Biocon Limited Q2 FY23 Earnings Conference Call Transcript

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Speakers and Participants from Biocon Limited and Biocon Biologics Limited

- Dr. Kiran Mazumdar-Shaw – Executive Chairperson, Biocon Limited
- Mr. Siddharth Mittal – CEO & Managing Director, Biocon Limited
- Dr. Arun Chandavarkar – Managing Director, Biocon Biologics Limited
- Mr. Indranil Sen – Chief Financial Officer, Biocon Limited
- Mr. Shreehas Tambe – Deputy Chief Executive Officer, Biocon Biologics Limited
- Mr. M.B. Chinappa – Chief Financial Officer, Biocon Biologics Limited
- Mr. Susheel Umesh – Chief Commercial Officer – Emerging Markets, Biocon Biologics Limited
- Mr. Matthew Erick – Chief Commercial Officer – Advanced Markets, Biocon Biologics Limited
- Mr. Paul Thomas – Chief Commercial Officer-US, Biocon Biologics Limited
- Mr. Abhijit Zutshi - Commercial Head - Global Generics, Biocon Limited
- Mr. Saurabh Paliwal – Head - Investor Relations, Biocon Limited
- Mr. Nikunj Mall – Head - Investor Relations, Biocon Biologics Limited

External Participants during Q&A session

- Prakash Agarwal – Axis Capital
- Shyam Srinivasan - Goldman Sachs
- Neha Manpuria – BotA Securities
- Damayanti Kerai – HSBC Securities
- Harith Ahamed – Spark Capital
- Masira Vasanwala – FSSA Investment Managers
- Sameer Baisiwala – Morgan Stanley
- Dhruv Singhal – Karmawish
- Tarang Agarwal – Old Bridge Capital
- Dinesh Mahajan
- Vipul Kumar Shah – Sumangal Investments
- Tushar Manudhane – Motilal Oswal Securities
- Alankar Garude – Kotak Securities
- Nitin Agarwal – DAM Capital
Prepared Remarks Session

**Saurabh Paliwal:**

Good morning, everyone. I am Saurabh Paliwal from Biocon’s Investor Relations team. And I would like to welcome you to the earnings call for the second quarter of Fiscal '23.

I would like to indicate that all participant lines will be in the listen-only mode and there will be an opportunity to ask questions after the opening remarks conclude. Should you need to ask a question, please select the Raise Hand option under the Reactions tab of the Zoom application. We will call out your name and unmute your line. While asking, please begin with your name and your organization.

Please note that the chat box in the Zoom application is disabled, but you can raise any technical concerns by sending us an email to investor.relations@biocon.com. Please note that this conference is being recorded. The recording will be made available on our website within a day and the transcript of the call shall be made available subsequently.

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

Before we begin, I want to remind everyone about the Safe Harbor related to today’s earnings call. Comments made during the call may be forward-looking in nature based on management’s current beliefs and expectations. It 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 me.

Now I’d like to turn the call over to our Chairperson for her opening remarks. Over to you, Kiran.

**Dr. Kiran Mazumdar-Shaw:**

Thank you, Saurabh. Good morning, everyone. I welcome you to Biocon’s earnings call for the second quarter FY ’23.

I would like to spend a minute to pay tribute to my late husband John McCallum Marshall Shaw, former Vice Chairman of the Biocon Group. John passed away on October 24th in Bengaluru. As a key member of the Board and management of Biocon since 1999, John Shaw has contributed majorly to the transformation of Biocon into a globally recognized innovation-led biopharmaceutical company.

In his 22 years with Biocon, he played a very important role in building the company, ensuring the highest levels of corporate governance, as well as contributing to the financial and strategic development of the Biocon Group. He retired from the Board of Directors of Biocon on July 23rd, 2021, due to health reasons.

John Shaw was a man who stood tall with his values and inspired many. He was a benevolent, erudite and compassionate person who truly believed in philanthropy and believed that it would make this world a better place. He was my greatest mentor and my trusted business partner. John's vision for Biocon will continue to guide us towards our purpose of enabling equitable access to healthcare worldwide and for Biocon to become a global leader in its chosen areas.

With that, let me now turn to the earnings call.

*Let me start by commenting on some macroeconomic dynamics.*
The global economy is in its steepest slowdown since 1970. The IMF has forecast that global economic growth will slow to 3.2% in 2022 and is likely to slide further to 2.9% in 2023 from the 6.1% that we saw in 2021.

However, India is an outlier in the current geopolitical scenario. The continued war in Ukraine, which seems to be now receding, the alienation of China, and other trade alignments are compelling a shift of manufacturing to countries like India. I therefore believe that India is uniquely poised for strong export-led growth in coming times.

While high inflation continues to make headlines across the globe, spiraling healthcare costs do need to be addressed. Adoption of both generics and more particularly biosimilars is a necessity and not an option anymore. The Biocon Group, with its export-led business profile, is well poised to break out of the economic challenges of both recession and inflation. Research services, manufacturing, and the increasing demand for both generics and biosimilars offer attractive growth opportunities for the group.

While growth is critical, sustainability is amongst Biocon’s top-most priorities, and the company is committed to build a sustainable future. On the back of key initiatives undertaken during the past year, I am pleased to share that in the 2022 S&P Global Corporate Sustainability Assessment, released in October ‘22, that Biocon has improved its ESG score to 52 from the previous year’s score of 45.

Let me now turn to some Board updates.

I would like to start by welcoming Peter Bains as an additional director on the Board of Biocon Limited. With over three decades of experience in biopharmaceuticals and a successful track record of building brands, businesses, and companies, we believe that Peter’s thought leadership will add tremendous value to the Biocon Board.

Before I turn to key financial highlights of the quarter, I would like to give you an update on the Viatris acquisition.

The acquisition of Viatris’ biosimilars business is expected to close shortly. Biocon Biologics will issue $1 billion of convertible securities and make an upfront payment of $2 billion to Viatris on closing of the transaction. Biocon Biologics has secured the $1.2 billion of debt and the balance amount of $800 million will be funded through $650 million of equity infusion by Biocon and $150 million equity infusion by Serum. With regulatory approvals that are required to close the Viatris transaction being in place, it is, we believe, imperative to close the transaction expeditiously in order to realize and recognize the benefits of the deal. This will allow us to start transition and integration of the business at the earliest.

The equity infusion of $650 million from Biocon will be funded from $230 million from its existing reserves, including the stake sale in Syngene, and the remaining $420 million through mezzanine funding. We are in the process of securing investments to retire the mezzanine finance post deal closure. Biocon’s stake in Biocon Biologics will be 68% post the Viatris and Serum transactions.

In terms of integration and commercial success, Biocon Biologics will accrue revenue and profits emanating from the Viatris acquisition. The deal also incorporates a two-year transition services agreement or TSA to ensure seamless business continuity. Under the agreement, Viatris will transfer key commercial teams to Biocon Biologics.

In the meanwhile, key leadership hires have been made at BBL to ensure smooth integration as well as commercial success, particularly in advanced markets, which include, of course, North America, Europe, and other advanced markets.

Key leadership hires include Mr. Matthew Erick, Chief Commercial Officer, Advanced Markets; Stephen Fecho, Jr.,
Global Head of Supply Chain Management; Stephen Manzano, General Counsel, Advanced Markets, and we also have on-boarded key talents in our Advanced Market Commercial teams to build market access and pricing, US policy and advocacy capabilities. We believe that this team that we have now hired puts us in a good position to address the integration and transition requirements of the deal in a very efficient manner.

**Let me now turn to financial highlights.**

At a consolidated group level, revenues for Q2 FY'23 were up 23% on a year-on-year basis at ₹2,384 crores. Revenues from our biosimilars business and research services delivered strong year-on-year growth of 34% and 26% respectively, while our generics business grew at a healthy 18%.

Core EBITDA grew 34% to ₹816 crores, representing healthy core operating margins of 35% compared to 33% in the same quarter last fiscal.

Our gross R&D spend was at ₹252 crores versus ₹165 crores in the same period in the last fiscal, an increase of 52% year-on-year. This of course reflects our advancing pipeline that will drive our future growth. This spend corresponds to 16% of revenues, ex-Syngene. Of the ₹252 crores, ₹242 crores are expended in the P&L, while the balance amount has been capitalized. This is ₹96 crores increase in R&D expenses over Q2 FY '22.

During the quarter, we also recorded a Forex loss of ₹82 crores as compared to a gain of ₹20 crores during Q2 FY '22. This includes ₹35 crores of foreign currency translation loss on account of the Goldman Sachs OCD investment in Biocon Biologics.

With this, the reported EBITDA for the quarter was ₹535 crores versus ₹551 crores in the same period last year, with the EBITDA margin at 22%.

Profit before tax and exceptional items stood at ₹246 crores, compared to ₹276 crores during the same quarter last fiscal.

The Net Profit for the quarter excluding exceptional items stood at ₹168 crores versus ₹188 crores in Q2 FY '22.

When it comes to exceptional items this quarter, I would like to basically focus on the fact that a MAT credit balance charge of ₹1107 crores has been incorporated as an exceptional item. The company has decided to adopt the new tax regime of 25%, which helps Biocon to reduce its tax outflow and P&L charges on a go-forward basis. We believe this is an important step that we’re taking, and this is of course a charge to our P&L.

Professional fees, net of taxes of ₹14 crores towards the Viatris deal also comprises part of the exceptional items, and therefore reported net profit for the quarter is at ₹47 crores.

**Let me now turn to segmental performance discussions.**

**Generics**

The generics segment delivered revenues of ₹623 crores during the quarter, which is a year-on-year growth of 18%. Profit before tax for the quarter was at ₹54 crores versus ₹50 crores, a year-on-year growth of 9%. Sequentially, revenues grew by 7%.

This quarter, we had two important API launches of Sitagliptin and Vildagliptin in the EU that were supplied from brownfield capacity expansion at our Bengaluru and Visakhapatnam plants.

The generic formulations business also secured several important approvals for our vertically integrated products in
the EU and Rest of the World markets, providing further impetus to our geographical expansion in the quarters ahead.

In terms of the pricing environment, we are seeing some moderation in raw material and logistic costs. However, the environment continues to remain challenging, especially in the US.

On the CapEx front, the generics business made progress on two important projects with the completion of commissioning and qualification of our Visakhapatnam immunosuppressants facility and our Bengaluru peptides facility. Process validation batches are scheduled to commence at both sites in Q3 of this fiscal.

**Biosimilars**

Biocon Biologics recorded revenues of ₹997 crores, a year-on-year growth of 34%, fueled by the growth of insulin glargine in the US. Core EBITDA stood at ₹449 crores, which is up 48% year-on-year and core EBITDA margin improved to 46% versus 42%, primarily on account of the rupee deprecation and accrual of PLI benefits.

We continue to make good progress on our R&D pipeline spearheaded by Denosumab and Ustekinumab, our biosimilar programs which are in global Phase 1 and Phase 3 clinical trials. Consequently, R&D investments for the quarter increased by 142% year-on-year to ₹184 crores or 18% of BBL revenues. While this is higher than our guidance of 12% to 15% of sales, we believe it will normalize once we accrue revenues from Serum's vaccines and Viatris' biosimilars businesses.

This quarter's EBITDA reflects an increase of ₹108 crores in R&D investments and a non-cash foreign currency translation loss of ₹35 crores pertaining to Goldman Sachs OCD investment in BBL, which I referred to a little earlier. On a comparative basis, last year's EBITDA included a one-off gain of ₹55 crores from a mark-to-market movement on our Adagio investment. Therefore, adjusting for the foreign currency translational loss and mark-to-market gains, EBITDA is at the similar level to last fiscal.

Profit before tax and exceptions stood at ₹78 crores.

The Viatris-led business continues to demonstrate a strong year-on-year performance, underpinned by increasing penetration of our interchangeable insulin glargine in the US. Our glargine's total prescription market share is trending around 12%, while new prescriptions are at 14%. We are seeing an increased uptake of our Fulphila or Pegfilgrastim in the US and its market share has now surpassed 10%. Ogivri's market share has also started to recover following a temporary dip in Q1 and is now around 10%. In Europe, Hulio continues its strong performance in key markets such as Germany and France where it has 18% and 9% market share respectively.

We entered into a strategic out-licensing agreement with Yoshindo in Japan for commercializing two of our pipeline assets, Ustekinumab and Denosumab in Japan.

In summary, the existing business continues to see healthy and profitable performance with an opportunity to ramp up revenues. The conclusion of the strategic deals with Viatris and Serum will transform Biocon Biologics into a leading, vertically integrated global biologics enterprise driving value for all our stakeholders.

**Novels**

Equillium, our US-based partner, announced encouraging interim data from the EQUALISE study evaluating Iitolizumab in patients with lupus nephritis. The study continues to enroll patients, with top line data expected in mid-2023.

An application for conducting Phase 2 clinical trials with Iitolizumab for Ulcerative Colitis was approved by DCGI in October 2022.
Our Boston-based associate Bicara Therapeutics’ lead molecule BCA101, in combination with Pembrolizumab was evaluated in front-line systemic patients with unresectable, recurrent, or metastatic head and neck squamous cell carcinoma with very encouraging response rates. During this quarter, BCA101 as a monotherapy was also evaluated in patients with advanced or incurable cutaneous squamous cell carcinoma who have received previous anti-PD-1 therapy.

Investor interest in Bicara has greatly increased following positive outcomes of the various clinical trials.

**Research services (Syngene International)**

Revenues from operations grew 26% to ₹768 crores over the corresponding quarter last year. Reported EBITDA was up 22% to ₹232 crores. Profit before tax and exceptional item was ₹130 crores, up 15% over the corresponding quarter last year.

The second quarter results reflect positive performances across all divisions.

Discovery Services experienced sustained demand, and during the quarter, the proprietary integrated drug discovery platform SynVent continued to gain traction with 18 integrated programs.

Development Services benefited from repeat orders of existing clients as well as an increase in the number of collaborations with emerging biopharma companies.

In Manufacturing Services, the long-term biologics manufacturing agreement signed with Zoetis in the first quarter is expected to be transformational for the manufacturing services division in the years to come. The agreement has the potential to be worth up to $500 million over the next 10 years.

**Concluding Remarks**

I would like to conclude by saying that our performance during the first half has demonstrated the resilience of Biocon's business model as we build the company of the future with all segments delivering strong revenue growth.

We believe that the second half of this fiscal is on a firm footing as we approach the closure of the acquisition of Viatris’ biosimilars business and the vaccine alliance with Serum. Enhanced capacities and new launches will drive growth for our API and generics formulations businesses while continued business momentum should help Syngene achieve its guidance for the full year.

With this, I would like to open the floor to questions. Thank you.

**Q&A Session**

**Saurabh Paliwal:** Thank you, Kiran. We will just wait a moment for the questions to assemble. As a reminder, please use the Raise Hand icon in Reactions tab in the Zoom application to ask a question. The first question is from Prakash Agarwal. Please go ahead.

**Prakash Agarwal:** Thanks, and good morning. Just wanting to understand the mezzanine funding that you spoke about. When is it expected to reverse? In the past we have talked about that we are looking for private equity investors to come in. What is the reason for the delay if you could elaborate it?
Siddharth Mittal: So Prakash, we are in discussions with various private equity investors, but as Kiran mentioned in the opening remark that we want to close the transaction quickly so that we can realize the benefits of this acquisition and start the transition. And within the next few months, we expect retiring the short-term debt we'll be taking immediately to fund this payout and would be closing raising the funds from private equity to square off the mezzanine finance.

Prakash Agarwal: Okay. And these are rupee debt or?

Siddharth Mittal: Yes. Rupee debt.

Prakash Agarwal: And around coupon of?

Siddharth Mittal: Around 7-7.5%

Prakash Agarwal: Okay. Understood. And secondly, if there is an update on Beva and Aspart approval timelines. I read in the presentation that the CAPA plans are already submitted, but what is our internal thought process in terms of the approvals?

Siddharth Mittal: Shreehas, if you can take that.

Shreehas Tambe: Yeah. Thanks Sid. You're right, Prakash, we have, post the inspection, responded to the agency with a comprehensive CAPA plan for Bevacizumab, and we are awaiting the response from the agency to see that we get that approval so that we can commercialize Bevacizumab in the US as quickly as it's possible. You know that we already have approval from the EU for Bevacizumab for that facility and that site.

Prakash Agarwal: But sir, any timelines that we think so that we can pen in the models?

Shreehas Tambe: At this stage, we have no indication on the timeline, but we are engaging with them to see how we can expedite. Typically post submission of a response, it takes anywhere between 45 to 60 working days for them to respond, but that's usually our past experience because we can't comment on behalf of the agency as to when they will come back to us.
Prakash Agarwal: And the other product from Malaysia, Aspart?

Shreehas Tambe: For Aspart, as you know, we responded to the inspection with the CAPA plan. We did receive a CRL, a Complete Response Letter in October. The agency did point out that there is no pending or a repeat thing from the previous CRL. There's also nothing that we see on the scientific aspect of the dossier or the science of the development of the product. They wanted to see the completion of the actions that we have committed to in the CAPA plan. They've invited us for a conversation. That is currently being scheduled with the agency, and post having that dialogue with the agency, we should be able to get clarity as to how we will be able to get that product to approval. Again, it's important to note that it's not a matter of 'if', it's a matter of 'when'. And we should be able to provide more clarity once we have an engagement with the agency.

Prakash Agarwal: Okay. Perfect. That helps. And lastly on the timelines, so Serum deal, the vaccines start effective 1st October. So, is that understanding correct?

Shreehas Tambe: Yes.

Prakash Agarwal: Okay. And the Mylan Viatris deal, once the payments are done probably before December, so would the financials be added in the October to December quarter itself or it would go to the next quarter?

Siddharth Mittal: It would be from the date of closure. So, let's assume if the closure happens by end of this month, it will be from December 1.

Prakash Agarwal: All right. Thank you and all the best.

Saurabh Paliwal: Thank you, Prakash. I'll request all participants to limit the questions to two to allow other people in line to ask a question. The next question is from the line of Shyam Srinivasan from Goldman Sachs.

Shyam Srinivasan: Yeah. Good morning and thank you for taking my question. Just the first one on the operational performance at Biocon Biologics. So, if you could help us understand, I think you talked about glargine market shares reaching on NRx about 14%. So, are we on track for the high teen kind of market share? What are some of
the dynamics that is leading us to continue the market share gains that we're seeing right now?

Shreehas Tambe: Let me respond to that, Shyam, and maybe Matt can add further color on that. We've seen a very positive growth in the way the US market has responded to our interchangeable Glargine and while we've seen the uptick over a period of time, where we started the year with a little under 3% and moved closer to the mid-teens that we've talked about, it's trending in the right direction. We see Viatris gathering more customers. Almost on a weekly basis, we see them adding more customers to the list and we believe we're trending in the right direction towards that mid to high teens market share in the US that we have targeted. But I'll let Matt talk a little bit more about that. Matt, over to you.

Matthew Erick: Thank you, Shreehas. In addition to what Shreehas was saying, we continue to on-board new customers weekly in our government business. So that's trending nicely, and we continue to look to secure additional business. And as we go into next quarter, we have some opportunities in which we are pursuing aggressively that could add nicely to the growth that you're seeing in the NRxs, which then will translate into the pull through you see in TRxs.

Shyam Srinivasan: Got it. Just a second sub-question is on pricing. There have been some concerns by market participants around biosimilar pricing, US pricing seems to be also kind of QoQ seeing deterioration. So just your comments on how pricing is trending relative to your expectations. Is that the only lever for market share or you think there are other ways to gain market share?

Shreehas Tambe: Again, to respond to that, of course, pricing is an important element. It's something that has to be looked at. There is no going away from that discussion. But beyond that, I think most customers are looking at reliability of supply to make sure that you have a complete portfolio. They're looking at suppliers who have the ability to stay in the market with an end-to-end capability to be there in the long run.

So clearly, there are several levers, not just pricing. Pricing is important, but it's also important that the supplier to these customers have a track record, credibility of high-quality products that they are developing, and they have supply ability for these demands that they are creating. So, I think it's a combination of this.

In terms of the discounting that you've talked about, it's, again, a factor of competition and market forces. It's been a very reasonable price decline, I would say. It's trended from that 50% to 60% in most markets globally. Even in the US, it's been in that range. We've not seen a cliff, the moment you have a biosimilar entry or, even if there have been four or five players in a particular asset, we haven't seen an erosion in pricing. So, I think
there is pricing sanity overall and we believe that this is likely to be a reflection of the biosimilars marketplace at least in the near term.

Shyam Srinivasan: Got it. And if I may, my last question is on the generic business. So, this quarter has been very mixed for the players. You have seen growth maybe on a smaller base relative to some of the larger incumbents. So Siddharth, what are you seeing in terms of both API and formulation trends for your business for the generics? Thank you.

Siddharth Mittal: So, we should continue to see some growth coming in in our API business as we have the newer capacities both from brownfield and greenfield in the coming quarters. Of course, the brownfield capacity expansion will give immediate boost to our growth and greenfield capacity addition would take some time.

When it comes to generic formulation, as we said, we've got a few approvals in emerging markets. We also have a few launches coming up in the US. And the combination of these launches plus the growth in our base business should generate growth in the coming quarters. So overall, the second half of this fiscal, we do expect a high single digit growth compared to second half of last year.

Shyam Srinivasan: All right. Thank you and all the best.

Saurabh Paliwal: Thank you, Shyam. Next question is from Neha Manpuria from Bank of America.

Neha Manpuria: Yeah. Thanks for taking my question. My first question is on the biosimilar business. We've gained market share in all of our products in the last few quarters. Gardiner has particularly been good. Despite that, we've seen flat revenues, which does seem to indicate either pricing pressure not only in the US, but in the other markets. So just wanted to get a sense on when do you see the next step up in the revenue traction that we're seeing. That's my first question.

And second, we have heard a fair bit of discussion on biosimilar for Humira from competitors. I know this is a partnered product for us, but if you could give any color on how we stand as the second set of entrants for this product.

Shreehas Tambe: So, Neha, maybe I'll take the first question and I'll let Matt talk about Adalimumab subsequent to that. So, in terms of what we had said on the revenue numbers, we had in the past said that the first two quarters of this year will be around that ₹1,000 crore mark, and then we will see it break away from that to a higher level. It will go up in steps and
we’ve moved up from that ₹750 crore average to about ₹850 crore-ish and then towards the ₹1,000 crore mark. We see that changing in the current quarter and moving to an upward trend.

Now, specifically to the market shares and the revenue correlation that you just talked about, two things to discuss there. One is, you're right, most of our products have recovered market share. Specifically, our Trastuzumab franchise in the advanced markets, which had undergone a dip in the beginning of the calendar year has recovered very strongly and we see that trending back towards the double digits. So, it’s certainly been a positive trend. In Glargine too, with the NRx, Matt just described, are trending towards the mid-teens. And Pegfilgrastim, we continue to hold that 10% market share, which is a significant threshold that we maintain.

In Europe, we have continued to also grow Trastuzumab in particular, and Adalimumab continues to grow there in certain markets, Germany and France in particular. But we have seen that the euro-denominated business that we’ve seen there has faced pressure on the currency side, with the euro depreciation to the dollar, and that has had an impact on some of those numbers that you have seen from a correlation perspective. We see a strong growth in the product, but unless we correct these currency impact, which we believe are transient, we will see the business continue to grow in the current quarter and going forward as well.

But maybe Matt, you can now talk about the Adalimumab preparations for the US.

Matthew Erick:

Yeah. Thanks, Shreehas. So, comments on our Hulio product, which is our biosimilar product to Humira. Some key things we're seeing is that no product or no manufacturer has everything to the innovator, but we believe we're in a very good position as we meet with our payer customers and talk with our partner, with Viatris that we have history, we have a significant European history within our supply for this product, which is key to payers, and we've been able to demonstrate that with our launch of products in Europe, especially with our Hulio product in the nice gains that we've seen in that market share.

The other thing, we believe, as we look at launching and the timing is that we believe we're in a very good position. As you see, what's going on with the payers now, there seems to be a wait and see with most of them as they are waiting to see what's coming with all the different suppliers at the same time.

We also have a uniqueness in our device itself, which we believe will be an advantage because it's very similar to the innovator. So, patients will be familiar with how they use the device. We've been having nice discussions, preliminary discussions, with payers and we believe we're in a good position because most of the payers are not going to have exclusivity. They will have a N +1 or N + 2 arrangement. So that means innovator plus one biosimilar or innovator plus two biosimilars. And with our history that we've demonstrated with our partner, with Viatris, and how we've already been in the market
with other products, the payers are familiar with, we believe it puts us in a very good position as we get ready to launch our Hulio product.

Saurabh Paliwal: Neha, does it answer that?

Neha Manpuria: Yeah. Sorry. Just one follow-up on Shreehas' question. Shreehas, on the emerging market, how has that been trending quarter-on-quarter? Are we seeing growth in the ex-regulated market business on the biosimilar side?

Shreehas Tambe: Yes, Neha. I think the emerging markets have also been doing very well for us in all the key franchises that we talked about, but I'll let Susheel comment specifically on it and why we believe second half will be stronger given that we're starting to see the tenders, which had moved to the later part of the year moving in the positive direction. But Susheel, maybe you want to talk.

Susheel Umesh: Thank you, Shreehas. In the emerging countries, I think that we have been doing very well over not just quarter, but over the years. If you see in FY '21, we were trending at around ₹200 crores per quarter; FY '22, about ₹250 crores, and this year we would be trending at about ₹300 crores per quarter. Overall, the business of the emerging countries is largely tender dependent. So sometimes it gets a little lumpy in terms of the nature of the business, but overall, we are relatively confident that many of the tenders, which were delayed in the quarter two will get onto quarter three, which we will win. So that way, the overall trend of the B2B business, as we call it in the emerging countries, is very strong for the products that we are in, especially in Insulins and with the Trastuzumab and now with Beva as well.

Neha Manpuria: Thank you so much.

Saurabh Paliwal: Thanks, Neha. The next question is from Damayanti Kerai from HSBC.

Damayanti Kerai: My first question is on Semglee. So, can you talk like how the current prescription is split between commercial and Medicare/ Medicaid patients and how this trend has been moving in recent time because you have seen good pickup? So that's my first question.

Shreehas Tambe: Matt, do you want to take that question?
Matthew Erick: Yeah. Look, I'll try. That's a very high-level question, but I think it's one of channels and how you're maximizing this. There's not a traditional shift in the way people are put on the plans in the US. It's how we're taking advantage of optimizing the channels within the payers as well as the price points. So, you're seeing some of these shifts and you can see it shift back and forth. It's really taking a look at where is Medicare Part D, Medicare Advantage, where are the commercial plans and how we go to market and strategically look at that. So, you see some shifts, but we are taking advantage where the opportunity lends itself. And so, you might be seeing some of that grow in some areas versus others.

Damayanti Kerai: Sure, Matt. And in recent contracting cycle for next year, has Semglee gained meaningful contracts compared to where we were last year?

Matthew Erick: Yeah. I think definitely you're seeing those market share growth in the channel. Some of the things we'll have to look at is, as we look at acquiring or partnering with additional customers, some of that data is not in IQVIA, but we'll see nice growth. And I think more that revenue piece is going to continue to watch because the way people report information. But I do see additional partnerships as well as additional pull through which you're seeing that with the NRxs in existing business coming in the future.

Damayanti Kerai: Sure. And my last question is, both your advanced market as well as emerging market biosimilars have picked up. So that's a good update. So, can you just tell us what is the split right now in terms of biosimilar sales between advanced and emerging market?

Shreehas Tambe: Chini, do you want to give a split.

M.B. Chinappa: For the quarter, Damayanti, it's just under 60%, the advanced markets.

Damayanti Kerai: Sorry, 60% -- under 60% for advanced market?

M.B. Chinappa: Advanced markets and just above 40% for emerging markets.

Damayanti Kerai: Okay. That's helpful. Thank you.
Saurabh Paliwal: Thank you, Damayanti. The next question is from Harith Ahamed from Spark Capital.

Harith Ahamed: Good morning. Thanks for the opportunity. So, on insulin aspart, the previous CRL in 2019, the FDA had some queries on the diluent you were using, and I believe you had provided information on the same. So does the recent CRL mention anything related to the diluent or is it just pertaining to the inspection and the GMP status?

Shreehas Tambe: Harith, we've been able to respond to the agency on the diluent that they had asked for and we do not see any inquiry, any further points or comments on that. The current CRL only talks about us completing the CAPA actions to their satisfaction and there are of course some labeling, packaging queries which are standard whenever you have to close an application in the pre-approval process. So, we don't see anything beyond just the facility inspection closure in terms of the CAPA actions.

Harith Ahamed: And how should we think of the next goal date? I missed that in case you mentioned earlier.

Shreehas Tambe: So, the agency has asked us to engage with them. They want to take us through what really is needed to close this because there is no outstanding item from the previous CRL as well. So, we've closed those observations as well. So, I think it's important right now to see what is it that the agency is looking for before we can look at the resubmission for a new goal date at this stage.

Harith Ahamed: Okay. And then regarding the licensing of two biosimilar assets, Ustekinumab and Denosumab to Yoshindo in Japan, just trying to understand how biosimilar penetration has been in that market. We've had our Glargine product since 2016 under partnership with FUJIFILM. So how has the experience been? How has the product ramp-up been? And what share do we have in the Glares market over there, if you could help me?

Shreehas Tambe: Yeah. Absolutely. I think very fair question. Japan continues to be a very important market. It's still the third largest pharmaceutical market in the world and for biosimilars as well. One of the key things about Japan, and it's taken us a while to get familiar with this, we've been in Japan since 2016 when we've got that approval for insulin glargine through our partner FUJIFILM. One of the key things in Japan is that a lot of the prices there are regulated through an NHI pricing index, and in terms of that, the order of entry and the discounting of biosimilars become extremely critical as products are launched and...
institutions go through contracting for a longer period of time. So, there's clearly been a lot of learning for us in the glargine commercialization process in Japan.

What Japan did for us was establish our scientific credibility that we can develop products of high quality for developed markets. So back in 2016, that was a big credibility mark for Biocon overall. And at this state, I think while we've been able to understand how that market operates and having a strong local partner like Yoshindo, who's already commercialized products like these biosimilars in the past in that competitive space, and knowing what is required to be successful in terms of the order of entry, we believe we have a very good opportunity here with these two assets, which between them have an opportunity of almost $700 million, split roughly equally, $350 million each, between Ustekinumab and Denosumab. So clearly, we are very excited about this, and we see that we should be able to make a success of this in Japan, Harith.

Harith Ahamed: Thanks, Shreehas. And one on the balance sheet. There is a decline in the tangible CWIP in the consolidated balance sheet by around ₹1,300 crores. So, this is related to which facilities? And then this corresponding increase in the net block. So, which are the facilities contributing to this?

M.B. Chinappa: This pertains to capitalization of one of the drug substance facilities that has gone online in the quarter of July to September.

Harith Ahamed: Okay. And will you be able to quantify the benefit from PLI scheme? You mentioned that in the context of improvement in margins at Biocon Biologics. Was it material, is what I'm trying to understand?

M.B. Chinappa: It is. As you are aware, we've been selected under the PLI scheme, the Biocon Group has been selected under the PLI scheme, which entitles us to ₹250 crores benefits over a five to six-year period. So, this will accrue over time. It will be now a standard in our P&L going forward.

Harith Ahamed: Okay. That's all from my side. Thanks.

Saurabh Paliwal: Thanks, Harith. And the next question is from Masira Vasanwala from FSSA Investment Managers.
Masir Vasanwala: Hey, thanks for taking my question. Just looking back at the history of the company, the company hasn't usually taken on too much debt or done very large M&A transactions. What's different this time that gives you so much confidence to take on the debt you are taking on or the M&A? What are you worried about as you do this?

Kiran Mazumdar-Shaw: So, let me start by saying that I think this is a unique opportunity for the company to basically become a global leader in biosimilars. I think this is an inflection point and a huge opportunity for us in a business segment that is very, very differentiated. I do not think that this opportunity is something that we can ignore or even feel cautious about because we are very confident about the opportunity and the opportunity to grow. We have products in the market, we have products in the pipeline, and we have products, which are to be approved very shortly. I think with all this in place, I think we have a huge opportunity to be enormously successful. So, I do believe that this is a debt that we have to take on to basically transform the business to the next level.

We also feel very confident that this is not an unserviceable debt. It is not hugely over-leveraging the company and we are also in the process of looking at investments that can even further reduce the debts that we originally have taken on. So overall, I believe that this is a unique opportunity for the company for breakaway growth that we have never been able to see before.

Masir Vasanwala: Thanks. And just one more question. The mezzanine financing that we're taking, is there any collateral or cash flows against which this is secured?

Siddharth Mittal: No. So, it would be secured debt against the underlying assets of Biocon Limited. So, there will be no other collateral that will be there.

Masira Vasanwala: Okay. All right. Thank you.

Saurabh Paliwal: Thanks, Masira. The next question is from Sameer Baisiwala from Morgan Stanley.

Sameer Baisiwala: Yeah. Hi, thanks and good morning, everyone. Shreehas, you must have been through with the contracting cycle for calendar 2023. So, if you can just share your market share outlook, especially for glargine and the other two as well.
Shreehas Tambe: Thanks, Sameer. So, for 2023, you're referring to the US insulin glargine. I think what we can indicate is that our current customers that we had contracted with, we will continue to retain those. So, we will stay with those markets, and which is why we feel confident about that growth from where we are today. You heard Matt talk about the NRxs. We will trend towards those mid to high teens that we've guided and that seems to be moving in the right direction, Sameer.

Sameer Baisiwala: Okay. That's great. And for Pegfil and Trastu as well, if you can share your thoughts.

Shreehas Tambe: So, for Trastuzumab, we'd just talk about that franchise first. I think we did go through that dip of around 7.5% - 8% early part of the year, and as you see, we've clawed that back. So, the Viatris oncology team has really been chipping away at making sure that we gain those accounts. We've got approvals to supplement that market. So, we really believe there is that 10% - 12% market share potential. We continue to build that. Going forward, I think there is a lot of focus. We are hoping Bevacizumab gets approved soon. So, we see that happening.

We're looking at Pegfilgrastim being a very resilient product. We've been in that space long. We had an early-mover advantage. The response overwhelmed us. Now we have significant capacity, which should allow us to play whichever segment or channel that is available to us. It's a matter of what commercial strategy Viatris and Matt and the other teams come up with, but we would have the ability to supply far greater than what it is today.

But beyond the US, Sameer, what the team is really looking at, at this stage is to see how we can expand our market shares in Europe as well. And over last year, if I can point out Trastuzumab has increased its presence in Europe significantly. So that's been a good positive and we see Pegfilgrastim also headed in a similar direction in Europe where the market shares will continue to grow. Overall, we see this trending in the right direction, and the team is quite excited to hold the oncology franchise now. And with Matt and team, we feel very confident there.

Sameer Baisiwala: Okay. Thanks. And I just wanted to revisit a couple of key numbers for Viatris. So, $1 billion CCPS is being issued at what valuations? And post the transaction, the early understanding was that BBL will have $1.5 billion net debt. So, is there any change to that?

M.B. Chinappa: Hi, Sameer. The CCPS, as we indicated previously, is based on equity value of $7.7 billion. So, the $1 billion CCPS will convert to 12.9% equity stake in BBL. There is of course a cap and a floor, so it can range between 12.9% to 14.9%, and is very dependent
on the IPO valuation. The debt levels, as said, there will be $1.2 billion of debt on top of the existing $300 million of debt. So, on BBL’s books, the debt target is $1.5 billion, which we expect to pay down through improved cash flows going forward and of course further equity raised from time to time.

**Sameer Basiwala:** Okay. Great, Chini. Also, you had earlier indicated that Viatris most likely will close this year with $875 million top line and $200 million EBITDA. So, any color you can share on that. Are we on track for that?

**M.B. Chinappa:** Yes, Sameer. Viatris did release their Q3, that's the July to September numbers. They are at $185 million for the quarter. That gives a run rate of $740 million. We see improvement in the last quarter, which should take us closer. And keep in mind that this year, as Shreehas also mentioned, the overall European revenues have been impacted by the depreciation of the euro to the dollar, sorry, and some depreciation in emerging market currencies. We also have had a moderate effect or impacted by the delayed launch of Beva and Aspart.

**Sameer Basiwala:** Okay. And one final question for the mezzanine financing. Over next few months, will this be then fully replaced by private equity or how will it work?

**Siddharth Mittal:** Yes. So, the intent is to replace it partially or fully with the private equity round, but we also do have an option to raise additional funds by divesting a few more percentage stake in Syngene. We of course don't want to keep too much of mezzanine finance for long on the balance sheet.

**Sameer Basiwala:** Okay. And quite obvious that it would be secondary sales of your stake.

**Siddharth Mittal:** That's correct.

**Sameer Basiwala:** Okay, got it. Okay. Thank you. Thank you so much.

**Saurabh Paliwal:** Thanks Sameer. The next question is from Dhruv Singhal.

**Dhruv Singhal:** I just wanted to ask about the potential timeline for the IPO of Biologics and if we can expect a demerger of Syngene and Biologics eventually in the future.
Siddharth Mittal: I think it would be a bit premature to comment on the timeline, but what we have said in the past, it will be not before the next 12 months or so. And at this stage, we are evaluating various options including demerger, but again, all these things would take some time before we come out with a plan for our shareholders.

Saurabh Paliwal: Dhruv, does it answer your question?

Dhruv Singhal: Yeah. Thank you.

Saurabh Paliwal: Thank you, Dhruv. The next question is from Tarang Agarwal from Old Bridge Capital.

Tarang Agarwal: Hi, good morning, everyone. Thank you for your time. Just a couple of questions from me. It's actually sort of a repeat of what's already been asked. If I look at the Biocon Biologics business for this quarter, on a Q-on-Q basis, the revenue has been largely flattish and the core EBITDA has moved up quite nicely. So just referring to the comments explained, euro has probably depreciated about 2% on a quarter-on-quarter basis and given the market share gains that we've made and the fact that emerging markets is roughly 40%, I'm just not able to connect the dots in terms of why the Q-on-Q revenues have been flat. That's number one. Number two, when I juxtapose it with how the EBITDA has actually moved up on a quarter-on-quarter basis, I'm just finding it a little difficult to understand what's been the builder here?

Shreehas Tambe: Chini, do you want to take that?

M.B. Chinappa: Yeah. Just to clarify, as Susheel indicated that the emerging markets performance is strong overall, but for the quarter, it has been lower than the previous quarter. So sequentially, though the underlying business is strong, the revenues booked in Q2 is lower than Q1, and that impacted the quarter or sequential growth numbers. So that is one. And as Susheel also indicated that we expect a pickup of this business in the second half.

Moving to the improvement in the core EBITDA, as we indicated in the opening commentary, we had the benefit of the exchange that reflects in the core EBITDA but gets written off or neutralized by the re-translation of our Goldman Sachs investments. So, while we had ₹56 crores gain on the top, we've had ₹59 crores of loss at the bottom and that's why it's not reflected in our PBT numbers.
Tarang Agarwal: Yes. Okay. The second is on the Viatris acquisition. So, you suggested that the mezzanine financing is going to be rupee-linked and the financing at Biologics, I'm guessing that'd be dollar-linked, right?

Siddharth Mittal: The bank debt, Chini, is rupee-linked as well, or dollar-linked, I think that's the question. But the mezzanine finance, which will come at Biocon level will be rupee-linked.

Tarang Agarwal: And both will be indexed to a particular benchmark in terms of how it's being priced?

Siddharth Mittal: Well, it's all the commercial or the market rates, the lending rates, whether it's NCD or ICD, it's all linked to the current prevailing rates.

M.B. Chinappa: Tarang, just to clarify, the debt in the BBL books will be a dollar denominated debt and as you appreciate the revenue that is coming from the acquisition is also dollar denominated and is benchmarked to the SOFR index.

Saurabh Paliwal: Tarang?

Tarang Agarwal: Yeah. That's it from me. Thank you.

Saurabh Paliwal: Thanks, Tarang. Next question, Dinesh Mahajan.

Dinesh Mahajan: Hello. Good morning. Thanks for the opportunity. I would like to ask two questions. First one is pertaining to insulin glargine. What market share we have in the long-acting insulin market in India? Any number you can provide on the Basalog sales in India? And insulin glargine coming under price control in India, should it impact our margins, or can it help us gain more market share in India?

Susheel Umesh: Maybe I'll take that?

Shreehas Tambe: Yeah. Go ahead, Susheel.
Susheel Umesh: Yeah. Thanks for that question. Glargine in India, Basalog is doing extremely well, if you compare it versus last year. We are growing at more than 25% in a market that's sort of growing at about 3%. So, most of the market change happening is a switch that is happening from the leader to our brand. And that's a very good sign. In terms of market share, we used to be at 11% market share before and now we are reaching about 13% market share and that's a very good trend going forward for glargine.

So, second question which you asked was on the pricing. Most of the discussion that we have in the marketplace is not really about the price. It's about the services that you offer to a doctor. Because in India, as you are aware, Dinesh, this is not a tender-based market. This is largely a retail market. And doctors prescribe this product to patients. So out there in the market, it is offering your services to the doctor, being present for the patient, helping the doctor treat his patient to target. And I believe we did that quite well and that is why we are growing the market shares of Basalog.

We are very unique in the fact that we have got some SKUs which doctors prefer, which is vials in 10 ml, 5 ml and 3 ml which give significant pricing advantage to the patients as well. So that's the differential we bring on the table to the patients and the doctors in the country. So, I would see that going forward, we would continue to grow market share, continue to be dominant with Basalog in this market.

Dinesh Mahajan: Okay. You highlighted that in Indian market, the procurement is less via tendering, but if you observe procurement in CGHS, Central Government Health Scheme or procurement by various state government, health ministries, is becoming more and more tendered. So, are we addressing that part of the market aggressively?

Susheel Umesh: If you look at it, this market is growing, you are right, but it is still about 10% or 12% of the total market, which is largely a retail market. I know there are sources like the ESIC, the Army, the defense, the railways who procure insulins and we have got a separate team to handle this kind of institutional business as well.

Dinesh Mahajan: Okay. Yeah. My next question is pertaining to the US market. Now with the Viatris acquisition, we soon will be rubbing our shoulders with big corporations like Amgen, Eli Lilly and Sanofi’s of the world. Now what are the key hurdles that we face in increasing the market share of our quality products, be it oncology segment or be it Semglee or insulin Aspart, which we will be launching in the US market? Like, is there is more resistance from medical consultants to shift to biosimilars or it is because of the high rebates which are being offered by the innovator companies to the pharmacies? And how do we plan to address it?

Shreehas Tambe: Matt, do you want to talk to that?
Matthew Erick: Yeah. Sure. I'll start here. Thanks for the question. Really appreciate it. Look, as we look at the competition, we see them as any other competition. We feel, with the platform and the foundation that's coming over particularly in oncology, we have a robust platform that has these advantages and relationships already established with the physician or physician clinics, your oncology clinics, your oncology distribution.

So, we are a known entity and those folks that are coming from Viatris over to Biocon are maintaining those relationships. We do understand how ASP works. So, we know those advantages, we know those hurdles, in which we can compete very competitively against any innovator. We've been around for quite some time, even though it is through Viatris. The payers understand us, and also in the oncology side, the physicians are very comfortable with biosimilars.

To answer your question on how we look at key winning in these markets, of course, you have to have the economics. That's the starting point. But you also have to have the payer contracts, meaning you have to land the formularies. And what's nice that we have the foundation that we built in the partnership together with Viatris, is then we have the pull-through apparatus with the sales force.

The other thing that we will be successful in competing against the innovators, we have the patient services, patient education and hub services. So, we have the formulary coverage, we have the ability to pull it through, and we have then the ability for patients to be able to afford and pay the medications. That's how we will compete very aggressively.

Dinesh Mahajan: Okay. Coming to insulin Aspart launch in India, is the launch like related to the fate of the court case or it's a separate thing and the DGCI trial thing should continue forward?

Shreehas Tambe: At this stage, we are still awaiting regulatory approval. We do not have approval of that product. So, unless the authorities approve that product, we are very eager to launch that, but we are awaiting the approval of that.

Dinesh Mahajan: Okay. That's it from me. Thank you.

Saurabh Paliwal: Thanks, Dinesh. The next question from Vipul Kumar Shah from Sumangal Investments.

Vipul Kumar Shah: Yeah. So, my question is, so biosimilar sales, you said 60% is regulated markets. So, can you split it between US and euro region?
M.B. Chinappa: Vipul, the audio is not too good, but I suspect that you asked for the split of the developed markets between US and EU, right?

Vipul Kumar Shah: Yeah. That's correct.

M.B. Chinappa: I don't have that exact breakup, but just our developed markets actually, where Viatris funds it, we recognize a third of that in our profit share. There's US, there's Europe, there is Japan, Canada, Australia, New Zealand and also emerging markets. So, the sales are distributed over a much larger geography, but I don't have the exact split to give you.

Vipul Kumar Shah: Second question relates to our Malaysia plant. So, are we breaking even at EBITDA level for Malaysian facility? Can you share some financials?

M.B. Chinappa: Vipul, we have had profits for the last three quarters. From Q4 of last fiscal, Malaysia has been reporting profit at the PBT, PAT line.

Vipul Kumar Shah: Can you share the figure for the last quarter, if that is possible?

M.B. Chinappa: $5 million profits for the quarter, July to September.

Vipul Kumar Shah: EBITDA or net?

M.B. Chinappa: In dollars. PAT.

Vipul Kumar Shah: PAT?

M.B. Chinappa: Yes.

Vipul Kumar Shah: Okay. Thank you. Thank you and all the best.
Saurabh Paliwal: Thank you, Vipul. The next question is from Tushar Manudhane from Motilal Oswal.

Tushar Manudhane: Yeah. Thanks for the opportunity. Just if you could refresh on the outlook for the Serum alliance led vaccine business in terms of how do we look at it over the next 12 months?


Saurabh Paliwal: I think they are asking about the Serum transaction, the visibility on that, Shreehas.

Shreehas Tambe: Okay. Chini, do you want to give some visibility on that?

M.B. Chinappa: Tushar, hi. So, as you are aware, we have a contractual arrangement with the Serum Institute to commercialize 100 million doses of vaccines per annum. Underlying there is a minimum commitment of revenues and profits, which is on a full year basis. So, as we've indicated, we could expect revenues in the range of $300 million per annum, and with an EBITDA close to our core EBITDA margins, which is the mid to high 30s. So that's the projection for the business. They will accrue on a full-year basis on these lines. I can't give you a quarter-by-quarter breakup or guidance.


Saurabh Paliwal: Thanks, Tushar. We have the next question from Alankar Garude from Kotak Securities.

Alankar Garude: Yeah. Hi, good morning, everyone. My question is on the immunosuppressants facility. Can you share some details on the capacity? Which are the key products being targeted, opportunity size, focus in terms of developed versus emerging markets?

Siddharth Mittal: Alankar, we do not give capacities of our facilities, but it's a very large facility. It's a greenfield facility in Vizag where we'll be manufacturing products like Tacrolimus, Sirolimus, Pimecrolimus and various other products, which are under development will also be manufactured there in the future. And of course, we have our existing facility in
Bangalore, which has been running completely at capacity. So, the growth would come in from this new facility and it will be across emerging and developed markets.

**Alankar Garude:** So, on that Sid, if I look at Sirolimus, Tacrolimus, the overall global market growth itself has been in that 7% to 8% range. I understand we have been capacity constrained because of Bangalore, but going forward, you expect a somewhat similar growth with this new capacity coming in or you expect to gain further market share across your existing markets in some of these products?

**Siddharth Mittal:** Yeah. I think it will be both. We will gain additional market share. We have been in discussions with various customers whom we have not been able to lock in or supply in the recent years because we did not have capacities to service these customers. Plus, we also expect our existing base business to grow as more and more transplant patients are enrolled by our customers. So, our base business both in formulations and API is also expected to grow.

**Alankar Garude:** All right. And maybe one final question there. So, we have been present in this space for a very long time. What would be our key competitive advantages compared to some of our global peers?

**Siddharth Mittal:** I think the immunosuppressant space is less competitive when you look at the global landscape. A few of our products like Tacrolimus, Everolimus, Sirolimus, we have a large market share globally in the generic space, and of course, it's the quality, it's the science behind these drugs, which makes us differentiated compared to others.

**Alankar Garude:** All right. Okay. That's helpful. That's it from my side. Thank you.

**Saurabh Paliwal:** Thank you, Alankar. The next question is from Nitin Agarwal from DAM Capital.

**Nitin Agarwal:** Thanks for taking my question. I just had one question on Aflibercept. One, have we decided to take on that molecule? And two, with the recent sort of patent litigation outcomes in the PTAB, if we're taking the molecule on, how are we looking at the commercialization opportunity there?

**Shreehas Tambe:** So, Nitin, as a part of the Viatris acquisition, we have the option to look at acquisition of that asset and we are proceeding with doing that. So, we are exercising that right to
acquire bEylea. Now, as regards to the ongoing litigation, I think it's in the public domain. Viatris is in litigation with Regeneron. Right now, it's a restricted patent litigation. The court has decided to litigate only on six patents. And as you've seen, the IPRs that have recently been announced have certainly validated Viatris’ view on the IP. So Viatris is quite confident about its position on these patents and Viatris believes that it will move in the direction that it has approached it with. So, we are very confident there.

Nitin Agarwal: And just following up on that, if I recall reading somewhere correctly, the goal date for the product was somewhere in the recent past. Is that correct? And where are we on the approval for the product? Any timelines for approval because, I think, the filing was done some time back, I guess.

Shreehas Tambe: So, as a part of the regulatory process, I think it will go through the current patent dance before it can be granted approval. So currently we are in that, not we, but at this stage, it is Viatris until the closure of the deal. It's Viatris which is in that current patent dance regulatory process. And once that is completed, only then will we have clarity.

Nitin Agarwal: Thanks, Shreehas. This is what I had. Thank you very much.

Shreehas Tambe: Thank you.

Saurabh Paliwal: Thanks, Nitin. If you want to ask a question, we have the last few minutes, please raise your hand.

Since we do not have any more questions, I'll take this opportunity to thank everyone for joining us in this earnings call. If you need any further clarifications or have questions, please do get in touch with me. With this, thank you very much and have a wonderful rest of the day, bye.