Biocon Limited Q2 FY24 Earnings Conference Call Transcript

November 10, 2023

Speakers from Biocon Limited, Biocon Biologics Limited & Syngene International

- **Dr. Kiran Mazumdar-Shaw** – *Executive Chairperson, Biocon Limited & Biocon Biologics Limited*
- **Mr. Peter Bains** – *Biocon Group CEO*
- **Mr. M.B. Chinappa** – *Strategic Finance, Biocon Group*
- **Mr. Siddharth Mittal** – *CEO & Managing Director, Biocon Limited*
- **Mr. Shreehas Tambe** – *Chief Executive Officer & Managing Director, Biocon Biologics Limited*
- **Mr. Indranil Sen** – *Chief Financial Officer, Biocon Limited*
- **Mr. Kedar Upadhye** – *Chief Financial Officer, Biocon Biologics Limited*
- **Mr. Matthew Erick** – *Chief Commercial Officer – Advanced Markets, Biocon Biologics Limited*
- **Mr. Sibaji Biswas** – *Chief Financial Officer, Syngene International*
- **Mr. Saurabh Paliwal** – *Head - Investor Relations, Biocon Limited*

External Participants during Q&A session

- **Dhaval Bhalodia** – *Individual Investor*
- **Yash Tanna** – *Ithought Advisory*
- **Surya Patra** – *Phillip Capital (India) Pvt. Ltd.*
- **Jainil Shah** – *JM Financial Institutional Securities Limited*
- **Nithya Balasubramanian** – *Sanford C. Bernstein & Co.*
- **Shyam Srinivasan** – *Goldman Sachs Group, Inc.*
- **Rumel Dahiya** – *Individual Investor*

Prepared Remarks Session

Saurabh Paliwal:

Good evening, everyone. I'm Saurabh Paliwal from Biocon Investor Relations team, and I would like to welcome you to Biocon's Earnings call for Q2 FY '24.

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 raise your hand 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 please begin with your name and organization.

Please note that the chat box is disabled, but you can raise any technical concerns by sending us an e-mail to investor.relations@biocon.com

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

Today to discuss this quarter's business performance and future outlook for the company, we have Dr. Kiran Mazumdar-Shaw, our Executive Chairperson; 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 point out to everyone 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 do get in touch with the team.

With this, I would like to turn the call over to our chairperson for her opening remarks. Over to you, Kiran.

Dr. Kiran Mazumdar-Shaw:

Thank you, Saurabh, and good evening, everyone. Let me begin by wishing everyone a very happy Dhanteras and a very, very happy and prosperous Diwali. Let me wish you all health, happiness and prosperity in your homes and let's hope that the year ahead is going to be very prosperous for all of us and for our country.

I would now like to provide you with a broad overview of the group's financials.

Total revenue for the quarter was ₹3,620 crores, up 52%year-on-year.

Revenue from operations increased by 49% year-on-year to ₹3,462 crores with biosimilars' revenue almost doubling, of course, reflecting the acquisitions from Viatris. Research Services delivered a strong revenue growth of 18% while Generics grew by a modest 4%.

Core EBITDA grew by 35% to ₹1,100 crores, reflecting a healthy core operating margin of 32%.

Let me now introduce two senior executive appointments, Mr. Kedar Upadhye, who joined Biocon Biologics as the new CFO. Kedar brings over 23 years of global financial leadership in the pharmaceutical industry. His deep experience and expertise will enhance our ability to unlock and drive future value in Biocon Biologics.

Secondly, I would like to welcome back Mr. Peter Bains, who, as you know, assumed the role of Group CEO in September. Peter will be responsible for supporting me in evolving strategy and driving synergies between the three group companies. And this is with the aim of maximizing the combined value for all stakeholders. Peter's comprehensive understanding of the Biocon group, coupled with his extensive global leadership experience and successful track record across the biopharmaceutical sector will enable us to capitalize on the shared value of our three businesses and add impetus to the group's growth strategy.

On that note, and as a part of Peter's new role, I would like to hand over the floor to Peter, who will lead the earnings' calls going forward. Over to you, Peter.

Peter Bains:

Thank you, Kiran, and good evening, everybody. And, let me first say how delighted I am to be rejoining Biocon. It's a real privilege and pleasure and I'm very excited to be rejoining the group at such an exciting and dynamic stage of its evolution.

Before discussing business performance, I want to take this opportunity to **welcome other new leadership hires in the group**. In Biocon Biologics, we have three appointments. Dr. Uwe Gudat joins as the Chief Medical Officer. Dr. Arlene Wolny joins as Global Head of Regulatory Affairs and Mr. Ramprasad Bhat joins as Head of Branded Formulations in India. At Biocon Limited, Mr. Nitin Tiwari has been appointed as the Head of Quality for the Generic business.

Q2 FY2024 Performance

Let me now expand on Kiran's opening view on the performance for the quarter.

As Kiran stated, Total revenue and core EBITDA for the quarter were ₹3,620 crores and ₹1,100 crores respectively.

R&D spends for Q2 stood at ₹264 crores as compared to ₹242 crores last year, corresponding to 10% of revenues, excluding Syngene. The R&D investments are largely attributable to advancing BBL's strong pipeline of biosimilar molecules as well as developing new peptides with a focus on GLP-1s in our Generic business. The benefits of these investments in research and development are expected to play out in the coming years.

EBITDA for the quarter was up 68% at ₹900 crores versus ₹535 crores last year with an EBITDA margin of 25% as compared to 22% last year.

Depreciation, amortization, and interest increased by ₹376 crores over last year, primarily related to the biosimilar business acquisition costs.

Consequently, Profit before tax and exceptional items stood at ₹238 crores, marginally down from last year.

Net Profit for the quarter before exceptional items stood at ₹142 crores as compared to ₹168 crores in the previous year.

Exceptional items during the quarter amounted to ₹16 crores, net of tax and minority interest. These relate to the reversal of production-linked incentive scheme accruals of the last fiscal consequent to the cap on annual claim allocation as well as transaction cost of the proposed Stelis facility acquisition by Syngene.

Exceptional items last year amounted to ₹122 crores. And therefore, reported Net Profit stands at ₹126 crores as compared to ₹47 crores last year.

Let me now turn to discuss the Generics business segment's performance. Generics reported an operating revenue of ₹676 crores for the quarter, a growth of 4% over the same period last fiscal. Core EBITDA margin for the quarter stood at 23% with a Profit before tax at ₹66 crores, representing a Profit before tax margin of 10%. Revenue performance for the quarter was driven by continued traction in the U.S. Generics Formulation business through additional volumes in statins and recently launched products and most-of-the-world market expansion.

On the API side, performance was muted due to the phasing of supplies because of a planned maintenance shutdown for one of our key products as well as pricing pressures.

We made two significant announcements during the quarter. First, we announced a partnership agreement with Juno Pharmaceuticals, a specialty pharmaceutical company in Canada for the commercialization of Liraglutide for the treatment and management of Type 2 diabetes and obesity in Canada.

And secondly, as part of our plans to strengthen our foothold in the North American market, Biocon acquired the oral solid dosage U.S. manufacturing facility of Eywa Pharma located in New Jersey. The acquisition of this U.S. FDA-approved facility, our first in the U.S., will strategically enhance and complement Biocon's existing manufacturing capabilities. The facility will enable the immediate addition of oral solid dose capacities for new products earlier than planned and ensure continuity of supply through the diversification of our manufacturing infrastructure. The facility's

employees have transitioned to Biocon and the process of qualifying the site for some of our products has already been initiated.

We are pleased to see positive outcomes on the regulatory front with several generic formulation approvals obtained in the quarter, one in the U.S., two in Europe and four products in most-of-the-world markets. Further to this, we've received two API product approvals each in the United States and in Europe.

Regarding our capital expenditure program, we crossed an important milestone in the quarter with process validation of the company's greenfield immunosuppressant API facility in Visakhapatnam, which is now successfully completed. We now expect commercial supplies to begin in FY'25, post qualification of the site by global regulators. This new capacity for immunosuppressants will enable us to diversify our manufacturing footprint and address the growing demand for these products globally.

In the second half of the year, we see a mix of both opportunities and challenges. On the generic formulation side, we expect a sustained performance supported by a gradually improving environment in the U.S. market. On the API side, we anticipate some recovery. However, pricing pressure and higher inventory stocking at our customers could impact offtake.

The recent and successful outcomes from inspection of two of our sites by the U.S.FDA reiterates our commitment to quality excellence as we continue to work on strengthening our mid- to long-term proposition with increased investments in portfolio, R&D capabilities, and infrastructure to deliver on our strategic plans.

Moving now to Biocon Biologics.

Let me start by providing an update on the transition of the acquired business from Viatris to Biocon Biologics. Our accelerated integration plan has been progressing well. In addition to the 70 emerging markets transitioned in July, we have now fully completed the integration of the North America business resulting in seamless commercial operations in the region from September 1st. We remain on track to transition the business in Europe, Japan, Australia and New Zealand and the remaining emerging market countries later during the year, which will complete the integration of the acquired business.

The transition and the integration of the two businesses is a critical milestone in our journey as it enables the most important strategic rationale of the acquisition and that is the creation of a globally scaled and fully vertically integrated lab-to-market biosimilar enterprise.

Turning now to the business performance and starting with the United States. We continue to see good momentum across our oncology and our insulins portfolio. Fulphila, our biosimilar Pegfilgrastim, market share has grown to 19% in September versus 11% last year.

The market share for Ogivri, biosimilar Trastuzumab, stands at 12% versus 10% last year. We continue to add new customers for these products. A large benefit provider covering 100 million lives has added Ogivri and Fulphila to their 2024 medical drug list enabling further market share growth in the coming year.

The market share for our Insulin Glargine is at 11% in September. The volumes supplied through a large managed care network contract, not captured in these market shares, are over and above the IQVIA data. Furthermore, starting on January 1, 2024, we have added two large payors to our Insulin Glargine customer base, which should help further

enhance our market share.

These strong market performances of our products demonstrate the commercial capability of our U.S. team and continued addition of new customers for these products enables volume growth accommodating for price erosion.

Turning now to Adalimumab**.** The market adoption of biosimilars has very clearly been slower than anticipated across the market. And of course, this has also affected Hulio, our biosimilar Adalimumab. Notwithstanding these early market dynamics, our focus remains on expanding market access to drive adoption. We remain engaged with customers to add our product to their formularies, and I'm pleased to share that our product has been enlisted with the commercial standard opt-out formulary of a large purchasing organization and corresponding Managed Medicaid business, covering over 8 million lives. It has also been added to the National Preferred Formulary for Medicaid members of one of the largest Medicaid managed care organizations - covering 7 million lives.

Turning now to Europe. Our products continue to make steady gains. The market share of Fulphila has grown to 8% against 5% last year and Abevmy, our biosimilar Bevacizumab, has grown to 7% against 1% last year. Hulio continues to have market shares of 18% and 11% in Germany and France, respectively. As we complete the transition of the business in Europe to a single fully integrated model, we see the potential to improve business performance.

In emerging markets, Biocon Biologics remains on a steady growth trajectory supported by continuing strong demand for insulins. We continue to increase the depth and breadth of our emerging market franchise.

In quarter 2, there were four new launches and eleven new approvals laying the foundation for future growth. Aligning with our global product focus, we announced the divestment of two non-core branded formulations India business units in dermatology and nephrology to Eris Life Science for ₹366 crores, representing a revenue multiple of around 4x.

Now coming to the financials of Biocon Biologics**.**

On a sequential basis, we have seen revenues marginally down by 2% at ₹1,969 crores despite significantly lowering licensing revenues versus last year. Excluding these licensing revenues, sequential growth stands at 6%, reflecting the underlying positive performance of our commercial products.

This has translated into a core EBITDA of ₹660 crores with margins of 34%, in line with our mid-30s guidance.

EBITDA margin for the quarter was 23%, with R&D investments at 11% of revenues.

Profit before tax stands at negative ₹15 crores, driven by an increase of ₹35 crores depreciation, amortization, and interest costs. PBT is expected to improve with future growth in revenue.

Now moving on to regulatory updates**.**

The European Commission has granted marketing authorization in the European Union for YESAFILI®, our biosimilar Aflibercept indicated for macular degeneration and diabetic retinopathy. As per IQVIA, Aflibercept had EU brand sales of approximately US$1.8 billion last year.

The U.S. FDA has issued a CRL for the BLA of our Insulin Aspart, which did not identify any outstanding scientific issues with the product and references the requirement for satisfactory resolution of deficiencies from the pre-approval inspection of our Malaysia facility.

Separately, the FDA conducted the cGMP inspection of the Malaysia facility in July 2023, leading to observations primarily related to enhancing operational procedures and strengthening training programs. We are fully engaged with the agency to resolve all outstanding concerns.

In summary, we are pleased with the accelerated progress in transitioning the acquired business and with the growth in market share of our commercialized products. While there has been delay in the activation of our immediate near-term catalysts, biosimilars Adalimumab, Aspart and Bevacizumab, these remain to be future growth drivers and beyond these and reflecting the strength of the Biocon Biologics pipeline, other future growth catalysts include biosimilars Aflibercept, Ustekinumab, Denosumab, representing total original sales opportunities of US$25 billion.

Turning now to Novels.

On the novel side, Bicara recently presented updated and positive interim data from its ongoing open-label Phase I, 1B dose expansion study of BCA101 at the European Society for Medical Oncology (ESMO) Congress. There was strong investigator interest shown in these data and Bicara is now well positioned to execute on its next round of funding, advancing BCA101 and progressing its pipeline.

To remind you, Bicara had announced a US$108 million Series B financing earlier this year, which is being realized in a staged manner. Because of this, during the quarter, we recorded a step-up gain of ₹75 crores in the consolidated P&L statement.

Turning now to Research Services.

Revenue from operations for the quarter was up 18% to ₹910 crores over last year.

Reported EBITDA was up 19% to ₹276 crores with an EBITDA margin of 30%.

Profit before tax was at ₹158 crores, up 22% over last year.

The performance during the second quarter was bolstered by strong performance in development and manufacturing services and supported by sustained momentum in the dedicated sentence. In Manufacturing Services, Syngene continued to make good progress on the long-term biologics manufacturing partnership with Zoetis.

Coming now to some concluding remarks.

I think that overall, we are very pleased with the progress the group has made in the quarter. Biocon Biologics is on track with its accelerated transition program to create a fully integrated and globally scaled leading biosimilars enterprise. This will advance our ability to leverage the benefits of the fully integrated model and to expand our footprint in the United States, in Europe and most-of-the-world markets in addressing the growing global demand for biosimilar products.

The sustained momentum we've seen in the market share gains with our commercialized products in the United States and Europe, as we complete the transition, demonstrates the effectiveness of our commercial engine as well as driving currently commercialized products. This provides a strong foundation for our future as we look to bring to market a rich pipeline with new product launches planned almost every year through to 2030.

Finally, and looking ahead to the full year, we remain on track to deliver US$1 billion revenue for Biocon Biologics, mid-

teen constant currency growth in Syngene and an improved second half performance in Generics.

That concludes my opening remarks. And before I hand over the floor to questions, let me end by wishing everybody a very happy Diwali and all the very best for the year ahead. May I now turn the floor over to questions.

Q&A Session

Saurabh Paliwal: First question for this evening is from Dhaval Bhalodia.

Dhaval Bhalodia: **I have the question regarding the U.S. biosimilar industry landscape. Currently, there are three largest PBM and specialty pharmacy holding majority share in the biologic product market. And our brand Hulio is on the formulary of one of the largest PBM. However, this particular PBM is planning to introduce their own biosimilar brand in collaboration with Sandoz. So given this competitive landscape, I'm curious to understand the strategic approach we are adopting. Could you please shed some light on what strategy we are implementing to negate this competitive environment and how we anticipate the sale of our Hulio brand to fare in the year 2024?**

Peter Bains: Shreehas, do you want to take that?

Shreehas Tambe: Thank you, Dhaval, for the question. And I think between Matt and me, we'll respond to your question. Maybe, Matt, you can start and then I can add to this. Do you want to go ahead?

Matthew Erick: Yes. Sure, Shreehas. Thank you. Thanks for the question. I think as we continue to watch the evolution in this whole biosimilar industry as it relates to Adalimumab and our Hulio product. This is a significant, what I would call, a change, but one in which it's not the full portion of everything that we see in the market and the opportunities. This is a position in which a large payor has taken, but it's still playing out. What we've seen is them announcing this. We have not seen the large payor now start looking at all formularies, both commercial and non-commercial formularies. So, we continue to look at our biologics and our platform in regards to the total market itself as it relates to Adalimumab and Hulio, and we're seeing good progression in what we call low-cost sensitive payors.

So, just because they've announced this on the commercial side, doesn't limit us to playing in the rest of the full market. So, we're going to continue to watch how this plays out with the company you mentioned and the third party that they have set up. We have been in active discussions with them. We do understand exactly how this market is shaping up. And I think, in my opinion, it's something that we need to continue to focus on, but not something that would limit us to the rest of the market as we go through this.

And remember, biosimilars, it's just not an exclusive. Most of the payors will be looking at this, we believe, going forward in a situation where they won't have just one biosimilar, once on Humira the payors decide what they're going to do or release this. We believe the market will reopen up again, and there'll be opportunities no matter what certain payors or

partnerships are looking like. So, we remain positive about the future and how we're looking at our products, especially our Hulio products. So, I'll turn it over to you, Shreehas, for additional comments.

Shreehas Tambe: Thanks, Matt. I think the only point I'll add to what Matt said was, these are strategies that payors will come up with and I think we will respond to these as the market progresses. I just want to point out that the payor that you referred to also has formularies outside of commercial. And those would be in the Managed Medicare space and the Medicaid space. And you've seen our product being listed on those. So, you will see outside of the particular collaboration that you pointed out, the same payor making selections depending on what prioritizes their decisions on those formularies. So as Matt said, we are aware of these things, and we remain in connection and contact with customers engaged in seeing how these decisions are made.

Dhaval Bhalodia: **Okay. And my second question is there are a couple of concerns recently that have come out due to the current environment. Firstly, with the 85% of the price erosion on the biosimilar product compared to the brand, in case of Humira and secondly, the higher interest cost on our current debt in the prevailing high interest rate environment. So, I just want to check, I know this is something that recently came up, this was not the case at the time of the Viatris acquisition. But I just want to check if this negative factor was adequately considered or factored into the decision-making process during the Viatris acquisition, and it would be helpful to know if our current debt has fixed or floating interest structure. And where we hedge our interest rate exposure for our debt.**

Peter Bains: Thank you for the question there. I think perhaps, again, Shreehas, if you'd like to address the first question and maybe, Sid, you can address the question on interest rates or Chini.

Siddharth Mittal: Yes, I think, Chini can address that as well.

Shreehas Tambe: Yes. I think the question Dhaval is very valid. I think from the time we've announced the Viatris acquisition back in February of '22, obviously, things have changed, then interest rates have revised overall.

As Peter mentioned, even in his opening remarks, we've seen Adalimumab behave differently in terms of the slower ramp up than expected. We had obviously guided for a slower 2023 with pick up beginning in '24 and '25 being the real opportunity. Things will probably play out in that manner, but '23 has been slower than what we had initially planned.

So, to that extent, you're right, things have moved a little bit. But the opportunity remains intact. And this moves by a couple of quarters into 2024. To your question on what these interest rates have been and how they've moved, I'll defer to Chini. Chini, do you want to take that up?

M. B. Chinappa: Yes. So as far as the US$1.2 billion loan is concerned, we've kept 1/3rd open to allow for early prepayment, 1/3rd has been hedged and 1/3rd is open for the pre-interest rate movements. So that's how we manage the...

Shreehas Tambe: It provides enough flexibility to accommodate for how we are moving forward Dhaval, if that's what you're looking for.

Saurabh Paliwal: The next question is from Yash Tanna.

Yash Tanna: **So, my question, sir, I'm trying to understand the PBT number for Biocon Biologics. So last quarter, we said that there is a one-off US$15 million expense due to the legacy contracts. And before that, I mean, if I add that back, and in Q4 we did about ₹150 crores. So, I'm not able to understand even with the ₹35 crores increase Q-on-Q, the number on the PBT side**.

Peter Bains: Again, I think that's Shreehas, Chini.

Shreehas Tambe: Chini, why don't we explain this to Yash, and then we'll walk him through. I think we've had a healthy performance in the business and how the PBT is impacted, maybe you can explain that.

M. B. Chinappa: As you noticed that there's been a strong improvement in our core EBITDA performance for the quarter. We have moved from ₹513 crores to ₹660 crores whereas the EBITDA is kind of flat at ₹450 crores mark, ₹457 crores in Q1 and ₹453 crores in Q2. And that's largely because Q1 had the benefit of licensing income, which played out and that help improve the EBITDA for the quarter. This quarter, you've seen strong sales performance, no licensing income or meaningful licensing income. And EBITDA is back up at ₹450 crores despite no licensing income. And as I indicated earlier, the strong performance at the core EBITDA line.

When we go to the PBT line, we have kind of moved from plus 24 to minus 15, and that's largely because of the increased amortization cost consequent due to the launch of the biosimilar Adalimumab in the U.S. So, there's been a step up or increase in the amortization charge.

Yash Tanna: **Got it. And my second question is related to the growth, at least in the near to mid-term. With observations on the Malaysian facility, are we anticipating Aspart for FY '24? And if not, how are we planning to grow above the US$1 billion target that we had set at the start of the year?**

Shreehas Tambe: Let me respond to that, Yash. I think from Aspart perspective, I think the development has been positive in terms of the engagements that we've had with the agency, and we will be in active engagement with the FDA early next year. So, once we have clarity on what exactly it is that they expect you to do, we will be able to give you more color in terms of when that opportunity is realized, whether it is early '24 or it's later. But I think it's important to see what the growth drivers were when we began the year. We exited Q4 of the last fiscal with an exit run rate of US$1 billion, and we were looking to grow that business with the growth drivers, particularly driven from the commercial products.

And as you heard in Peter's opening remarks, all our products have grown in market share over the last year. So, one of the most reassuring things is in the major geographies both in the U.S. and in Europe now, we're seeing very strong growth in all our commercial

products. Now as U.S. still moves on with these approvals with the FDA, one of the important things for commercial products and we've got seven products approved in the EU.

And Adalimumab has done well in Germany and France, but we have a lot of headroom in the other products where we could grow from the base that we've got. And we're starting to see that with Bevacizumab, which has moved from a low base of 1% to 7%, and we are starting to see that in other products as well.

So clearly, there's an opportunity to grow from the base that we exited last fiscal, to where we are now. We also do look forward to the opportunities with Hulio. Like Matt said, we haven't given up on that or it's not a closed opportunity. We believe that this is an opportunity which is intact, but just shifted at this point in time. And as payors and as markets outside of the commercial channels open up, we will look at that also driving growth into calendar '24. So that's where we are in terms of where we see this growing from the base that we exited last fiscal.

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

Surya Patra: **My first question is about the like-to-like growth that we will be seeing in the biosimilars operation. So, in fact, the specific question is that we have seen a kind of good ramp-up and good adoption of our biosimilars by payors in the recent period. And also, the integration has provided some kind of additional foothold in the U.S. market and simultaneously, we have seen some kind of incremental pricing pressure for the biosimilar. So, net-net, if you see on a Y-o-Y basis we have almost doubled in terms of reportable revenues in the biosimilar business. But is it possible to share what is the like-to-like growth that we would have seen? And the extension to that is that, see whether we are doing better in the non-U.S. market compared to the U.S. market at the current juncture, if you can share that?**

Peter Bains: Shreehas, I think, again, to you.

Shreehas Tambe: Surya, I think one of the things that we've not done so far is give product by product details. So that's something that we've not disclosed at this point. I think one of the things when we look at better over last year, and we see almost all geographies performing better over last year. We've put out the major geographies in the U.S. and EU by product. And we've shown that growth in terms of how we performed over last year. So, I think it's been a very clear pattern that in the U.S. as all products have performed well, and we are seeing that growth across the EU as well. So, we are seeing that move up. Price erosion, as I've said even in the past, is an outcome of competition. So that's something that you will continue to see. And that's where volume growth is extremely important. So, these market shares have come at a stage where we've looked at preserving ASP. So, we haven't gone chasing market share at a crazy ASP. So, we've been able to conserve, preserve value and build those market shares in a very steady, measured manner so it's grown over time in a profitable way as we've offset the price erosion that's happened over the course of time. But to go and look at every product by geography, I don't think we've shared those details

so far.

Surya Patra: **In fact, the basic point I was trying to draw from my question is that, see the spend on the U.S. biosimilars, it is obviously significantly higher compared to the emerging market. Basically, we are utilizing the same dossier for the other markets, non-U.S. market. And non-U.S. market, it seems is growing better than the U.S. market in the current juncture, because of a branded play and all that. So, my sense is that, see, unless until we cover up the R&D spend, the incremental R&D spend after the integration of Viatris operation, what we have seen, from the incremental U.S. revenue, we may not see much ramp-up in or increment in the margin profile. So that is why I was trying to assess that whether the current performance has been supported by the non-U.S. market, which is branded business growing relatively better compared to U.S., but U.S. possibly we'll see the ramp up only after the commercialization of the pipeline products**.

Shreehas Tambe: Chini, do you have any additional color for Surya in terms of the margin profile by regions?

M. B. Chinappa: We don't disclose margin by geography or product lines.

Surya Patra: **Sure, sir. Okay. My next question is on the large Medicare payors who have adopted our products in the recent period. So, with that, what is the kind of theoretical market share that we can see for our Glargine as well as Herceptin.**

Shreehas Tambe: Matt, you want to go ahead?

Matthew Erick: Yes. I'll take it, Shreehas, and then I'll pass it over. I think what this demonstrates is good demand for Biocon Biologics' products. As we bring on these new payors, certainly, we are looking for that market share increase, and we anticipate that. But right now, to say exact numbers, it's early. All we know is what Peter highlighted in his opening comments is that we have won 2 significant payors that will be starting in the first of the year or have started that will be a nice contributor to our insulin franchise.

And then also we continue to see additional traction, and this is what we are excited about, in North America, additional traction in our Trastuzumab, in our Pegfilgrastim as we continue to win those payor awards as well as adding new ones. And then we've also seen, as Peter said in his opening comments, some nice wins in regard to our Adalimumab and our Hulio. So, to say exactly what those market shares will be, it would be hard to project, but we are anticipating that growth because the additional wins and the demand for our products across the board, whether that be in our insulin or oncology or even in our immunology.

So, I think it shows and demonstrates as Peter and Shreehas shared as we are cutting over and we say this, and I've said it before, biosimilars is not just what we do, it's all we do. And I think that's really the focus that allows us to continue to see this progression as well as our manufacturing and our vertical integration to continue to compete.

Lastly, I'll say across our products and why I think we continue to see this uptake is (No audio @ 45:55) can come back in, but we are dedicated to the market. And I think that

shows in our value to our customers and the ability to maintain the products that are needed for patients that rely on all of our products and our commitment to the market, both in North America and Europe, as you can see, market share continues to increase there.

Surya Patra: **Sure. Sir, just with your permission, one last question from my side related to regulatory compliance. So, my sense is that insulin Aspart possibly was the low-hanging fruit on that regulatory compliance or advancement front. And subsequently, we were thinking about Bevacizumab linked to the Bangalore site. So, is it fair to believe, with the CRL what we have achieved for Malaysia site, the development of this Bevacizumab and the plant related development regulatory in the Bangalore site will only happen post Malaysia plant's clearance or both are happening parallelly?**

Shreehas Tambe: Surya, let me respond to that question. The Aspart CRL is an independent issue from the current status that we have with the FDA at this point in time. The Aspart CRL is an outcome of the inspection that we received in August-September of last year. And they had already accepted our CAPA. They found it to be adequate, and they had written to us that they would need to verify the completeness and the effectiveness of those CAPAs when they do that in a follow-on, pre-approval inspection. That inspection was to happen before the goal date in October of this year. That pre-approval inspection was not scheduled. So, the Aspart approval is linked to us having that inspection, which has not been scheduled. The status in Malaysia is linked to the surveillance GMP inspection which was scheduled for products approved and commercial, which is not related to Aspart at all. So, these are 2 de-linked activities. And as far as India site is concerned, we continue to supply the commercial products. The pre-approval inspection is for Bevacizumab and for additional capacity for Trastuzumab. So those are different requirements. And at this point, we await that inspection, which is scheduled for Q4 of this fiscal year.

Obviously, whenever you have a regulatory observation, you want to make sure that globally, all your sites and all your networks benefit from whatever actions you take. And our quality team, led by Michael and then our Chief Operating Officer, Rhonda, who are also on the call, they've put in place a very comprehensive program to make sure that we've implemented these practices, so that the agency continues to see the upgrades that we've made on our quality maturity journey that we have been on. Clearly, it's a step up in terms of what we are looking to do. And that's a process, that's a part of our business, which we continue to invest in.

Saurabh Paliwal: We have the next question from Jainil Shah from JM Financial.

Jainil Shah: **My first question is on Aflibercept. So, is there an update on the litigation? And if all goes well, when is the earliest we can launch this product?**

Shreehas Tambe: So, Jainil, the litigation update is as we've shared in the past. We do not have any further updates. The trial is completed and at this point, we await the decision from the judge to see what the next steps would be. That's where we are on Aflibercept. In terms of launch date, I think at this point, since we are in an IP litigation, it wouldn't be fair to comment on what that would be.

Jainil Shah: **Sure. And at the time of acquisition, there were certain deferred payments to be made in FY '25. So, is it linked to any milestone? And what is the quantum payable? And how do you plan to pay that?**

Shreehas Tambe: I don't think there's any milestone. Chini, is there any milestone linked to this? Not to my knowledge.

Jainil Shah: **Okay. But it is payable in FY '25, right?**

Shreehas Tambe: That's correct. Right, Chini?

M. B. Chinappa: Yes, it is payable in FY '25.

Jainil Shah: **And we'll be paying from our internal accruals, or we'll be raising money for that?**

M. B. Chinappa: Combination. We have different ways to pay down the deferred payments. Largely, yes, internal growth, and we could have some other fund flows that we planned for.

Jainil Shah: **Okay. And just on the filing status. So, we were supposed to file Stelara by this year end, Denosumab by next year and Humira interchangeability. So how are the trials progressing?**

Shreehas Tambe: So, Jainil, happy to share with you that we are on track for both Ustekinumab, which is before the end of this year, and for Denosumab at the end of next year. So that stays on track. And we have passed the trial, but we, of course, talk about it only once the applications are made and the dossiers are submitted and accepted by the agency.

Saurabh Paliwal: We take the next question from Nithya Balasubramanian from Bernstein.

Nithya Balasubramanian: **First question is on Glargine. You had alluded to two new payors now adding Glargine to their formulary. If you can tell us what number of commercial lives or I'm assuming it's commercial, but what number of lives that it represents?**

Shreehas Tambe: Matt?

Matthew Erick: This point, this remains confidential on these lives. But I can tell you, they are large payors. And why it remains confidential, we're still on track to be able to announce this. But at this point, we are not disclosing that.

Nithya Balasubramanian: **Understood. You had spoken about managed care organization where you were expecting to see better traction in insulin glargine this year. However, if I look at the data, I'm actually seeing a slight slippage in market share. So, what's happening there? Why haven't we seen progress?**

Matthew Erick: Yes. Shreehas, would you like me to answer?

Shreehas Tambe: Yes, please go ahead.

Matthew Erick: Yes. Some of the IQVIA data, there are some large payors, closed door networks that don't report. So, you're seeing some quarter-over-quarter buying patterns but you're not seeing the full picture because of the way folks in IQVIA report or don't report, but we continue to, as Shreehas said, maintain that mid- to high teens. And I think with the new large payors coming on board, we'll definitely have something to be able to hit that target with.

Shreehas Tambe: Just one thing to add, Nithya, to what Matt said, when you have a closed-door network like Peter referred to also in his opening remarks, when they do not report in the IQVIA data, one of the good things about this is that it's an exclusive channel, which also sees a very high degree of conversion to the brand. So, it straightaway comes to Semglee or insulin glargine with an over 90%, 95% conversion in a quarter's period.

Nithya Balasubramanian: **How do you see the adoption of GLP-1s impacting insulin volumes? Do you see that as a mid- to long-term trend?**

Shreehas Tambe: At this stage, and again, this is just to be qualified appropriately, but we see this as complementary treatments, things that will co-exist over a period of time and I will defer to Peter. Peter, if you would want to give an overarching view on GLP-1s and insulins together?

Peter Bains: So, I think you take the nature of the answers, Shreehas. I mean I think they would be complementary. Insulins would be, obviously, for Type 1 diabetes. GLPs would be more to the Type 2. And of course, beyond that, the weight loss opportunity. And this talks to the investments that we're making in the Generics business and building a peptides technology capability and capacity to take advantage of what could be a very, very strategic peptide opportunity with GLPs at the center. Analyst estimates of what the loss of exclusivity for GLPs could look like over the next 10 years, hover around the $100 billion mark. So that's a very big opportunity for the Generics business and very complementary to the Biologics business with insulins.

Nithya Balasubramanian: **Got it. And finally, any updates on your interchangeability study for Adalimumab, when might you be expected to file the product? And for Stelara, again, would you again be going after interchangeability? We know that a peer now has an interchangeable designation for their biosimilar**.

Shreehas Tambe: So, two things. On the Adalimumab study, we've already said it's underway, and we should have the outcome to discuss in the coming calendar. So that's one. On the Stelara piece, we feel quite confident on the interchangeability discussion. We're starting to see that come through. The agency believes that it can happen, and we feel very strongly for our product as well.

Nithya Balasubramanian: **Sorry Shreehas, do you mean an interchangeability designation of Stelara without doing a switching study or...**

Shreehas Tambe: We don't want to disclose, Nithya, specifics of our strategy, but we feel good about how our interchangeability should work.

Saurabh Paliwal: The next question is from Shyam Srinivasan from Goldman Sachs.

Shyam Srinivasan: **Just want to reflect on the last 12 months from a Biocon biosimilar perspective. I remember when we were talking about the acquisition or even in the first quarter of the acquisition, we were talking about this US$1 billion run rate. We are talking about the same US$1 billion for this fiscal as well. So, I just want to understand, which are the pieces that we think did not materialize for us to see growth over a 12-or a 15-month period?**

And underlying profitability for the business, I remember at that time, it was roughly 25% is what was kind of thought of and I'm including R&D, not looking at core EBITDA or something. Net debt to EBITDA at that time, it probably looks like now closer to between 4 and 5. What are the plans for us? If you remember, as cash flow gets generated, we wanted to pay down debt. So just the overall piece of doing the transaction at that point of time and 12 months out, how does it look? And which are the pieces that are probably not working, maybe which are working?

Shreehas Tambe: Let me take it, Peter. Is it okay?

Peter Bains: Yes, please do, Shreehas. I'll comment at the end.

Shreehas P Tambe: Okay. Shyam, I think that's a very fair question in terms of where it is. And I think you're right, some things have worked well for us, and some things have not gone well. And it's not just gone well for us, probably not gone well even from an industry perspective, so more like a class effect. From what's gone well, we've talked about it, where we've seen that off the base that we came off from last quarter last year, we've been able to do what's in our direct control, where we've been able to gain market share as we've transitioned that business sooner than what was there.

So, we are more in control of our destiny than before. So, in terms of value, more than 50% of the value of the business is now transitioned to Biocon Biologics. So, these are all the good things that's allowed us to gain control of it. Things what surprised us and what didn't go well in terms of the legacy contracts that led to rebates, which we had to accommodate in the P&L, some of which hit us in a big way from a quarterly perspective. We have better control on that now.

The growth drivers that we looked at have certainly deferred. So, what didn't work very well was the Hulio launch, which we expected on July 1. We were able to launch the product as planned, but from the entire industry segment itself, none of the biosimilars have been able to win market share in 2023. And I think that's something that's to be looked at, because the opportunity moves and remains intact at this point in time. We have some work to do because we've taken over the business post the launch. But our teams are working and engaging with customers to see how we can get into formularies because that's an area that we haven't been successful in yet. So clearly, we are doing that for the commercial formulary.

Aspart is something that has indeed surprised us. The pre-approval inspection, we believe that we have a very strong quality management system in place. But of course, given that we've got approvals in almost every other geography, we still have to win the confidence of the FDA. And at this point, that's the process and we are just going to be working to see how we can win credibility with the agency.

We have approvals with EMA, with Health Canada, TGA, Anvisa, Cofepris, you name the agency. But I think what's not gone well for us yet is that we haven't been able to get across the line from an FDA perspective. And that's something that I can tell you, our entire leadership is focused on, and we should see success sooner than later, because of the efforts that we are putting in and the discussions we've had.

So, I think if you do a full SWOT of it, there are things that have gone in our favor, and there are things that we could have done better. But the important thing is that these are opportunities which have shifted, and we believe they're still to be realized in the coming quarters. But I'll pause, and I'll see Peter, if you want to add something to that.

Peter Bains: Sure. Thank you, Shreehas. I think the only thing that I would add to which I think you've given a very comprehensive answer is, the progress made in the transition. As Shreehas has alluded to, we have not yet got our hands around 50% of the business, only just in the United States.

So, it's not a steady state. We're going through a complex transition and we're doing it in an accelerated shortened period of time and there are a lot of things that we need to do. Shreehas has alluded to very many of them. And again, I think the entire team is focused on navigating through the transition, getting our hands around the full business and our hands on the steering wheel.

Once that integration is complete and we've consolidated, as I think many of the questions have provided point us to, we see a very healthy growth future ahead, driven by the market share gains where we've got into commercial products. Of course, those are offset to some extent by price declines. But by a very healthy pipeline that once we get through the FDA discussions, augur well for the future. So, it's not, I think, the right way to look at this is a steady state at this point in time. I think in another 2 quarters, we will be really gone through the integration and consolidated and then we'll be steady state and have the kind of trajectory that we're looking at.

Shyam Srinivasan: **Got it. Very helpful. Just a second question to Siddharth on the Generics piece. I think API business, I think you mentioned that there were pricing pressures, muted growth, I think one product where you have taken pause perhaps. So just want to understand what's happening there. We already had some guidance for Generics but looks like we have not mentioned anything except that 2H will be better. So just that color on both API and Formulations.**

Siddharth Mittal: Thanks, Shyam. Yes, we've had a H1 growth of 9% in the Generics business. In quarter 2, specifically, we have also seen a very good growth in the Formulations business, which continues to perform well. We continue to gain market share in statins, and we also expect to launch a couple of new products, and that's what is going to probably drive the growth in the coming quarters. Of course, it will take some time before we see this ₹200 crore odd number per quarter that we are clocking in the Formulations business go up significantly.

But in the API business, the reasons you mentioned, we have one of the plants which underwent a planned shutdown. Hence, there were capacities that we could not manufacture, and we expect to cater to that customer's demand in the coming quarters. So, it has just moved to the next quarter.

But at a macro level, when I look at it, there has been an impact, seen as a result of the pricing pressure that some of our customers have faced and either they have asked for much lower prices, which we are not able to cater to those demands at that price or our

customers in certain cases have lost the business that they had with their end customers which has led to lower offtake.

Directionally, I do not see a huge change for the kind of products we have, the genericized products, in the coming quarters. Of course, a lot will depend on when we launch new products, especially peptides in the coming quarters. And that's where we'll see growth kicking into that mid-teen level in FY '25.

Just to reiterate, H2 will be better than H1. We will see a steady performance of Formulations at the level which we had in H1, which is around ₹400 crores and H2 API business should pick up compared to H1. But on an overall basis, the guidance that I had given last year of mid-teens might be more titrated down to low teens to high single digits.

Saurabh Paliwal: We have the next question from Mr. Rumel Dahiya, a retail investor.

Rumel Dahiya: **I speak as an investor, a long-term investor in Biocon and with a large number of concerns to share. I have been on social media. I've been interacting with the chairperson. She has very kindly been replying also from time to time. Also, with your Investor Relations team. But I thought the concerns are still not addressed. I thought they would have been addressed in the presentation by Mr. Bains, but no, they were not. So, I thought let me just bring them up front. And I have a couple of questions. I'm sure you'll update me with this.**

My first question is, has there been an analysis, the cost benefit analysis or, let's say, the opportunity cost that we have lost because of poor inspection records, particularly in our Johor Bahru plant? And has there been anybody held responsible for that loss that has been caused because of poor things like sterile scissors not being there, or an exhaust pipe being blocked and things of this nature.

If we take pride in quality consciousness and quality readiness, how can we have such things and repeatedly multiple observations, then CRLs, then official action indicated, how can that happen? And what are we going to do about it? And whom are you accountable for this? And what is the total loss that would have occurred. Opportunity cost that we had to incur. That's my first question.

Peter Bains: I'll happily start that. Others may want to contribute. Thank you very much for the question, Mr. Dahiya. Let me start by saying that the Biocon Group has a long, strong and a very proud track record in terms of quality and compliance. And you can see that in very, very many dimensions, including some of the comments made on the call today with FDA approvals. And of course, the CRL in Malaysia, Shreehas has explained the background to that. And the current situation in which we are actively in a very focused manner, engaged with the agency. Shreehas said that the next meeting is scheduled for Q4 this fiscal year, and we can update then.

I think it's also entirely reasonable to pull the lens out a little bit, look at the wider picture and the FDA in terms of post-COVID activity, the bar on quality has been lifted a little bit.

And we do not have any fundamental issues there. We've described the nature of the findings in Malaysia related to Aspart in this call. And we're working expeditiously to resolve them.

Again, as Shreehas has alluded to, any learnings that we gained from this exercise will be cross fertilized across the entire network, and we will be looking at doing that to ensure that going forward, we're ready and compliant across the lessons learned from there in all our sites and to further build, I think, the very proud reputation that the company has in terms of agency inspections. Shreehas, do you want to add anything to that?

Shreehas Tambe: Yes. Thanks, Peter, and thank you, Mr. Dahiya, for your question and for your long-term association with the company and your belief in us. I think we share your frustration to a large degree because there are situations where despite efforts, we are not able to move past the FDA hurdle, like I said, at this point in time. We've had an exceptional track record with global regulators. So, I just want to balance that, and this is not to justify that we haven't been able to work across the FDA right now. There is, of course, a heightened expectation of the Biologics facility and picking out a particular observation and discussing it would be a little challenging.

But I think it's important to note that we've been able to work with global regulators, we're able to show them what are the developments and improvements that we've made across our facilities, across the network. But as I said, it is not enough. At this point in time, there is an effort ongoing to make sure that we can work with the expectations that FDA has. And I'm very confident that the team that we have put together, and we have them on the call and the efforts that have gone in, into putting this together will yield results and success. So, it is a matter of time, I believe, when we will start seeing the results of these efforts that are going on.

Rumel Dahiya: **That's helpful. And I'm glad that there is an acceptance of the need to do more. Now my second question is about a deep discomfort as far as the shareholders are concerned. Now Mr. Tambe mentioned about got more control of destiny of its own country, but probably the shareholders of Biocon do not have the control over their own destinies. People like me have lost 40% of their investments over the last 4 years, 3 years and sit on large, huge losses because the share prices haven't moved up. I remember in one of the meetings last time, the Chairperson said we can do nothing about the share price.**

But I think it's a listed company and the management has to be responsible for it and answerable to the shareholders for bringing down their value. We seem to be the only people whose concerns are not being taken care of. Every time I hear strong growth, growth in EBITDA, but what matters and what investors are more concerned about is net profit and net profitability percentages have been low. Even in this quarter, where one expected thing will be better, the net profit is only 4.6% of the revenue, which is low by industry standards and the company of this nature.

May I know if the agony of the shareholders concerns management at all? And if

yes, what are they going to do about it? And when are things likely to improve going forward?

Peter Bains: Sure. Let me start again, Mr. Dahiya. And certainly, the management are concerned about shareholders' concerns and the feedback that we get. Our job is to build our business in a profitable manner and to play in the market. And the markets will ultimately set price, but that's not an abrogation of responsibility. I can assure you that everyone in the Biocon Group is working extremely hard to drive profitable growth in the business models that we're engaging in.

I mean, quite clearly, we are in the midst of a transformational initiative with the Biologics business. And I think as I alluded to before, we're not yet at steady state. And quite clearly, the Research Services business has continued to grow very profitably as has the Generics business, but when you take on an undertaking of this global nature and transform the business into very much a top-tier global integrated operation, it does take a little bit of time. We've accelerated that timeline, and we're making very good progress. And of course, we recognize that we have a lot more to do, and you've put your finger on several of those areas. And I think Shreehas has very comprehensively described what we're looking at, what we're doing and the timelines on the regulatory front as he has on many other aspects of drivers for growth.

So, we are extremely focused on building a profitable and growing company. But right now, we're in the middle of this transformational shift and the steady state, as I alluded to, I think, is a couple of quarters away.

Rumel Dahiya: **Although it does provide hardly any comfort and the ball is just kicked to the next quarters. But that notwithstanding, simple things like foreign exchange losses. I mean the company hedges foreign exchange, but 4 out of 5 times, at least it makes losses in foreign exchange this thing. Is there a lack of understanding of the dynamics of foreign exchange? Or is there less effort being put into that or what? That's one part of this question.**

And the second part is that, what are we going to control our expenditure? I think our expenditure is too much as a result of which, obviously, net profit will go down. Have we bitten more than what we can chew? Have we taken on far too many things on which a lot of expenditure is incurred simultaneously without consolidating? Is there any thought about managing the finances? Is there any plan, please?

Peter Bains: Maybe Shreehas or Chini or Sid, you want to address the hedging question, and then we can come back and talk a little bit more about cost control.

Shreehas Tambe: No, I think we should look at that data in terms of foreign exchange. Maybe I think it's best to look at the data with Indranil and Chini and maybe see what the reference at BL level is, overall, what is the comment that Mr. Dahiya has and what is the reference. So, we can address it with facts.

And then we'll, of course, certainly address your comment, Mr. Dahiya, in terms of how

we are looking at this and what kind of a transformation we are on. Because when you are looking at these kinds of transformational opportunities, which are once in a lifetime, I think it does take a bit of time to get this ongoing and firing in the way you want.

So yes, I can understand that there is frustration along the way. So, I completely appreciate what you're trying to say. But let's get the facts first on the forex and then we will address that concern, if it's okay with you.

Okay. So Indranil, Chini, do you have anything on the forex and then we can move on.

M. B. Chinappa: Yes, I think we need to present that as a Group, combined gain or loss, and we will clarify that.

Shreehas Tambe: We can also do this with you, Mr. Dahiya, offline with our finance team just so that you get the facts proper because we can look at the data and then where we are on the policy. I can tell you, our finance team looks at this very closely. And we will look at the concern that you've raised and see how best we can respond to your concern.

Rumel Dahiya: **I was just saying that if you're spending some money on hedging and still making losses, is it worthwhile hedging thereafter? We might as well not do hedging. And then take on the profit or loss whatever comes. So why are we suffering losses on both counts, paying fees and yet suffering losses. That was my main concern. So obviously...**

M. B. Chinappa: I'll just clarify. So really, I mean whatever, gain losses includes the hedging costs. We have largely seen the gains play out. But there are some things in our books, particularly the Goldman Sachs investment basically is getting retranslated. These are the products you can't hedge and that reflects as book loss, that's not a cash loss. Largely, if we've seen robust forex management and gained.

Siddharth Mittal: And maybe, Sibaji, can also add because there is also a large component of loss coming from Syngene. So Sibaji, maybe you can give a context there?

Sibaji Biswas: Sure. Sid, thank you. So, Mr. Dahiya, we hedge to manage risk forward. So, if you look at Syngene's hedging losses and gains, in financial year '21 and '22, we had hedging gains simply because the Rupee did not depreciate and the banks were giving higher forward rates. The case has been different in the last 2 years. In '23 and now in '24 also because, for example, in Syngene, our hedge rate was ₹81, the current is ₹83. So, we are booking hedge losses.

However, why we hedge, because it's a policy, because we have to bring certainty and don't want to leave our top line and the profit number exposed to uncertainties coming out of the forex market, we do that. Having said that, whenever we have a hedge loss, we have equivalent higher revenue over there. Because if, for example, the rate is ₹83, our revenues will be higher. So, we'll book a higher gain in forex on the revenue line, and we have a hedge loss on the expense line. The profit impact is neutral. So, it's more optic and it brings certainty to the financials, and that's why the hedging policy is over there.

So, I can assure you there is generally very little profit impact and cash impact coming out of hedging, but it provides some certainty.

Indranil Sen: Yes. And also at a group level, just to -- I think one of your questions was that do we pay cost to get these hedges. So as a group policy directionally, I think most of our hedges are range forwards or forwards where we do not pay cash to acquire these contracts. And just at an H1 level, just for 3 businesses, the Generics business is largely forex neutral this year, so far. And like Chini mentioned, there is a certain instrument in Biocon Biologics, which is getting notionally restated and there is no cash loss, but there is a restatement effect which is why you see that loss. And the third aspect is on the research business, which my colleague Sibaji just clarified.

Rumel Dahiya: **And another question about how do we manage the expenditures, what are we doing about that, so that our net profits increase?**

Shreehas Tambe: This is an open question in terms of how we are looking to control costs. And I think that is signified in terms of and we can respond to this as 3 different companies as well. But let me respond on Biocon Biologics to you, Mr. Dahiya. And I think one of the key indicators of how the business is performing and the health of the business. If you leave aside all these exceptions that we've been discussing is to look at the core performance of the business of what we're looking at as core EBITDA, where you've taken out all these onetime things and say, okay, if this is what I'm operating, what is the gross profit I make? What are the staff costs that are included? And what is it that I see as my margins? And if you look at that, that's always been in that mid-30s regardless of where we've been. And that is clearly very, very comfortable. It is better than most other peers in the Indian pharma. Now this is not a signal to say that we are the best, but this is something we've been consistent about, and we have been staying to that extent.

We do invest a significant portion of our revenues in R&D because, as you know, that's our lifeline as Kiran has been saying all along. And that is something that is higher than most of our industry peers, which has been usually around that 6%, 7% range. We have been in the past, up to 14% as well.

So, we've capped that at around 11% to 12%, so that brings our EBITDA margins, which is at this transformational stage, a reflection of what the business is doing, even if you take the investments in R&D, which is at the mid-20s, now that's remained more or less consistent and a true reflection really of the health of the business. As long as you accommodate for these transformational costs, which will be more transitionary in nature until you settle down and get to a steady state that we were talking about.

We do expect to get to a steady state. There are, of course, these pluses and minus that I was responding to earlier when Shyam asked that question. We are fully aware of what has worked, what hasn't worked, and we will make sure that these things even out over time. So, I think at this stage, as you've been patient and long-standing with us, I think what is really required is to have that patience to clear this out. And we believe that going forward, this will play out the way we're all expecting it to.

Rumel Dahiya: **My final question then...**

Peter Bains: Mr. Dahiya, if I may, because we're running out -- we're on the hour and about to close. We'd be very happy to take this -- to take your questions off-line. If with your permission, I propose that we do that. I hope we've answered some of your questions. You clearly have more. We'd be happy to pick them up off-line, as I've said. With your permission, I'll then hand it over to Saurabh to close the call.

Saurabh Paliwal: Thank you, Peter. Ladies and gentlemen, this was the last question. For any further clarifications or questions, please do get in touch with us. Nikunj and I are available to answer any of the follow-ups which we may have missed today. With this, I wish you all a happy Dhanteras, a very happy Diwali and a prosperous new year ahead. Have a good night.

- Ends -

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