then actually, BBL margin looks negative. So, I know there are many one-offs. So how are we going to manage cash programs because I fear that it can affect our other research programs**.

Peter Bains: Perhaps, Indranil, you can address the first question on the interest rates related to the debt. And I think, Shreehas, you already touched on how we're looking at one-off costs related to transition freeing up even further margin going forward, and maybe you can follow up on that part of the question. But Indranil, on the interest rates, please?

Indranil Sen: Yes. So, I'll cover a part of it, and let Kedar maybe confirm some of the facts. But from an interest rate perspective and acquisition it was somewhere around 6%. The current market environment, we still see the SOFR levels pretty high. And while there are indications of tapering down, at current market levels, they are hovering around 7%. But there are indications with IRS that this would come somewhere around 5.5%. And so, our current debt profiles are still kind of at that level, I'll let Kedar confirm in terms of the strategy that we have in terms of the mix of our debt and how do we plan to hedge the balance.

Kedar Upadhye: Yes. So, you're right, Indranil, I think the SOFR linked facility, and as the SOFR moves, obviously, the effective rate that we have gets addressed, so that's fine. And yes, while there's an indication that there will be a reduction, current rates are high. But let's wait for the news in the 6 to 9 months. So that's on the rate and the way we capture interest in books. Sorry, what was your next question?

Peter Bains: I think the second part of the question was looking at the BBL margin opportunity for expansion. And I think Shreehas has covered it both in terms of looking at the growth of

existing products and existing markets and existing products in new markets. And also, the recognition that in this quarter, there is, as Kedar has explained, roughly 5% of revenues that's related to onetime one-off costs related to completing this accelerated transition.

Pranav Tendolkar: **So, my question is that is cash flows limiting our development and product research programs? Are we pausing something to prioritize something else? Are existing biosimilar products facing pricing pressure so that the revenue Q-o-Q is a little bit less than expected in spite of volume ramp-ups.**

Peter Bains: Shreehas, I think, perhaps, you can start on that.

Shreehas Tambe: Thanks, Peter. And I think, Pranav, I've consistently talked about this, even in the past, that pricing is always an outcome of market competition. And you will see competition challenge pricing in the market as products mature. We've seen that kind of a behavior where you've seen a very mature price erosion on the medical benefit side in the U.S. and you've seen that hold steady for the last 5, 6 years. We are seeing a reasonable price erosion over a period of time. You've seen very different behavior on Part D product where you've seen the first such product in Adalimumab, which lost exclusivity. So very different behavior, same market, different influences, and that is going to happen given there is competition.

Now whether that is reflective of what will continue to happen going forward, I think one of the things we should be prepared for is competition will challenge pricing. The key thing to look out for, which Matt talked about earlier, is policy changes. And those are the ones that can dramatically change how pricing is looked at. IRA in the U.S. is one such policy change that has recently come into play, which, of course, changed the insulin landscape starting 1/1/24, where the administration talked about $35 co-pay for any insulin, no matter which product it is.

So, some of these things we need to look out for and the business needs to have the resilience to be able to combat this. And that's where our strength in portfolio, our strength in process development, our strength in having done this for a long period of time, and now more importantly, being fully integrated gives us the levers to actually combat this. And there will be quarterly aberrations, which, I've said even in the past, should normalize over a period of time. But yes, it will require you to look at a broader horizon.

Saurabh Paliwal: Pranav, does it answer your question?

Shreehas Tambe: I think, Yash has something, Saurabh you could allow.

Saurabh Paliwal: The question is from Yash Tanna from ithought Advisory.

Yash Tanna: **My question is on the BBL IPO, if we can have an update on the same, on the timelines of the IPO? And are there any prerequisites that we need to fulfill before we have to go ahead with the IPO? So that's the question.**

Peter Bains: Thanks, Yash. I think Shreehas has spoken about the ideal time and timing on several occasions. But Shreehas, perhaps, you could emphasize the insight again.

Shreehas Tambe: Yes. Thanks, Peter. Yash, thanks for your question. I think one of the things that I've

always talked about is that there are certain things that are very critical to focus on right now, is to create value for all stakeholders. And one of the key things, after we went through the large acquisition that we did, was to make sure that it was not just acquiring the business but gaining control of all the business across the countries, which we didn't have when we were operating under a TSA.

And it was important that even before we talk about any IPO, we first focused on gaining control across all geographies. It was a 2-year TSA. We focused on gaining control as soon as possible, so we can be in a better control of our destiny. So that is now complete. As of last quarter now, we are now able to make our own decisions, have full visibility going forward, even though it's just 1 month old today.

The second thing is from a prerequisite that you asked, I think it is extremely important that we focus on the FDA approvals. This is an enabling provision which allows us to unlock value in the portfolio that we have been investing in. And I think it has dodged us for quite some time, which I think all the leadership has been very focused on, engaged with the agency, and we are awaiting them to come and inspect us. So, we are very focused on making sure that we have the FDA unlocked before we talk about that.

The third very critical piece is we need to move from an integration acquisition phase to a more consolidated and growth phase, which is how our strategy has been focused. First was to preserve value, and you heard Peter talked about it, that we are focused on the business continuity, not drop any customer, any order, any patient supply. So that was first.

Now we consolidate the business, bring it to a steady state. So, we don't have these one-offs that we are talking about at this stage. And we can then talk about what is the appropriate time for an IPO, and Peter and the leadership team, we can all discuss what that would be. But I would lay out some of these things as very important for us to focus on in the near-term priorities at Biocon Biologics. Peter, back to you.

Peter Bains: Yes. No, I think you've covered that, Shreehas. I think clearly, we would look at an IPO when we have the right story and shape. And a big part of that is going to be related to momentum that we have with existing products in existing markets. And as Shreehas and the team have described, pushing that into new markets. Of course, the new products is going to be a new driver and that relates to Shreehas' comments on the regulatory time line. So, we'll be looking at that through those lenses.

Saurabh Paliwal: Thank you, Peter. We take the next question from Harith Ahamed from Avendus Spark. This will be the last question for this call.

Harith Ahamed: **So, first question is on Ustekinumab filing. Previously, we had talked about completing the filing for this in the near term, so any update there?**

Peter Bains: Thanks, Harith. I think that's a question either for Shreehas or Rhonda.

Shreehas Tambe: I think the answer to that is yes.

Harith Ahamed: **So, we have completed the filing. Okay. And the second one is on the integration-related costs that we've seen in this quarter as part of other expenses. You said that**

this is roughly 5% of Biocon Biologics' revenue. So, can we assume this is a one-off? And to this extent, we'll see an improvement in Biocon Biologics' EBITDA margins starting the fourth quarter?

Kedar Upadhye: So Harith, I would be -- sorry, Peter, if I can take the question.

Peter Bains: Go ahead.

Kedar Upadhye: I think for doing margin analysis of the quarter, those 2, 3 adjustments, Harith, which I referred to, I think, that, you should consider. So, the gain in the P&L, not in the revenue line, on the sale of brands is about 330-ish; SG&A is 5%; R&D, just take quarterly average rather than this quarter, because this quarter is a slight bump up. So that will give an idea about the margin for this quarter.

And with respect to steady-state margins, we would like to be in the same range, right? And your question is whether 5% will go up, it will go up next quarter. The question is whether we have to invest on that something else. So, I think we would like to reserve our comment on that part. But for this quarter's margin analysis, I think these are the adjustments that you need to make.

Harith Ahamed: **Okay. Got it. And Shreehas, on the RH insulin comment that you made that we have suspended our activities there. So, I was a bit surprised given that we have completed trials and we've done a filing there. And I see that it's a fairly large opportunity and with very limited visible competition out there. So, can you explain a bit more on the thought process there?**

Shreehas Tambe: Yes. No, fair question, Harith, and Kedar did talk about it in the beginning. The color that I would like to provide on that is, see, we have been always very committed to insulins globally, particularly in the U.S. as well. And today if you look at it, Glargine has been a big success. We are seeing Aspart at a point where we are awaiting inspection. So, science has been well developed. We've also seen our RH insulin where it's not one product, it's 3 different products. We've filed for insulin R. There is also insulin NPH, there's also insulin 70-30, which is a mix. And you must develop all 3 as different products and do clinical trials for all of them, at least Phase I, Phase III we have a waiver right now. Now once you've done that, that 3 products put together is roughly a little under $1 billion as a franchise in the U.S. Now in light of the recent policy changes which I talked about to a previous question, I think it's important to see how this shapes up and which is why we have paused that, like Kedar said, because right now, the policy advisory is that it's $35 no matter which insulin is prescribed as a co-pay. So, we just want to make sure that we understand this, we see how the market evolves. We have 2 great products in that market. You heard Matt talk about us gaining market share, gaining customers. So, we first want to capitalize on the investments we've made before we can embark on further development and take on further costs. I think that is really the rationale.

Harith Ahamed: **Okay. Got it. And last one, with your permission, on our B3 facility. Can you talk a bit about whether we have started commercial supplies from there? I understand that we have an EU GMP certification for the facility. But in terms of U.S. FDA timelines and our supplies to the U.S., can you comment a bit?**

Peter Bains: Shreehas, do you want to comment on that?

Shreehas Tambe: Yes. Thanks, Peter. I think the B3 facility is an exceptional facility, Harith. It was awarded the ISPE Facility of the Year award, so it's really one of the most awarded facilities in the country for biologics. It has been approved and we continue to supply products from that facility to Europe and several other parts of the world.

We are awaiting the agency to inspect us, so that we can supply to U.S. as well from this facility. But I will let Rhonda comment on this just a little, just so that you get a flavor, because she has been the one leading the entire operations efforts. So over to you, Rhonda.

Rhonda Duffy: Thank you, Shreehas. Yes, the B3 facility is definitely something that we're really keen to make sure that we actually utilize for the U.S. also. However, it's not a case that we're not utilizing it. It's certainly very active and very much used right now in terms of supplying Trastuzumab, Bevacizumab to the rest of the world. So, it's very much in use, very active in that sense. And of course, we need to approve every new facility for use in whichever region it is, and we are awaiting that inspection from the FDA for the site in Bangalore, so that we can put it into use for the U.S. also. But remember, we have B1, very much active in terms of supplying the U.S. So, there's neither a challenge to supply nor is there a delay in actual utilization of the facility overall.

Saurabh Paliwal: Thank you, Harith. That was the last question of the day. Thank you, everyone, for joining us. If there are any further questions or clarification you need, please get in touch with us. Have a good rest of the day.

- **Ends** -

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