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Biocon 5.0

**Biocon Limited Q1FY23 Earnings
Conference Call Transcript**

July 28, 2022

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. Shreehas Tambe** – Deputy Chief Executive Officer, Biocon Biologics Limited
- ❖ **Mr. Indranil Sen** – Chief Financial Officer, Biocon Limited
- ❖ **Mr. M.B. Chinappa** – Chief Financial Officer, Biocon Biologics Limited
- ❖ **Mr. Abhijit Zutshi** - Commercial Head - Global Generics, Biocon Limited
- ❖ **Mr. Nehal Vora** - Commercial Head - Global API, Biocon Limited
- ❖ **Mr. Matthew Erick** – Chief Commercial Officer – Advanced Markets, Biocon Biologics Limited
- ❖ **Mr. Paul Thomas** – Chief Commercial Officer-US, Biocon Biologics Limited
- ❖ **Mr. Susheel Umesh** – Chief Commercial Officer – Emerging Markets, Biocon Biologics Limited
- ❖ **Ms. Aishwarya Sitharam** – Head - Investor Relations, Biocon Limited
- ❖ **Mr. Nikunj Mall** – Head - Investor Relations, Biocon Biologics Limited

External Participants during Q&A session

- ❖ **Damayanti Kerai** – HSBC
- ❖ **Shyam Srinivasan** - Goldman Sachs
- ❖ **Harith Ahamed** – Spark Capital
- ❖ **Neha Manpuria** - Bank of America
- ❖ **Prakash Agarwal** – Axis Capital
- ❖ **Yash Tanna** - iThought Advisory
- ❖ **Sameer Baisiwala** – Morgan Stanley
- ❖ **Nithya Balasubramanian** - Sanford Bernstein
- ❖ **Surya Patra** – Phillip Capital
- ❖ **Sheersh Jain** - Apex Capital
- ❖ **Tushar Manudhane** - Motilal Oswal

Prepared Remarks Session

Aishwarya Sitharam:

Good morning, everyone. I am Aishwarya Sitharam from Biocon Investor Relations Team and I would like to welcome you to Biocon's Earnings Call for Q1FY23. I would like to indicate that all participants will be in the listen-only mode, and there will be an opportunity for you to ask questions after the opening remarks conclude. Should you need to raise any questions, please select the 'Raise Hand' option under the 'Reactions' tab of your Zoom application. We will call out your name and unmute your line to enable you to ask the question. While asking, please begin with your name and your organization. Please note that we will not be monitoring questions on the chat box, but you can raise any technical concerns that you may be facing for our support team to help. I would also like to bring to your attention that this conference is being recorded. The recording will be available on our website within a day and the transcript for this call will be available within next 5 working days.

To discuss the company's business performance and outlook, we have with us today the Biocon leadership team comprising of **Dr. Kiran Mazumdar-Shaw**, our **Executive Chairperson** and other senior management colleagues.

I would like to take this opportunity to remind everyone about 'Safe Harbor'. Today's discussion may be forward looking in nature, based on management's current beliefs and expectations. It must be viewed in concurrence with 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 Nikunj or me.

I would now like to turn the call over to **Dr. Kiran Mazumdar-Shaw**. Over to you, Ma'am.

Dr. Kiran Mazumdar-Shaw:

Thank you, Aishwarya. Good morning, everyone. I welcome you to Biocon's Earnings Call for the first quarter of fiscal 2023.

I would like to start this Earnings Call on a note of optimism on the resilience displayed by India, whilst a large part of the global economy is bracing itself for a potential slowdown next year. Businesses the world over are reshaping their supply chains at a time when the world is facing uncertainties due to various geo-political tensions. Every economy is trying to offset the impact of pandemic spend by lowering healthcare spend.

Backed by strong domestic demand and steady global investments, I do believe that India is on its way to becoming the world's fastest-growing economy in the years to come. As the Pharmacy of the World, India has a key role to play in driving inclusive and equitable growth globally, particularly in healthcare. Policy support such as the 'production-linked incentive scheme' and more recently, the proposed 'research-linked incentive scheme' will boost investment in innovation. Enabled by continued investments in capacities, capabilities and R&D over the last few years, the Biocon Group has a window of opportunity to surge ahead into a stronger leadership position in biopharmaceuticals.

Another important differentiator of global leadership in times of uncertainty is 'ESG'. As we transform into a future-ready leader, the Biocon Group is poised for strong and sustainable growth. Our vision towards environmental stewardship, diversity and inclusion and governance has been articulated in our recently published ESG report for FY22.

Before I discuss the business performance, I would like to make a few announcements.

Mary Harney and Daniel Bradbury, independent directors of Biocon Limited, have completed their second term of tenure with the Company and have stepped down from the Board at the conclusion of the Company's Board meeting yesterday. On behalf of Biocon's Board of directors and management, we express our deep appreciation and gratitude to both Mary and Daniel for the extensive contribution and stewardship.

I would also like to share a management update. I'm pleased to announce that Michael Cutter has joined Biocon Biologics as the Chief Quality Officer. As part of the executive leadership team, Michael will be responsible for leading the global quality organization across all locations and will be based in Bangalore. Michael brings with him over three decades of experience across quality control, quality assurance and pharmaceutical manufacturing, setting the right quality culture and building credibility with global regulatory agencies.

I would now like to present the key financial highlights of the quarter.

At a consolidated group level, revenues for Q1FY23 were up 23%, on a year-on-year basis, at ₹2,217 Crores. Revenues from our Biosimilars Business delivered a strong year-on-year growth of 29%, while that of our Generics Business grew at a healthy rate of 19% and Research Services revenues grew by 8%.

Core EBITDA, which is a very key part of our business performance, grew at 25%, with a margin of 31% versus 30% in the same quarter last year.

Profit Before Tax for the quarter, stood at ₹197 Crores, up 19%, over ₹166 Crores, during the same quarter last fiscal.

Net Profit for the quarter stood at ₹144 Crores versus ₹84 Crores in Q1FY22, reflecting a growth of 71%.

During the quarter, we also recorded a Forex loss of ₹38 Crores, primarily due to restatement of Goldman Sachs' OCD investment in Biocon Biologics, as compared to a gain of ₹17 Crores during the same quarter last fiscal.

Our Gross R&D spend was at ₹223 Crores versus ₹136 Crores in the same period in the last fiscal, an increase of 64% and corresponding to 15% of revenues, ex-Syngene. Of the ₹223 Crores, ₹198 Crores is expensed in the P&L, while the balance amount has been capitalized. ₹120 Crores were expensed in the P&L in Q1FY22.

With this, the reported EBITDA for the quarter was ₹478 Crores versus ₹437 Crores, reflecting a 9% year-on-year growth, whilst margins stood at 22%, against 24% reported in Q1FY22. EBITDA was primarily impacted by the forex loss as mentioned earlier, higher operating costs, particularly due to the inflationary impact on raw materials and freight, as well as, personnel costs linked to new hires and annual increments, which obviously will be at a higher level in Q1 but will get normalized over the year. Furthermore, R&D investments increased by ₹78 Crores, reflecting pipeline progression for future growth.

Now, let me turn to segmental business performance during the quarter.

Generics Business

The Generics segment delivered revenues of ₹580 Crores during the quarter, which is a year-on-year growth of 19%. Profit Before Tax for the quarter was at ₹63 Crores versus ₹29 Crores during the same quarter last fiscal, a year-on-year growth of 116%. PBT margins were higher at 11% as against 6% in Q1FY22.

The year-on-year growth during the quarter was primarily due to ramp up in API sales, particularly our statin and immunosuppressant portfolios and the continuing performance of recently launched generic formulations. The corresponding period last fiscal was significantly impacted by COVID related operational and supply chain challenges,

which are now behind us. However, the business does continue to encounter headwinds in the form of pricing pressure and rising input costs. Sequentially, revenues declined by 19%, largely due to temporary shutdowns undertaken during Q1 to facilitate capacity expansions, which will augment growth for the business in the second half of the fiscal.

During the quarter, we launched our vertically integrated formulation, Mycophenolic Acid Delayed Release tablet, an antimetabolite immunosuppressant, indicated for the prophylaxis of organ rejection in adult patients receiving a kidney transplant. In line with our strategic priority to expand the generic formulations business beyond the US, we have received approvals for our oncology drug, Lenalidomide, in the EU, Fingolimod capsules in the UAE and Rosuvastatin Tablets in Singapore.

During the quarter, we received a GMP certificate from MHRA, UK, following their on-site inspection of our oral solid dosage formulation facility, located in Biocon Park in Bangalore.

We continue to be on track to qualify and validate our greenfield, fermentation-based immunosuppressant API manufacturing facility in Visakhapatnam, Andhra Pradesh in FY23.

Growth in our Generics business in FY23 is supported by a strong product pipeline, expanded manufacturing capacities, and continued efforts to digitize processes and optimize costs.

Biosimilars

Biocon Biologics recorded a revenue of ₹977 Crores, a year-on-year growth of 29%. Adjusting for the one-off COVID-19 related sales of Itolizumab and Remdesivir in Q1 last year, the business witnessed an even stronger year-on-year growth of 46%. On a sequential basis, however, revenues were flat, impacted by lower realization of European profit share from the Viartis-led business, due to devaluation of the Euro against the US dollar.

Core EBITDA which excludes, R&D, forex, licensing income and mark-to-market movement on investments, stood at ₹361 Crores, up 33% year-on-year. Core EBITDA margin remains healthy at 37% vs 36% last year, in line with our guidance of it being in the mid-to-high 30s. It is also important to call out increased personnel costs this quarter.

We have made good progress on our R&D pipeline with biosimilars Ustekinumab and Denosumab in global clinical trials and advancements in other assets. These are unpartnered assets wherein the full R&D cost are borne by us as compared to the shared cost model that we have had in the past. Consequently, R&D investments for the quarter increased by 120% year-on-year to ₹130 Crores, representing 13% of BBL revenues vs 9% for the full year FY22.

These R&D investments to secure our future growth, coupled with a non-cash foreign currency translation loss of ₹43 Crores on Goldman Sach's OCD investment in BBL led to a 12% year-on-year decline in EBITDA for the quarter to ₹190 Crores.

Profit Before Tax stood at ₹71 Crores.

The Viartis-led business has delivered strong year-on-year performance, underpinned by the successful launch of our 351(k) interchangeable biosimilar insulin Glargine in the US. In Europe, the market share for our biosimilars, Pegfilgrastim and Trastuzumab, continues to grow. In Canada, following the launch of our biosimilar Bevacizumab last year, Viartis will be launching biosimilar Glargine and Apsart later this year, opening new avenues of growth.

The Biocon Biologics-led business continues to see strong demand. In FY22, we had entered 44 new partnerships which will drive growth in the coming quarters.

After a pandemic linked hiatus, we expect site inspections to be conducted by the US FDA in August, which hopefully

will pave the way for our biosimilars Bevacizumab and Aspart approvals later this year. Our new state-of-the-art B3 mAbs facility has recently been EU GMP certified.

Our strategic deals with Viatris and Serum are progressing towards closure as planned. On the operational front, efforts are underway to ensure a smooth integration and transition.

In summary, the business fundamentals continue to be strong, enabling us to ramp up revenues and sustain core EBITDA margins in the mid-30s. There are multiple near-term catalysts including ramp up of biosimilar Glargine, potential approvals of biosimilars Bevacizumab and Aspart in the US and approval of new manufacturing capacities. The strategic deals with Viatris and Serum will transform Biocon Biologics into a leading vertically integrated global biologics company.

Novels

During the quarter, our partner, Equillum, initiated patient dosing for the pivotal Phase III clinical trial of Itolizumab in patients with acute Graft-versus-Host disease, while recruitment continues for the pivotal Phase 1b clinical study of Itolizumab for Lupus Nephritis, which will read out interim data later this year.

Our Boston based associate, Bicara's lead molecule, BCA101, has demonstrated encouraging safety, pharmacokinetic, pharmacodynamic and efficacy profiles based on the findings from the dose escalation phase of the ongoing Phase 1/1b trial, which was initiated in February this year. The recommended dose has been established at 1500 mg weekly for BCA101, as monotherapy and in combination with Pembrolizumab.

The combination of BCA101 and Pembrolizumab is currently being evaluated in front-line systemic patients with unresectable, recurrent, or metastatic head and neck squamous cell carcinoma and as a second-line therapy in patients with advanced squamous cell carcinoma of the anal canal, who have received prior chemotherapy. BCA101 is also being evaluated, as a monotherapy, in patients with advanced or incurable cutaneous squamous cell carcinoma of the lung, who have received previous anti-PD-1 therapy. Primary results for the dose expansion arm of this study are expected in the second half of calendar year 2022.

Post the first round of seed funding, Bicara continues to secure funding from external investors to support its clinical development activities.

Research services - Syngene

Revenue from operations stood at ₹645 Crores for the quarter, indicating a year-on-year growth of 8%. Profit before tax for the quarter was at ₹93 Crores as against ₹95 Crores in Q1FY22.

The first quarter results were against a strong quarter last year due to sales of COVID treatments, where Remdesivir, in the midst of the second wave of the pandemic was a key product. No sales of Remdesivir were recorded in the first quarter this year. Excluding the impact of Remdesivir, the underlying growth in revenue from operations in the quarter was around 30% year-on-year. The first quarter results reflect strong underlying performance across all our business divisions.

A recent highlight was the signing of a 10-year agreement with Zoetis for the commercial manufacturing of the drug substance for Librela®, a first-of-its-kind injectable monoclonal antibody to alleviate pain associated with osteoarthritis in dogs. This deal is expected to start generating revenues in the second half of the fiscal and will be worth up to US\$ 500 Mn over its term of 10 years. This is a strategic move for Syngene's biologics business, providing a pathway towards the FDA and EMA regulatory approvals anticipated later this year.

The Company continued to invest in infrastructure, including a kilo lab in the Development Services division, as well as a lab housing over 150 scientists and analysts in Hyderabad, dedicated to PROTACs - Syngene's novel cancer drug discovery strategy for its clients.

Syngene has raised its revenue guidance for the year from mid-teens to high teens, taking into account a favorable change in the Rupee/US dollar exchange rate and of course, the recent agreement with Zoetis.

Concluding Remarks

I would like to conclude by saying that FY23 will unlock the potential of several of our investments across businesses, be it in capacities, pipeline, or partnerships. New launches and enhanced capacities will drive growth for our API and generic formulation business, while the strategic transactions with Serum Institute and Viatriis, which are on track towards closure, will accelerate growth of our Biosimilars business. We see strong demand, contract extensions and the new inflection point in contract manufacturing, catalyzed by the Zoetis bio-manufacturing contract, that will drive the growth momentum for Syngene. In line with our focus on sustainable growth, we continue to invest in people, policies and processes to ensure value creation for all our stakeholders. And with this, I would like to open the floor to questions. Thank you.

Q&A Session

Nikunj Mall: Thank you Ma'am. Should you need to raise questions, please select the 'raise hand' option under the 'Reaction' tab of your Zoom application. We'll call out your name and unmute your line to ask the question. The first question is from Damayanti Kerai from HSBC.

Damayanti Kerai: **Hi, good morning. Ma'am, you mentioned that pickup in market share for Semglee will be one of the key near term driver for biosimilar sales. So, what we have seen in last few months is that the market seems to have saturated in low single digit number. So, what will be factors which will improve pickup in Semglee market share from current level. And also, for other two launched biosimilars, Ogivri and Fulphila, again, we see some kind of saturation in the market share. So, just wanted to understand what are the key hurdles which are stopping you to improve market share from current levels? So, this is my first question.**

Kiran Mazumdar-Shaw: Damayanti, thanks for your question. I will turn this question to both Shreehas and Matt, to respond to, but all I can say is that we are seeing good pick up of all these products you mentioned, we're tracking in the right direction, and I think what we're really seeing is a strong performance in the second half of this fiscal.

Shreehas Tambe:

Thanks, Kiran and Matt, please feel free to add more to the question. I think, Damayanti, to answer your question product by product in the US. Starting with Glargine, I think your comment was that the market share seems to have saturated. Just to correct the data point, we started this year with a sub 3% market share, and we've moved that towards 9%, just a shade off that 10% which we did in July. So, when we started this fiscal, we guided that towards the second half of the year, we will be seeing this move towards the mid-teens. And the way that Viatris has been progressing, we see that growth from 3% to 9%, moving to 10% and then towards the mid-teens in the direction that we had projected earlier. So, we do see that move happening in the direction that we have projected. Viatris has also recently added significant plans beyond the Express Scripts and Prime Therapeutics that we had talked about earlier on to be moving to regional pharmacies. We've also got regional formularies. We've also got significant customer addition towards the beginning of this month. And these are all the right steps which will help us get towards that mid-teens market share that we had guided towards the beginning of the fiscal. Now, you've talked about the other two products, which is Trastuzumab and Pegfilgrastim, and we'll talk about them in a bit. Starting with Trastuzumab, there was a particular situation, where in April, May, we've seen the market share kind of dip from that 10-11% to 7-8% and that's because Viatris did lose a customer during the process and they've gained that in June and July and we're again starting to see those market shares move up towards 10% and back to where we are. So, I think these are normal course of business activities where you win a customer, you lose a customer, you lose some share in a particular formulary or a particular account and effectively what you need to see is that they've been able to be resilient in the market and held on to its market share despite increased competition. Likewise, with Pegfilgrastim where our market shares held on that 8-9%, even though we've seen the innovator themselves lose market share as well as Coherus, which was a big market player at one time, significantly lose market share to newer competition. So, I think overall, if you look at it, we've held the market and that market is steadily moving towards where we have guided at the beginning of the fiscal year. Anything else, Matt, that you may want to add, then please go ahead.

Matthew Erick:

Thank you, Shreehas. That was a really good explanation, I would just call out the Viatris commercial team, as we continue to look at how this industry especially within the US flows, the team is rightfully situated to address those hurdles. And I think you're seeing that particularly in Trastuzumab. As you know, every company kind of goes through a potential pullback but I think what is important here is you've seen a great comeback, so I would just say that Shreehas, but everything else is exactly what I would say.

Damayanti Kerai:

So, do you believe that we have ample headroom to improve on market share from current level? The few factors, which you mentioned should be helping from here on.

Kiran Mazumdar-Shaw: Yes, I certainly believe that this is the case. I'd also like to sort of draw your attention to the fact that we are in a very strong and pole position to actually drive growth because of all the capacities that we have put into place. And I think now that the worst of the pandemic challenges are behind us. I think growth is something that we will pursue very strongly.

Damayanti Kerai: Thank you, Ma'am. And my second question is on R&D. So, in last two quarters, we had seen a sharp jump in R&D expense, which is due to unpartnered assets, which Ma'am mentioned in the call previously. So, once we are done with major trial for these two assets, should we see some moderation in R&D costs or should continue to increase from this level also?

Kiran Mazumdar-Shaw: So, Damayanti, if we want to future proof our business and if we want to really attain global leadership, I think it would be not very prudent to cut back on R&D. R&D drives growth for us, which is important for us to drive EBITDA growth, which is what we are pursuing. And I think what you must also understand is that the Viartis deal actually gives us the ability to invest more and faster in the R&D pipeline. So, the pipeline is very fundamental and integral to growth. And pipeline progression is what drives growth. So, to cut back on R&D, I don't think would be prudent and we should be at these kind of levels of R&D spends, and it might even increase over the coming quarters. But I think for the investors and analysts to expect us to cut back on R&D would not be the right thing to expect because that is why we keep harping on core EBITDA, because I think core EBITDA is always very important to really get to the understanding of where our business is heading. The fact that we're making such good clinical progression, will actually tell you that our R&D is delivering very well for us.

Damayanti Kerai: Sure ma'am. So, R&D should remain in the 10 - 15% range, which you earlier indicated?

Kiran Mazumdar-Shaw: Absolutely. Anything lower than that actually is not something that we would prefer.

Damayanti Kerai: Thank you. I'll get back in the queue.

Nikunj Mall: We request the team to ask two questions so that everyone has the opportunity to go through. Next question is from Shyam Srinivasan from Goldman Sachs.

Shyam Srinivasan: Good morning, everyone. Thank you for the presentation. I think just first question on biosimilars again. Kiran and team, if you could just help us understand the geographical split of how this business is currently. Where the growth rates are? I think a lot gets discussed about the US market shares, but we know less about Europe, I think you called out Canada in your opening remarks. So, just help us understand geographically how the biosimilars is, you used to give us a split of the rest of the world and developed world, so any color there will be very helpful.

Kiran Mazumdar-Shaw: That's a very good question, Shyam, and I'll ask Susheel to really tell you about how well our emerging markets business is also tracking.

Susheel Umesh: Thanks, Shyam. The emerging countries actually has potential, very often we realize very good returns from the emerging countries. So, the entire emerging country model for biosimilars is growing, it's growing quite fast, that is mainly because of two reasons. One, patients and doctors both are getting aspirational and they want to use the biosimilars more and more. Second, more and more tenders open up for our biosimilars. So going forward, while we increase our numbers of countries that we operate in, and the depth in the countries that we do business in, the biosimilar business is going to grow significantly and will ramp up. Right now, it is much smaller than the US and the European markets, but in many other places and in many of the countries the prices that we get is much better than even Europe. So, the emerging piece of the countries is quite big.

Kiran Mazumdar-Shaw: And maybe, Matt, you'd like to comment on the non-US markets.

Matthew Erick: Yes, sure. Thank you for the question. I think, we still see continued good growth within Europe, especially from the Viatrix clusters, Germany as well as in France. You're going to see those continued launches of new products that we talked about in R&D. And also as we progress within our integration with Viatrix, we're going to be looking at new markets and expansion there. So, Europe is still a very key focus for Biocon Biologics and has a tremendous amount of opportunity for us as well as you know, the US and North America.

Shyam Srinivasan: Got it. Second sub question on this, will be brief, is on the pricing dynamics in these different markets, I think EMs was briefly touched upon. But if you can also help us understand, there is market share progress, but there is no value share progress, if I can use that term. Maybe the only data we have is US. So, what has happened to pricing in some of these markets, including the US?

Kiran Mazumdar-Shaw: Shreehas, maybe you want to take this.

Shreehas Tambe: Shyam, these things will vary for two things. One is from the market and other is on the product category that we're talking about. Say, if we were to look at the oncology products in the US, we've typically seen, if you were to take the pre-biosimilar entry launches of products, you would see discounting anywhere in the region of about 50 to 60-62% from that pre-biosimilar days. If you were to move that into Europe, you would see that discounting to be much lower in the range of about 30 to 35% for the molecules that we operate in. And that's also a factor of the competition, of the market, of the tenders, also of the base pricing that these molecules were vis-a-vis where the discounting would be. You'll also see different categories of product attract different discounting like if you were to look at insulin which is in the US, a product which is more of a contracting cycle kind of a molecule and where the way Biocon or say in this case Viatris is able to displace Lantus and move into a formulary position. This discounting will probably be slightly sharper than what we've seen for the buy and bill kind of category in the oncology space. But if you really look broadly across the category of products that we've launched in the oncology biosimilars, as well as the insulins, more or less the pricing discounting has been reasonable. We have not seen any cliff despite the competition. In oncology, you see about 4-5 players per molecule, but there has been pricing sanity overall. It's been in the US, particularly as I said, in that 50% or 60% range. And then in the Europe, probably it's in that 30-35% range. So there has been some respect for the kind of work that has gone in developing the products and it's reflecting in the stability that you've seen overall, that's prevailed.

Shyam Srinivasan: Thank you and all the best.

Nikunj Mall: Thank you. So, the next question is from Harith Ahamed from Spark capital.

Harith Ahamed: Good morning and thanks for the opportunity. On Denosumab and Ustekinumab, last quarter you talked about starting Phase 3 trials in the first quarter of FY23. So, can you update us on the status of those two trials and trying to understand if the R&D spend for the quarter reflects the Phase 3 spends as well? And will there be a further step up in R&D in the coming quarters?

Kiran Mazumdar-Shaw: Shreehas, you want to take this?

Shreehas Tambe: Harith, the question wasn't very clear. I think you were pointing towards saying that the progress of Ustekinumab and Denosumab into the clinic, I think you are looking for an update on where these products are headed. Is that what you were looking for?

Harith Ahamed: **Yeah, if we started Phase 3 trials already.**

Shreehas Tambe: Yeah. So, we have, I mean, I would like to confirm that those things are progressing as we announced, and we would be looking to move these products further. We have started these global clinical trials, Phase 1 and Phase 3 and we should be looking to get to filing towards the end of Calendar Year 2023 for Ustekinumab and end of Calendar Year 2024 for Denosumab. They are progressing as per plan, and we expect them to move through the quarters as we'll see those R&D expenses come up as we progress these molecules.

Harith Ahamed: **Okay, got it. So, my second question is on the fund raise at Bicara. So, what's our stake? We have talked about continuing to raise funds through the first quarter. So, my question is on our current stake in this associate entity as of June.**

Kiran Mazumdar-Shaw: They have raised \$26 million in the first round and they have managed to raise about \$6 million in the second. They expect to raise an even higher amount, which they believe that they can raise by the middle of September. These amounts, as you know, are really required to see the clinical trials get to a certain level and they're very confident. They have also entered into various business development discussions because the data is trending in a very promising direction. So, there's a lot happening at Bicara and we will keep reporting it over the coming quarters.

Harith Ahamed: **So, from the disclosed stake in Bicara, which was around 74% at the end of March, has there been a further reduction? I am trying to understand if the share of losses from the associate, which has declined to a lower number in Q1 versus Q4, will reduce further.**

Siddharth Mittal: The stake as of June was roughly 67%. And I think as the fund raise continues, we will see the stake further go down below 50%.

Kiran Mazumdar-Shaw: I think he wanted to ask you about the share of loss.

Siddharth Mittal: So, share of loss, of course, we are taking a 67% share of loss in our P&L. This quarter, because of the fund raise, there was also a step up in the valuation of the investment. The P&L impact of the step up in the valuation, less the share of loss, was not significant. It was a very low number.

Harith Ahamed: **Okay. Last one with you permission, the forex loss of ₹38 Crores at the consolidated level, that includes the loss of ₹43 Crores at Biocon Biologics related to the Goldman Sachs OCB instrument, right?**

Siddharth Mittal: That's correct. So, there were gains in other parts of the business.

Harith Ahamed: **And the Other Income for the quarter at ₹78 crores - there's been a bit of a spike. Are there any MTM gains related to Adagio there?**

Siddharth Mittal: No, Adagio, there's no gain. I think the main gain is that mark-to-market or the step of the Bicara investment. So that's the main flux compared to previous year.

Nikunj Mall: Thanks, Harith. The next question from Neha Manpuria from Bank of America.

Neha Manpuria: **Thank you so much for taking my question. Siddharth, on the Viatrix funding, have we decided on what would be the amount that Biocon would have to put in after the private equity and the debt at BBL?**

Siddharth Mittal: Yes, so we do have a commitment of \$250 million to invest in Biocon Biologics and we will invest that amount. The rest of course, Biocon Biologics will be raising directly, as a combination of debt and new private equity investments.

Neha Manpuria: **And this \$250 million would be a combination of our subsidiary stake sale and debt.**

Siddharth Mittal: Yes, there are various options we are working on, and subsidiary means only Syngene. We do have a couple of other structured fund raise options that we're working on.

Neha Manpuria: **Understood. And second question. You know, Shreehas or Chini just wanted to understand from here, while the R&D part of the investment is well understood,**

outside of R&D, is there any incremental investment or large investment that we would require in the business to get it ready for the Viatris deal completion? How should I look at the cost structure for BBL let's say over the next few quarters other than the integration that would happen with the Viatris?

Shreehas Tambe:

Neha, I think from the overall big expense ticket perspective, we're looking at R&D being a big ticket item, which we've talked about. We're also looking at the capex or investments that we've talked about in the past where we've discussed investments in capacities for our Recombinant human insulin and the analogs. And that's something that we've discussed recently. We've talked about that and we budgeted that. The integration costs that will come as we get the Viatris business coming on board and we further strengthen our commercial infrastructure in various geographies. We could have typically built it out organically. Now, of course, that would be far muted, because a lot of this will come in to us through the acquisition. To dimension this, I will let Chini talk to you about it to see if we can give you a sense of what these investments would look like outside of R&D. Over to you, Chini.

M.B. Chinappa:

Neha, there will be increased investments in people as we do the organization build that will be absorbed by the higher revenue base and the increased profits that will come through post-merger. We have, as Shreehas mentioned, in terms of capex, while most of our monoclonal drug substance capacities will be up and running from this quarter, particularly the B3, which gets commissioned in this quarter, that's July to September. We have increased investments into expansion of Malaysia capacities, and also the expansion of our drug product capacities for monoclonal antibodies. So, these are the large investments going into the business on top of R&D.

Neha Manpuria:

Understood, thank you so much. Shreehas, one last question, any additional update on Aspart, is there a chance that we get the approval before the current contracting cycle or do you think the probability of that is lower now based on your conversation with the agency?

Shreehas Tambe:

Thanks, Neha. That's an important part. I think we've been discussing with the group and we've responded to the agency on the CRL that we've received and the agency has indicated that they will visit us in this quarter and there will be an inspection. We are quite confident that we should be able to get the approval once they've visited us. So, we are still hopeful that all of this should be done and Aspart approval should be in the bag towards the end of the calendar year. Yes, there is a contracting cycle which runs from July, through, I would say, September, October and there is that risk that we may not be able to be in the middle of that contracting cycle, taking us away from that big chunk of the commercial business that is available for this asset. But we would certainly have the

opportunity to look at any midcycle contracting as well as any regional businesses like we did with Glargine. And now that we've got presence with Semglee, I think there is an opportunity to see how we can get past the main commercial contracting national formularies into a more distributed phase. So yes, it's not the best situation that we could have been in, but we don't also see that as a complete lost opportunity. The focus right now of course is getting the approval in place.

Nikunj Mall:

Thanks, Neha. The next question is from Prakash Agarwal from Axis Capital.

Prakash Agarwal:

Thanks for the opportunity and good morning. I just wanted to understand a little bit on the margins better. I do understand R&D, you've already guided it will go up, commercials obviously will expand and so the revenue is expanding. More from second half when we add the Serum deal, which is expected to be at 30-33% margin business, as well as Mylan consolidation. So how should we think about margins there? I mean last year margin were good, this quarter, I would say it's softer. How do we see the margins rolling in? And this I'm saying reported margins, not the core margins because R&D has to be there, expansion has to be there. So just a little color would help.

Kiran Mazumdar-Shaw:

Chini, you might want to comment.

M.B. Chinappa:

Good morning, Prakash. A couple of things, let's start with the core EBITDA margins. The core EBITDA margins this quarter is slightly soft in comparison to the sequential quarter, but it improved over Q1 of last year. The softness in this quarter versus Q4 is because of, as Kiran mentioned, there's an impact of the increased salary costs as increments kicked in which levels off over the quarters. And the second one is they've been impacted by the Euro-dollar movement. So that reduced the profit share and hit our margins during this quarter. If you look ahead, particularly post Serum and Viatrix acquisition we expect to maintain core EBITDA margins in the mid to high 30s. So there, as a consolidated, as you look across the three businesses, the core EBITDA margins remain the same, and we expect to remain in that mid to high 30s. Coming to R&D cost, of course, the increased revenues coming both from Viatrix and Serum gives us the ability to invest more into R&D and we have always guided for the 10% to 12% in terms of revenue. So, we'll have to look at it from that range. Of course, it wouldn't be quarterly, it's more on an annual basis or across the program. On a quarterly basis, things could go up or down, depending upon, you know, the progress of the trial. But on an annual basis particularly over the life cycle of the program you will see the R&D cost to be 10 to 12% of the increased revenue, which is indicating that we are investing more into R&D with more of the pipeline products moving into the clinic.

Prakash Agarwal: Okay understood and secondly on, updates on the vaccines, you have put out COVID related and mosquito borne related. So, I mean, globally, we are seeing that volumes are coming down and mosquito borne apart from Africa, the volume has been coming down. So does the deal include the new range of vaccines, maybe the monkey pox or you know, a lot of new things are happening globally on the vaccine side. So, is the vaccine deal with old and new portfolio, how should we think about this, as well as the second part to this is you mentioned about Beva inspection poised around August. So Aspart, is there any update? Thank you.

Kiran Mazumdar-Shaw: I think Prakash, first and foremost as you know, viral diseases are becoming very rampant and there's a lot of concerns around viral diseases which wasn't there in the past. So, I think vaccines are going to become a very important segment and I think Serum Institute is well placed to basically develop new vaccines and cater to these global needs. So, from that point of view, I think even though the COVID vaccine demand has come off, I don't think that it will completely come off because as you can see, COVID is still very much in the air. And I think annual COVID shots, like annual flu shots will become the norm. So, I don't think it's going to completely fall off. And then you have many other viral diseases that are being looked at. Now when it comes to the Bevacizumab and Aspart, I think we have mentioned that we are anticipating inspections in August. So, both these will undergo inspections and that's why we are hopeful that we will get approval for both these products by the end of this calendar year.

Prakash Agarwal: Ok. So, Aspart also in August that's what the clarification is?

Kiran Mazumdar-Shaw: Yes

Prakash Agarwal: Okay, perfect. And on vaccine part of the question was on the future vaccines also is it covered in the deal?

Kiran Mazumdar-Shaw: Yes, the vaccine deal is covering all vaccines.

Prakash Agarwal: Okay, perfect. Thank you and all the best.

Nikunj Mall: Thanks, Prakash. The next question is from Yash Tanna from iThought Advisory.

Yash Tanna: Hi, good morning, team. So, I went through the Annual Report and I wanted to clarify a few things. So Biocon Pharma Inc. USA, which is our US based subsidiary for the formulations of Biocon Pharma Limited. So, it had revenues of ₹472 Crores and a PBT of ₹30 Crores for the year while, last year it had revenues of ₹442 Crores and similar PBT levels. So, is it the right understanding from my side that the US generic formulations portfolio has just grown 7% year-on-year, despite launching Everolimus?

Abhijit Zutshi: We've seen some headwinds on the base business, but the growth will come from new product launches, one of them was Everolimus. While there has been headwinds on the base business due to pricing pressure, with Everolimus, the revenue growth has been based on the market share we are seeing. We've also seen more launches on Everolimus coming in and even on those accounts, we are seeing that there is price erosion while we've held on to the market share.

Siddharth Mittal: And Yash, let me just add that don't look at the profits of standalone entity because the profits are split between the Indian entity and the US entity. The revenues what you reflected are the correct revenues for our US business.

Yash Tanna: That's the US formulations.

Siddharth Mittal: That's right.

Yash Tanna: Okay. Got it. And just related to that, so Biocon Pharma Limited sales was ~₹630 Crores, so does that mean that USA forms approximately 75% of the generic formulation, is that right?

Siddharth Mittal: Actually, revenues from US is 100%. There is also certain portion of API business in Biocon Pharma Limited. So, the delta between what's reported in Biocon Pharma Limited and Biocon Pharma Inc. would be mostly the API business.

Yash Tanna: Okay, so almost the entire one is from US.

Siddharth Mittal: Yes. I mean, our Emerging Market revenues and European revenues would start in this fiscal year.

Yash Tanna: Okay, got it. That's helpful. My second question was, so there was this media article relating that Sanofi has reduced prices for insulin for uninsured patients to \$30 a month supply and there are talks to cap the insulin prices as well in the US. So how does this impact us and our competition, like will it affect the profitability in the US for insulin business?

Kiran Mazumdar-Shaw: Well, I think Biocon Biologics is in a very good position to really play a key role in these market price expectations for insulin and I think that's what we believe will really increase our presence and market share in the US. Maybe Matt, you want to add to this.

Matthew Erick: Thanks. Look the rHIs, there are multifaceted channels. So, you have your payer channel, you have your cash channel, you have even long-term care hospital. Being vertically integrated and well positioned, we're able to play within all those channels, and then also what Viatris has already done and now moving over to Biocon Biologics allows us to continue to play on that leverage. So we're well positioned within our diabetes therapeutic area, as well as our rHIs as we look at the full market within the US.

Yash Tanna: Got it. Thank you.

Nikunj Mall: Thanks Yash. The next question is from Sameer Baisiwala from Morgan Stanley.

Sameer Baisiwala: Thank you so much and good morning, everyone. Just continuing with the previous question on rHI. Is it possible to discuss a bit more, what's the addressable market and when do you see the approval cycle begin for you? When can this be a meaningful product?

Kiran Mazumdar-Shaw: Shreehas, you might want to take this.

Shreehas Tambe: Thanks Sameer. As we've said earlier, the rHI franchise is not one product but multiple products, multiple SKUs. So, you have the soluble, you have the mix which is a 70:30 and you have the N formulation, as they call it. Now, they are available as vials and they are available as pens and there's also the highest strength of 500 IU formulations as well. So it's all recombinant human insulin, but there are a whole bunch of products around it. The whole insulin rHI or recombinant human insulin franchise is somewhere in that \$1 billion dollar range, give or take a little bit. And the dominant player of course is Eli Lilly. So they have been running that franchise and they have most of the market share. We have been working with the agency, bringing products from a filing perspective, starting

with the soluble to the mix and then we would of course get the NPH as they call it, we will do that as well, and the high strength. So, we are looking to progressively move into getting the full franchise to the US somewhere in the next year. We have already got the agencies to agree that we may not need a full blown for Phase 3 trial because we have characterized the product very well. So, we are expecting a waiver of the Phase 3 because of the kind of characterization we have done for the asset and the agency has agreed with our assessment of scientific evaluation of the product. And most importantly they believe that we have confirmation from the agency to say that these can be used interchangeably once launched. So, we believe that the full opportunity that is there currently in the US is available to us, Sameer. And as these products get approved, we tend to launch the full franchise towards 2024, where all of this should get available. Does that answer your question, Sameer?

Sameer Baisiwala: **Yes, it does. Thank you. And just on the Shreehas, how is the capacity utilization in Malaysia right now, and related to that is, are we having any capacity constraints, either for Malaysia or for drug substance antibody here in India for near term growth?**

Shreehas Tambe: So, in Malaysia if you remember we had invested substantial capacity for drug substance, for drug product. We have also added an additional pen assembly line so, we don't have a capacity challenge at all because we had also planned for the upcoming Aspart launch, which we are expecting this year. And we don't believe that there is an issue on either the drug substance or the pen assembly or the fill-finish. Obviously, we are targeting a much higher capacity and which is why we are looking to invest in the drug substance capacity which we had shared with you in the previous quarter and we are further building up capacity so that further ahead into the decade we should be able to launch more capacity across the world. On the non-insulin side, we've been making investments progressively in drug substance facility which was recently approved. But beyond our in-house capital investment, we have developed an external manufacturing strategy which is an asset light model which is not necessarily something where we invest in but we partner in such a way that our manufacturing is then closer to the market that we supply in and that's a conscious strategy which has begun from India. But then we will of course, expand it to other geographies, so that we don't necessarily have to ship glass and water across the oceans. So that's really how we intend to meet demand which we expect to grow several fold. You heard Susheel talk about it and Matt and I have the same view. So, we don't see a capacity constraint Sameer, to summarize this.

Sameer Baisiwala: **Okay, thank you so much. With your permission one final question, what's the timeline to take Toujeo which is Glargine 300 and Pertuzumab into clinical trials?**

Shreehas Tambe: So, again that's a very interesting question because Toujeo is essentially the same drug substance as Glargine drug substance. It's formulated differently in a higher strength which is a 300 unit strength against a 100 unit strength for Lantus. So, it's not a new clinical trial per se from a Phase 3 perspective, but it's a new Phase 1 study that will need to be done. But there's a different device which is very unique and we are making sure that we have that new device covered, so that we can be prepared for a potential approval. Now this product currently has an IP which runs towards the later half of the decade. Now we will have to see what IP strategies that we come up with which will allow us to decide what our launch strategies would be, which would be different than the approval strategies.

Sameer Baisiwala: **And for Pertuzumab?**

Shreehas Tambe: So Pertuzumab, we are progressing well. It's certainly an asset that we have partnered with Viartis and we are developing that asset. We have very good exchange going on with the agency. We have a position where we believe we can develop this in a very economical way. So, we have the opportunity to be amongst the few players who are developing this asset. There are not very many players, and we have the opportunity of probably being there at market formation with this asset and it'll be very synergistic with our other oncology portfolio. So, we are very bullish about that as well.

Sameer Baisiwala: **Okay, that's fine. Thank you.**

Nikunj Mall: Thank you Sameer. The next question is from Nithya Balasubramanian from Bernstein.

Nithya Balasubramanian: **Thank you so much for the opportunity. One question on insulin Aspart. So will you have the flexibility to launch two brands like you did in insulin Glargine, one at a higher price point and one at a lower price point?**

Shreehas Tambe: Matt would you like to respond? The high-level response first to that Nithya would be yes. It's an established model in the US to launch an authorized generic so to say in a very broad way, the model exists, the precedent exists. There are other brands and other companies which have followed it. So that's an opportunity we could look at but maybe Matt if you would want to comment on that.

Matthew Erick: Sure, Shreehas. 100% I agree with you. I think we have to look at all those channels, both branded and non-branded. And I think the Semglee set a unique path and one in

which we have great experience. So not ruling out any of those options, I think what we're looking at and always have at Biocon Biologics, is accessibility and affordability. And having those two types of situations drives that initiatives for us in the US.

Nithya Balasubramanian: Thank you so much. My second question is on Europe. I think the biggest challenge in Europe biosimilars has actually been, let's say the lower than anticipated price points for biosimilars because your starting price is already lower. And if I look at the data, your price erosions have been in the range of 70-75%. But now that Biocon is fully integrated and that you don't have to share economics with Viatris, should we expect you to, I mean, I'm seeing very low market shares for your current in-market products. So, can we expect you to get a bit more aggressive about price discounting now that you have room in order to gain market share?

Shreehas Tambe: I think we can look at the data points one more time, but I think you are right in the sense that the way Viatris is currently looked at Europe, there is certainly headroom for improvement and we are collectively looking at what are the strategies that could help us. As we've discussed previously, Europe is not a monolith - there are several different market archetypes and the therapy areas that we operate in are also vastly different in terms of how you realize these opportunities. Some of those could be, trying to get those opportunities through realizing the retail opportunity in say Germany or in France, in products like the insulins or they could be oncology which is largely a tender driven market across Europe and then there is of course, the Nordics, where it's a federal tender, where there are bits of all kinds of model, where I think you refer to the 70% discounting which even the originator companies have kind of subscribed to. So, there are different models, different therapy area of models. The integrated option is now with us that we will be one company, will certainly allow us more headroom to look deeper and closer into this and Matt and his team are closely connected into this to see how we can we move this forward. Certainly, agree with you there is a lot of headroom there.

Nithya Balasubramanian: Thank you so much and all the best.

Nikunj Mall: Thanks. The next question is from Surya Patra from Phillip Capital.

Surya Patra: So just wanted one clarification, let say you mentioned about the margin impact for the Biologics business was largely led by the R&D spend, and also what we are indicating now, that post Viatris integration, the intensity of R&D spend is likely to continue. So, by that are we indicating even the margin profile of integrated operation will be similar, what we are currently seeing?

M.B. Chinappa: Yes. So, to clarify I will again start with core EBITDA margins. See that the core EBITDA margins will be sustained post integration, and after all the eliminations. And with the increase in revenue base, we will look to increase our investments in R&D to fund our future growth.

Surya Patra: **Okay. Sir, in the initial period is it like that the benefit of this end-to-end integrated operation will that not be incrementally benefiting kind of theme for the integrated organization?**

M.B. Chinappa: As Viartis put out the guidance at the time of the acquisition, we had indicated that Viartis business has the potential to deliver \$1.1 billion revenues in 2023 with a \$250 million EBITDA. But as you go through all the eliminations, you look at the final core EBITDA margins, it is still pointing into the high 30s, when you combine the Serum business, the existing BBL business and the acquired Viartis business.

Surya Patra: **Okay, sure. Second question is on the biosimilar business again, so in the presentation ma'am you have mentioned that the growth of the biosimilar business excluding the COVID related contribution in the current spending previous quarter, the growth could have been 46% otherwise the reported number is 29%. So, I just wanted to know whether there was any COVID related benefit that the biosimilar business had witnessed in the corresponding previous quarter?**

Kiran Mazumdar-Shaw: No, so basically what we're saying is that year on year, if you look at the growth it could have been reported as 46% as opposed to 29% because last fiscal, we had the benefit of COVID related products.

Surya Patra: **Okay, but which product would have contributed.**

Kiran Mazumdar-Shaw: Itolizumab and Remdesivir.

Surya Patra: **But whether that was part of the biosimilar sales, or no?**

Kiran Mazumdar-Shaw: It's a part of our branded formulations business, we have an India Business, and that was part of that business.

Surya Patra: Okay. So, I was relating Itolizumab to the Novel biologics and Remdesivir to Syngene business, so that's why.

Kiran Mazumdar-Shaw: So, Syngene made the drugs substance and drug products and Biocon Biologics through its branded formulation business, marketed the product in India, and also exported the product to many of the emerging markets.

Surya Patra: Okay, sure. Just last one question. So, whether am I right that the contracting cycle for most of the biosimilar for the current season has been done? If that is so, then could we have some clarity about the progress in terms of market share for interchangeable insulin and Peg?

Shreehas Tambe: Yes, it's still underway Surya we should be able to talk to you in due course.

Surya Patra: Sure. Okay. Thank you.

Nikunj Mall: Thanks, Surya. The next question is from Sheersh Jain from Apex Capital.

Sheersh Jain: Good morning, everyone. Just wanted to understand the double counting of revenues that might happen upon the integration of Viatris. So currently based on Q1 numbers, Biocon Biologics run rate is roughly \$400 million and Viatris has guided for \$1.1-1.2 billion of revenue for the whole year. So, upon integration, what shall be the total ballpark range of revenue that might happen eliminating the double counting of deal?

Kiran Mazumdar-Shaw: Chini you might want to answer this question.

M.B. Chinappa: Sheersh, Hi. Roughly about 30% would get eliminated in the intercompany elimination, 30% of the \$1.1 billion.

Sheersh Jain: Okay, understood. So, the ballpark will change and would again come down to \$1.2 billion for the combined entity, is that correct?

M.B. Chinappa: Yes. So, on top of the Viatris business, what we have is our sales in the emerging markets and last year we ended with about \$240 million, these are sales directly through the emerging markets and not through Viatris. So, you could model growth on that and then you have the Serum business that we're acquiring which has a potential of \$300 million of revenues.

Sheersh Jain: **Understood. Thank you so much.**

Nikunj Mall: Thanks, Sheersh. The next question is from Tushar Manudhane from Motilal Oswal.

Tushar Manudhane: **Thanks for the opportunity. On Generics, while there has been some temporary shutdown for the quarter, just would like to have your comment on the profitability. How much has been the impact of pricing erosion and how much would come back with the revival in this?**

Siddharth Mittal: Price erosion is a continuing thing. Our gross margins are at still decent levels. We have seen increase in operating costs during the quarter, including the salary increments which were given in the first quarter. In terms of the overall revenue guidance, we had a couple of brownfield capacity expansion projects going on, which are expected to complete in Q2 for our synthetic manufacturing blocks in Bangalore, and these would lead to incremental sales in the second half of the fiscal. So, Q2 would be more or less at similar levels, like Q1 for the Generics business.

Tushar Manudhane: **Got it, that is it from my side. Thank you.**

Nikunj Mall: Thanks, Tushar. The next one is from Sameer Baisiwala from Morgan Stanley.

Sameer Baisiwala: **Yeah, just a quick clarification. Chini just to a participant back, did you see \$300 million from Serum deal? I thought it was closer to \$400 million.**

M.B. Chinappa: \$300 million plus. It's all dependent on the pricing of the vaccines.

Sameer Baisiwala: **Okay, but your initial communication when the deal happened was closer to \$400 million. So, you are sort of taking it down?**

M.B. Chinappa: It's linked to the pricing of the vaccines not taking anything down which is really went to 300 plus, which could go from 300 to 400. We will have to see, it is really a mix of things, there are products that are at \$3 range, 100 million of which gives you \$300 million, that's kind of minimum assured revenues. And there are products that are priced higher, that will take up the average price.

Sameer Baisiwala: **Okay, and for both types of vaccines, your margin profile remains same, which is 33-34%.**

M.B. Chinappa: Yes, there's minimum committed margins, which will give us at least 36.67%.

Sameer Baisiwala: **Got it. Thank you.**

Nikunj Mall: Thanks Sameer. Next one, Nithya from Bernstein.

Nithya Balasubramanian: **Hi, a follow up on the vaccine deal. If you can help us understand in FY23 and 24, what is the portfolio of vaccines that you will end up selling? Is it just the COVID vaccines, Covishield and COVAX because I understand the malaria, dengue, etc. are still in the pipeline? Some color please.**

Kiran Mazumdar-Shaw: So, Nithya we are entitled to sell any vaccine that are offered or produced by Serum Institute and it goes beyond COVID vaccines. As you know, there are many other vaccines, recently, in fact, they announced the HPV vaccines, there are flu shots, there are pneumococcal vaccines. So, there are a lot of options for the portfolio of vaccines.

Nithya Balasubramanian: **Understood. So, you will take a call based on the demand etc. to meet that 100 million doses number.**

Kiran Mazumdar-Shaw: Yes.

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

Nikunj Mall: Thanks, Nithya. The next question is from Prakash Agarwal from Axis.

Prakash Agarwal: Hi, thanks for the opportunity again. Question is on, if there's any update on the Sandoz deal that we had done in 2018. We have heard about our unpartnered two molecules coming in but nothing from the Sandoz side for long.

Kiran Mazumdar-Shaw: So, the two Sandoz programs are in a preclinical stage of development.

Prakash Agarwal: Okay, understood and secondly, on the two R&D programs that you disclosed last quarter, and saying that phase three is already started, so these are simultaneous studies, which I understand Phase 1 and Phase 3. But when we see the competition who already started Phase 1 and then now entered Phase 3, how are we different in terms of approval and launch timelines. Are we in the second wave or we should we still have chance to be in the first wave?

Kiran Mazumdar-Shaw: It all depends on the review process, and it depends on how the others are being reviewed and how strong their programs are. I'll just give you one example, for instance, Biocon was probably the third or fourth company developing Pegfilgrastim and yet we were the first to be approved. Similar case was in the case of Trastuzumab, again, we didn't think we would be the first company to be approved but we were, so it's very difficult to predict or project what can happen.

Prakash Agarwal: Okay, fair enough. And one more on the funding of \$800 million, clearly mentioned \$250 million from Biocon, but this remaining \$550, is it largely the existing PE guys or new PE guys or Serum might also pitch in?

Kiran Mazumdar-Shaw: Yeah, so it's a combination of both existing and new.

Prakash Agarwal: Okay, but Serum could add more.

Kiran Mazumdar-Shaw: Yeah.

Prakash Agarwal: Okay. So, thank you so much and all the best. Thank you.

Nikunj Mall: Thank you, Prakash. That was the last question. We thank you all again for joining us today. If you have any additional question, please feel free to reach out to Aishwarya or me. We're looking forward to seeing you again next quarter. Have a good day.