



**Unwavering
Purpose**

Biocon Limited Q2 FY22 Earnings Conference Call Transcript

October 22, 2021

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

External Participants during Q&A session

- # **Prakash Agarwal** – Axis Capital
- # **Surya Patra** – Phillip Capital
- # **Damayanti Kerai** – HSBC
- # **Yash Tanna** – ithought Advisory
- # **Shyam Srinivasan** – Goldman Sachs
- # **Sheersh Jain** – Apex Capital
- # **Tushar Manudhane** – Motilal Oswal
- # **Ankush Agarwal** – Surge Capital
- # **Sameer Baisiwala** – Morgan Stanley
- # **Sheersh Jain** – Apex Capital
- # **Charulata Gaidhani** – Dalal & Broacha
- # **Kunal Dhamesha** – Emkay Global Financial Services
- # **Harith Ahamed** – Spark Capital
- # **Vipulkumar Shah** – Sumangal Investment
- # **Tarang Agarwal** – Old Bridge Capital
- # **Sonal Gupta** – L&T Investment Management

Prepared Remarks Session

Aishwarya Sitharam:

Good morning everyone. I am Aishwarya Sitharam and I have recently joined the Investor Relations function for Biocon Limited. I would like to welcome each one of you to Biocon's Earnings Call for Q2FY22. 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 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 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. This conference is being recorded.

To discuss the company's business performance and outlook, we have today with us 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 the 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 call, if you need any further information, or if you need any clarifications, please get in touch with Nikunj or me.

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

Dr. Kiran Mazumdar-Shaw:

Thanks, Aishwarya and good morning everyone. Welcome to Biocon's Earnings Call for the second quarter and first half of FY22. I would like to start this Earnings Call on a note of cautious optimism when it comes to the pandemic. The timely mass vaccination drive that we saw across the nation in the past few months has certainly helped to abate the spread of the virus considerably. Having crossed the mega milestone of a billion vaccine doses yesterday, which I think was a huge milestone for the nation, we hope that we will soon see the worst of the COVID-19 pandemic behind us. However, I'm sure all of you will agree that we just cannot afford to allow complacency to reverse the situation and we must all continue to exercise caution and stay safe.

Biocon, as you know, has been at the forefront of the fight against COVID-19 through our portfolio of Remdesivir, Itolizumab and Cytosorb. We have added to these efforts through our collaboration with Adagio Therapeutics for their novel antibody therapy, ADG20 and thereafter, with Serum Institute Life Sciences for vaccines. This certainly takes us several steps further in strengthening our portfolio of therapies for the treatment and prevention of COVID-19. These collaborations, we believe, will enable us to expand our focus into the communicable disease space, thereby, providing a comprehensive portfolio of affordable therapies for global healthcare.

Let me begin with a Board update:

Pursuant to the vacancy created by the retirement of Mr. John Shaw, Dr. Eric Mazumdar has been appointed as a non-Executive Director to the Board of Biocon Limited with effect from 1st November 2021. Dr. Mazumdar is an Assistant Professor of Computing and Mathematical Sciences and Economics at the California Institute of Technology. He has worked extensively in research at the intersection of engineering, machine learning and economics at reputed institutes, such as the University of California Berkeley, the MIT Computer Science and Artificial Intelligence Laboratory and the MIT Koch Institute for Cancer Research. Dr. Mazumdar holds a PhD in Electrical Engineering and Computer Sciences from the University of California, Berkeley and a Bachelor of Science in Electrical Engineering and Computer Science from the Massachusetts Institute of Technology. We believe that his induction will give a strong impetus to

our digital initiatives, especially in the areas of artificial intelligence and digital transformation.

Coming to business highlights, let me now take you through the key highlights of this quarter:

- Before I talk about Everolimus, we did see the launch of Labetalol Hydrochloride tablets and Esomeprazole Magnesium Delayed-Release capsules earlier in the quarter, but of course, the most significant launch was that of Everolimus tablets, a generic version of Afinitor® in the US as a 'Day-1' launch, on the 1st of October. We expect that this will significantly drive the growth of our Generics portfolio in the second half of this fiscal.
- Another bit of important news was the approval that we received for the world's first interchangeable biosimilar from the U.S. FDA for our biosimilar glargine, Semglee, which has now been included as a preferred Glargine brand on the National Preferred Formulary of Express Scripts. This was indeed a great impetus to the interchangeable label, which is expected to drive significant future growth for our Biosimilars business, especially in the insulins segment.
- We had earlier reported that we entered into a strategic alliance with Serum Institute Life Sciences to foray into vaccines, by which we will get committed access to 100 million doses of vaccines annually for 15 years, in exchange for approximately 15% stake in Biocon Biologics at a post-money valuation of US\$ 4.9 billion.
- We also entered into a partnership with Adagio Therapeutics to manufacture and commercialize a broadly neutralizing novel antibody, ADG20, for the prevention and treatment of COVID-19 for several markets across GCC and Asia, including, of course, India.

Let me know move on to the financial highlights for this quarter:

- Revenues for Q2FY22 were at ₹1,945 Crores versus ₹1,765 Crores, which represents a year-on-year growth of 10%. Our revenues were mainly driven by Research Services, which were up 17% and Biosimilars that were up 10%. Revenues in our Generics business saw a 12% decline.
- We recorded a gross R&D spend of ₹165 Crores for this quarter, which is very similar to that of the last fiscal and corresponds to 13% of revenues, ex-Syngene. Of this, Rs.146 Crores is expensed in the P&L while the balance amount has been capitalized.
- We also recorded a forex gain of ₹20 Crores as compared to a loss of ₹18 Crores during Q2FY21.
- Core margin, that is EBITDA margin net of licensing, forex, Adagio revaluation gains and R&D, stood at 33% compared to 32% in the same quarter last year, on account of an improved performance in both Biosimilars and Research Services.
- EBITDA for the quarter was ₹551 crores, a growth of 35% year-on-year. The EBITDA margins stood at 28% as against 23% reported in Q2FY21.
- Profit Before Tax or PBT for the quarter, excluding an exceptional charge of ₹70 crores, stood at ₹276 crores up 27% versus ₹218 crores during the same quarter last fiscal.
- The exceptional charge relates to modification of the optionally convertible debentures of a PE investment in Biocon Biologics Limited and reversal of SEIS claims relating to the prior period, which, as all of you know, has been restricted to ₹5 Crores per exporter. This has actually hit Syngene's and Biocon Biologics' sales and profitability.
- Our Net Profit for the quarter, before such exceptional charge and associated tax, stood at ₹188 Crores versus ₹169 Crores in Q2FY21, which represents a growth of 11%. After adjusting for the exceptional charge, the Net Profit stands at ₹138 Crores.

Now, let me turn to the performance of our business segments during the quarter.

Generics business

Generics business witnessed a subdued performance this quarter, as a result of continuing pricing pressure in the US for our formulations portfolio and a slower than expected ramp up of demand for some of our key APIs.

Advanced buying by customers in the corresponding period of the previous fiscal, being apprehensive of COVID-related disruptions, is reflected in the year-on-year decrease in our revenues.

Operational and supply challenges in the earlier part of Q2FY22 also impacted the performance of the API business.

The segment delivered quarterly revenues of ₹530 Crores, a degrowth of 12% over Q2FY21. The quarter's PBT was at ₹50 Crores versus ₹70 Crores in the same period last fiscal, and PBT margins were at 9% compared to 12% in the last fiscal.

Our Statin formulations portfolio in the US comprising Rosuvastatin, Simvastatin and Atorvastatin held on to their market share despite continued pricing pressure, while Tacrolimus capsules maintained similar volumes to Q1FY22.

Labetalol Hydrochloride tablets and Esomeprazole Magnesium Delayed Release capsules were launched earlier in the quarter and following this, we launched Everolimus tablets, a generic version of Afinitor® as a 'Day-1' launch on October 1, 2021. This is the first 'Day-1' launch for our Generics Formulation business. Everolimus is a prescription medication that is used to treat certain types of cancers and tumors.

In September, the US FDA conducted a Remote Interactive Evaluation for our oral solid doses manufacturing facility in Bengaluru, as part of the pre-approval review for previously filed ANDAs. The final close-out report from the agency is awaited.

Our greenfield Immunosuppressants API manufacturing facility in Visakhapatnam, remains on track to be commissioned in the latter part of FY22, with qualification and validation in FY23.

With remote inspections finally underway, we are hopeful that future inspections will pave the way for our new product launches and expansion into key markets.

We will continue to focus on capacity enhancement projects, as well as operational efficiencies and expect strong growth from FY23 onwards, in terms of our Generics business.

Novel Biologics

Equillum, our US based partner, has announced plans to initiate a Phase 3 Pivotal Study for the use of Itolizumab in First-Line treatment of Acute Graft Versus Host Disease (aGVHD), following regulatory feedback from U.S. FDA, and is on track to commence the study in Q4 of CY21.

During the quarter, our Boston-based associate, Bicara Therapeutics, continued to make progress in the dose finding part of the Phase 1 trial for its lead program, BCA101, as a single agent and in combination with the PD1 inhibitor. On the basis of the current progress, Bicara anticipates declaring the recommended dose for expansion by the end of CY21.

Biosimilars

Biocon Biologics recorded revenues of ₹743 Crores for Q2, a year-on-year growth of 10%. The previous quarter had benefited from a higher contribution from our COVID portfolio, which has come off this quarter. Excluding the COVID portfolio, we have seen sequential growth of 11% for our Biosimilars business.

EBITDA for the quarter was up 72% year-on-year at ₹303 Crores. This includes the revaluation gains made from the equity investment in Adagio Therapeutics at its IPO.

Core EBITDA margins, excluding R&D, forex licensing income and Adagio revaluation gains, stood at ₹304 Crores which is up 15% year-on-year. Core EBITDA margin was at 42% for the quarter. The improvement in margins resulted primarily from incremental profits in developed markets.

Profit Before Tax, excluding the exceptional charge, stood at ₹119 Crores, up 47% year-on-year. This also excludes the revaluation gain arising from our investment in Adagio.

We continue to strengthen our presence in emerging markets with the launch of new products, as well as sustaining our existing business. The Branded Formulation India business continues to witness strong performance on the back of improved secondary sales.

In the US, Fulphila and Ogivri continue to be resilient despite competition, with market shares hovering around 9%. A steady improvement in the market share of our oncology products is expected to support the overall growth of our Biosimilars business.

The US FDA has approved Semglee as the first interchangeable biosimilar product under the 351(k) regulatory pathway, which allows substitution of Semglee for the reference product at the pharmacy counter. This has been a marquee milestone for Biocon Biologics and Viatriis. Our partner, Viatriis, plans to transition the current product to the 351(k) interchangeable product in the coming months.

We received breaking news yesterday that our biosimilar insulin glargine, Semglee, has been included as a preferred glargine brand, on the National Preferred Formulary of Express Scripts, which, as many of you know, is one of the largest Pharmacy Benefit Management organizations in the US. The formulary covers more than 28 million lives. As a result of this, we expect Semglee to gain commensurate market share in the US from CY22, making it an important growth driver for Biocon Biologics.

The US FDA conducted a pre-approval inspection of our Malaysia facility last month for our biosimilar Aspart BLA. We have responded to the agency with a CAPA and are confident of addressing the observations made during the inspection. We do not expect the outcome of this inspection to impact our commercialization plans in the US.

We continue to work closely with the US FDA to expedite the pre-approval site inspection in India for biosimilar Bevacizumab. We have, as you can imagine, requested them for a remote inspection like they have done for the Biocon's Generic facility. However, we have not yet had a positive response from the US FDA for such an inspection.

Our market share in Europe continues to improve, with products like Ogivri crossing the 5% mark in July and Hulo continuing to see steady improvement. In Q2, our biosimilar Bevacizumab, Abevmy, was launched in several EU markets, including Germany, Croatia, Czech Republic and Slovakia. In Canada and Australia, we continued to see a robust performance of Ogivri.

We have also just received regulatory approval for our biosimilar insulin Aspart in Canada.

We have also made a strategic move into communicable diseases through two key partnerships, one with Serum Institute Life Sciences for vaccines and infectious disease antibodies, and the second with Adagio Therapeutics for a novel COVID antibody therapy.

The Serum Institute Life Sciences strategic alliance provides Biocon biologics an asset light and accelerated entry into the vaccine segment. Pursuant to the terms of the agreement, Biocon Biologics will generate a committed revenue stream and related margins commencing H2 FY23. The near-term focus will be on COVID-19 vaccines, since a large part of the global population remains unvaccinated. Only 3% of people in low-income countries have received at least one dose. There is also strong potential from the booster dose of COVID-19 vaccines. Additionally, the partnership will have access to Serum Institute Life Sciences' current development pipeline to address unmet needs in other communicable diseases like mosquito borne infections. The platform enables Biocon Biologics to add next generation

vaccines that will drive long term growth.

Biocon Biologics has also entered into a partnership with Adagio Therapeutics for ADG20, a novel antibody therapy for COVID-19. This entails manufacturing and commercialization in several emerging markets, including India. ADG20 is being developed for the prevention and treatment of COVID-19 as a single dose intramuscular injection. It has the potential to effectively neutralize a broad range of sarbecoviruses, including SARS-CoV-2 and its emerging variants. The company is currently conducting its Phase 2/3 pivotal trials to support an Emergency Use Authorization application by the first quarter of CY22.

To summarize, we clearly see the Biosimilars business gaining momentum with the launch of interchangeable glargine in the US and continued launches and market share gains for our portfolio globally. This will be augmented by our strategic foray into vaccines and biologics for infectious diseases. We continue to invest in creating a robust pipeline of products, enabling sustainable value accretion for our shareholders.

Research Services – Syngene

For Q2, Revenue from Operations was up 17% to ₹610 Crores from ₹520 Crores last fiscal.

Profit Before Tax, excluding the exceptional charge increased to ₹130 Crores versus ₹94 Crores. The second quarter was characterized by strong performance in all divisions, including adding 25 new clients in discovery services which lies at the heart of our research activities.

Syngene also continues to expand relationships with existing clients and long term partners in the dedicated research centers.

Syngene continued to manufacture Remdesivir during the quarter, although the volumes are dropping as the impact of vaccination reduces the need for treatments such as this.

A strong performance delivered in the first half of the year and it is expected to also deliver a good performance in the second half.

So, in conclusion, I would like to say that the expansion of our Generics portfolio, the grant of interchangeability of our biosimilar insulin glargine and its inclusion in Express Scripts in National Preferred Formulary and the collaboration that we have entered into with SILS and Adagio, have now created more opportunities than ever to build for a stronger future and fulfill our goal of making large scale impact on global healthcare through affordable access. With this, I would like to open it up to questions and answers.

Q&A Session

- Nikunj Mall:** Thank you, Ma'am. I would like to remind everyone, in case you need to ask a question, 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 ask the question. The first question is from Prakash Agarwal of Axis Capital.
- Prakash Agarwal:** Hi, good morning, Ma'am and good morning to the team. My first question is on the outlook. So, from an outlook perspective, you mentioned that the second half is looking better obviously with insulin Glargine interchangeability and with the tie up with Express Scripts from CY2022. My question is actually on the other base business, Trastuzumab and Pegfilgrastim. How do we see the journey from here for these two products and for the other two products, which is Beva, which is awaiting the approval, what are the timelines there, and Aspart? So, basically ex-insulin Glargine because insulin Glargine is, I think, pretty much set for its growth path.
- Kiran Mazumdar-Shaw:** So Prakash I'll just answer some of those questions and then I'll sort of leave it to Shreehas to answer the rest. Basically, I think you're right, I mean Bevacizumab is an approval we are eagerly awaiting and at the moment we have really no visibility in terms of when we will have this inspection done, as you know, in recent times, there have been multiple reports of many product approval delays in the US and we happen to be one of them. So, we do hope that this inspection will happen sooner than later. We have tried to get them to even consider the remote inspection but we will keep you informed as soon as we get any information, I think the rest of the questions I will leave it to Shreehas to respond.
- Shreehas Tambe:** Thanks Kiran. To respond to the two products that you talked about particularly Fulphila and Ogivri in the US, I think we've discussed this in the past that we've seen the pandemic phase that Onpro, particularly in the Fulphila basket had held on to a market share in a sense artificially, given the convenience factor as patient footfalls reduced to hospitals. We are seeing that particular market share come off from a little above 60% to the mid 50% and that part is starting to move towards the syringes space, which is where we are operating. We've not got all of it moving towards Fulphila, but we will be starting to see that as a positive point. We've obviously had gone to a strong market share which is just below that double digit and we see that progressing well, as we get into the next calendar year. For Trastuzumab, we've seen to hold the key position or around second position, I would say after the other biosimilar on the 150. On the 440, you've seen some competition push past on a more aggressive pricing strategy but it hasn't really overall impacted the Ogivri brand strategy that Vitaris has come up with and we have held on to that just under 10% market share, even in the recent couple of months. We see this as a steady positioning which will only improve as we move along with the next fiscal. Bevacizumab, I think Kiran has already covered, we remain bullish on that as it completes our portfolio offering in the oncology space and allows us a more complete portfolio to discuss with peers.

- Nikunj Mall:** The next question is from Surya Patra from Philip Capital.
- Surya Patra:** **Thanks for this opportunity, and good morning to everybody. Before getting into the questions, can I just get the clarity about the other income number, why is that so elevated and quantify that what is a kind of the revaluation gain on that and the nature of that?**
- M.B. Chinappa:** Can I clarify.
- Kiran Mazumdar-Shaw:** Yes, please.
- M.B. Chinappa:** Hi Surya, good morning. In August we had invested \$5 million in Adagio Therapeutics in the IPO at \$17 a share. The share was trading at \$42 on 30th September and the gains on account of that has been recorded as other income.
- Surya Patra:** **Okay. Can you quantify is that what is that number that is there in other income?**
- M.B. Chinappa:** ₹55 Crores.
- Surya Patra:** **Ok. Just extending that, so the progress on the product, ADG 20. So, what is the commercial scope there and what is the competitive advantage of that molecule in neutralizing COVID cases compared to other antibodies that are there in various stages of development or in various stages of progress and what is our aspiration there anything on that front?**
- Kiran Mazumdar-Shaw:** I think Shreehas can take this question.
- Shreehas Tambe:** Yes, sure. So, I think ADG 20 that we partnered with Adagio is a broad neutralizing antibody and it really has shown very high efficacy in all known variants, in fact, recently Adagio has published an *in vitro* study, where ADG 20 has really shown a very high efficacy against all known variants, including the delta variant, the Lambda variant, the Mu variant. Even as other antiviral therapies are available where efficacies are in the region of 50% thereabouts, I think it is quite obvious that the antibody therapies that have an efficacy of over 80% remain the gold standard. ADG 20 specifically has a very unique positioning where it's a single therapy or monotherapy with a one-shot intramuscular dose which can be given in an outpatient setting, really even improving the convenience of it. It has been designed with an extended shelf life which is expected to offer protection for close to a year or thereabouts which really you know, then offers a lot of security to a wide section of population which is at a high risk or immune-compromised who were unable to develop immunity despite vaccinations.
- So, there are two studies that Adagio has been conducting, apart from the six-month study that they have already published in the Phase 1. They are doing a Phase 2/3 study, one is the STAMP study for the treatment that I just talked about. And the other study is EVADE, which is a pivotal study looking at prophylaxis, which should then target a very large section of the population thereby allowing peace of mind as we go along, without necessarily

getting infected, but a kind of assurance that you can protect yourselves directly without waiting for an incubation period of two weeks, which a typical vaccine would do.

We believe the product positioning is very strong and offers several USPs over existing therapies, either in the small molecule space or even in the antibody space which are either approved under the EUA today or are under development.

M.B. Chinappa: Shreehas, if could you clarify the markets, we are present in.

Shreehas Tambe: We are present in India and several India-like markets that we've looked at. We are present in countries in the Middle East and Asia Pacific where we've chosen select markets to focus on or maybe believe this therapy can make a very big difference.

Nikunj Mall: The next question is from Damayanti Kerai from HSBC.

Damayanti Kerai: **Hi good morning, thanks for the opportunity. My first question is coming back to Ogivri and Fulphila. We are hovering in high single digit market share, you obviously mentioned some of the reason behind that but looking ahead with the kind of manufacturing capacity we have and marketing outreach which our partner might have achieved so far, potentially, what kind of market share, we can gain in these two key products?**

Shreehas Tambe: I think we wouldn't want to count on specific market shares. I think that wouldn't be fair but if we really looked at the past, we've been able to hold on to a steady market share overall and it's nearly, been moving upwards, despite the competition that we've seen. So, we've really seen our partner Viartis been able to navigate the increasing competition, as well as the other products which have entered that space over time. We believe that as products like Bevacizumab join our portfolio it will only strengthen our position that we've had in the US overall. So, we would you know remain optimistic as to how Viartis has held on to this and we remain positive about how we will pursue it in the coming year.

Damayanti Kerai: **Thank you, my second question is again on biosimilars. So, can you specify the broad sales split between the emerging market and developed market as of Q2 and on the emerging market side, what kind of growth, we should be anticipating in next few quarters. Related to that, sequentially biosimilars sales were largely flat, but we have seen good pick up on the margin part so, can you also please explain that?**

Shreehas Tambe: Chinappa you want to go on the on the split and then we can maybe we can than add on.

M.B. Chinappa: The numbers around the split for Q2 we have the developed markets going towards the 50% mark, it is just above 45-46%. The second question was the margin improvement - yes, the margin improvement reflects the higher profits as Kiran mentioned has played out from the developed markets.

Damayanti Kerai: **And what will be the key driving factors which we should be looking for.**

Kiran Mazumdar-Shaw: I just want to answer that question of yours, by saying that I've already mentioned that the second half, will get bolstered by obviously insulin Glargine, and we also expect that the improvement in some of the other biosimilar portfolios. So, I think the main spurt of growth will come definitely from insulin Glargine.

Damayanti Kerai: **Even in other emerging market because I was specifically asking for growth drivers in the non-developed markets.**

Kiran Mazumdar-Shaw: Yeah, that continues to grow. I think Susheel, you might want to comment on that.

Susheel Umesh: The first half in the emerging countries we have seen good growth and we have got a demand book that is full in the different countries that we operate. So, I'm also very optimistic that the growth trajectory will continue the same way it was in the first half for the other emerging countries. In India too, in the first half we have seen very good growth, and we hope to continue the growth trajectory as well, so I would keep the trend of the growth, more or less similar as it was in the first half.

Damayanti Kerai: **Thank you, for your response. I will get back in the queue.**

Nikunj Mall: Thanks, Damayanti and the next question is from Yash Tanna from ithought Advisory.

Yash Tanna: **Hi good morning team. My first question is I know that we are very small business in India, but I would like to know the impact that we have due to the insulin Glargine coming under NLEM. Like how much price cut we have in percentage terms for the product, and with the decreased price, can we expect the volumes to go up for the product like higher adoption for the product?**

Kiran Mazumdar-Shaw: Susheel, why don't you take this question.

Susheel Umesh: In India the insulin business, the bigger part of the business in India is still the human insulins. If you look at the analogue business, it's about 20% of the patients that are there in the market. There is a huge scope for the analogue business, is one. The second, our own business in this particular area, we are not promoting this product only in terms of price differential and that's very clear. Though we have a price differential from the leader product, we are promoting our products strongly on quality. So, whatever the price decrease will come in, we have got two SKUs that are unique in this market, and that is the vial SKUs of 5ml and 10ml in which the price differential will continue to be there. So, we have got a significant advantage here. I don't think the impact in terms of what the leader price will come down, will impact us that much because there is a huge scope to gain market share from the human insulin. We continue to focus on the high quality and the interchangeability that we have got in the US, which will give us that further impetus. Though the same rules don't apply in India, but it definitely gives more confidence to doctors, that what we have with us is a very high quality Glargine and we have seen that in

the last two months, the traction definitely has improved. So, I'm very optimistic about this entire business of Glargine of our brand Basalog in India.

Yash Tanna: **My second question is on our Visakhapatnam Greenfield facility. So, we have invested ₹600 Crores in the facility. So, I would like to know what would be the approximate asset turnovers for the facility and we said that we can get approvals by FY23, so when can we expect significant revenues to start flowing in from this facility?**

Siddharth Mittal: Yash, we cannot give guidance in terms of what revenues would be generated from this facility. All that I can say is Immunosuppressants is a very important growth driver and a differentiation factor for the Generics business. Today, we are capacity constrained in our Bangalore facility and the additional capacity that we will get from Vizag would drive the segment growth in the coming years. Now, what we said is that the commissioning would get completed by end of this fiscal, followed by validation and filing in the next fiscal and then, it will be followed by FDA inspection and approval. So, we expect the commercialization to start somewhere in CY23, if everything goes as planned.

Yash Tanna: **Okay, so H2FY23, if everything goes as per plan?**

Siddharth Mittal: Yes.

Yash Tanna: **Thank you so much.**

Nikunj Mall: Thanks, Yash. Next one is from Shyam Srinivasan from Goldman Sachs.

Shyam Srinivasan: **Good morning and thank you for taking my question. So, first one is, CMS pricing data for biosimilars came out very recently for Q2 and if you see the products that have seen the maximum Q-o-Q erosion, have been the products that we are there, or potentially going to be there, like Herceptin, Avastin, Neulasta, so largely on the onco space. Somebody like a Celltrion has been very, very aggressive in terms of taking prices down in Herceptin. While there is the angle of volume share gains for us through this next six months, and then calendar next year, just want to understand how we place in terms of pricing and in terms of cost competitiveness, especially against Asian manufacturers that's question one. The second question is on the Small Molecule Generics. We have seen another weak quarter. So just want to understand what's happening in terms of price pressure, when do you think we will likely see some kind of a bottoming out and things improving? So, let me pause there.**

Kiran Mazumdar-Shaw: So maybe Shreehas and Abhijit may take these two questions, starting with Shreehas.

Shreehas Tambe: So, Shyam I think the CMS point which you raised is absolutely valid and we've seen that in our discussions. Viatris has been in active discussions there and while we do not see a direct impact on our margins overall, we do see the amendment situation there given that

our products will come off and take some of those benefits, particularly on the reimbursement side.

But to address the question of cost competitiveness, I think you can clearly see, we're quite confident on the cost competitiveness versus the Asian partners for that matter, and other peers in that group too because we have conventionally been a strong emerging market player for several years, whether be in the small molecule space in the past and even today, we've always been very cost competitive we've always stood first in the emerging markets and we've always succeeded in our small molecule business, in our insulins business and as we now get to the US and other parts of the of the developed markets, we believe these will be more remunerative opportunities for us than what we've seen in the past. These are some things that we are not really concerned about. We are of course vigilant on the cost competitiveness part but nothing that we are overly concerned about at this point. I'd let Abhijit to respond to the small molecules question.

Abhijit Zutshi:

Thanks, Shreehas. Good morning, Shyam. So, on your questions about the price erosion that we're seeing in the performance on the Generics Formulation business. You know the only market where we are commercial right now is the US and the portfolio that we have is also quite limited right now, we have seven commercial products. Some of the products that have been commercial, we've consistently maintained our market share between 15 to 20% but there has been some pricing headwinds on that, despite that we've maintained our market share. However, the launch of molecules like Everolimus, as we expand the portfolio with more complex products, I think we can start seeing some growth coming in from these markets and as other markets also open up in the near future for us, you will start seeing some growth.

Shyam Srinivasan:

And the split of API to formulations remains at 80:20?

Indranil Sen:

That's right, Shyam. Currently, it is at 80:20.

Shyam Srinivasan:

Got it, thank you and all the best.

Nikunj Mall:

Thanks, Shyam. The next one is from Sheersh Jain from Apex Capital.

Sheersh Jain:

So my question arise from the concern that we are not able to gain substantial market share in US in the biosimilar market and given the stellar margins that we have had, and continued price competition in biosimilar business, is it not possible for the company to be aggressive on the pricing front and give out some margins temporarily to gain market share, and make this a sustainable growth story for the company?

Kiran Mazumdar-Shaw:

So let me answer that by saying that, Viatrix is absolutely focused on making this into an important business growth driver for their business, and I think what we have seen, thus far, is basically making sure that we are in the market with a sustainable market share, which, as you can see, has been in the high single digit. As you know that there are not too many competitors, at the same time I think we are confident as partners of making progress

and gaining greater market share in the coming quarters and years. So, I think this is a patient business building kind of phase where I think once we are entrenched in that market with biosimilars, as you know biosimilars uptake also has now been very positively received in the US and so now onwards, I think you are likely to see an uptick in market share. So, we are very confident as is our partner Viatris that things will improve in the future.

Sheersh Jain: **But your confidence has been visible for past few quarters, but there hasn't been visible market share gain. So, I'm just concerned like what is Viatris doing exactly to turn your optimism and your strategies into substantial market share gain because that has been constantly in the high single digits.**

Kiran Mazumdar-Shaw: The reason why we remain confident is because if you can see the interchangeability label that Glargine secured certainly should give you confidence that our insulin business is likely to benefit from this particular approval, as you know, Aspart will be the next product to follow. Our insulin segment is getting strengthened with these approvals. As you know, the Express Scripts announcement of including Semglee into the National Preferred Formulary is also a very important step in this direction. Similarly, I think you know that we are awaiting our approval for Bevacizumab. This is something beyond our control. The only step remaining is a Pre Approval Inspection (PAI). We had asked for a waiver but US FDA has not agreed to that. As soon as the facility is approved, we hope to receive approvals soon thereafter. You need to have a portfolio of products which we do have, it's unfortunate that COVID disrupted some of our strategies but we remain very confident that in the future, you will see a very good uptick in market share as Viatris focuses on making sure that they start gaining market share. So that's, all I can say, we remain confident, because we have the capabilities, we have the capacity and we are vertically integrated that's what gives us the confidence that we will be a very strong player in biosimilars. When you compare us to many other companies who are playing in this field, they are not vertically integrated, except for a few there are most who are not vertically integrated and, therefore, we believe that we do have a very strong reason to be confident that we will succeed in the near term.

Sheersh Jain: **I have just one last question, so just as we have the interchangeable status for Semglee, can all biologics have an interchangeable biosimilars and if, yes, what happens to our market share when other players get interchangeable status for the products that we are not interchangeable, so do we still sustain our market share in that scenario?**

Kiran Mazumdar-Shaw: Interchangeable labels have also been given, as you just heard, adalimumab has also received an interchangeable label recently. I think there is an exclusivity period for the interchangeable label. We have a one-year exclusivity. We will have a first mover advantage and you need to basically garner market share and make the most of a first mover advantage. That is what we're trying to do with the interchangeable label.

Shreehas Tambe: Just to add to what Kiran said, interchangeability also is a high bar so it's not something that's easy access. There is a requirement for high degree of analytical characterization showing that your product meets to the expectation that have been set by the agency, of

course together with Viatris, Biocon Biologics has set that bar and paved the way for interchangeable insulin including access and there will be others who will follow. But like Kiran said, you know, it is something where we carry an exclusivity period, and this is something that's not easily accessible, unless you have the scientific credibility to get pass that bar.

Nikunj Mall: Next question from the Tushar Manudhane from Motilal Oswal.

Tushar Manudhane: **We have both Semglee and the authorized generic, so what is the strategy of that?**

Shreehas Tambe: These are products that we have launched in the US market. Viatris has brought this to the market, basically. This is a commercial strategy to allow us a broad access as we can do to patients in the US, or to people with diabetes in the US. As much as you know, whether they are bearing insurance plans or they have coverages. You know their payer preferences and coverages, I think the intent is to see how we can maximize reach of the product, regardless of how the patient is placed. Viatris, of course would be at the best place to respond to it, but the intent is to see how we can make the product accessible to a wide section of people, whether they are covered through the formulary or limit their co-pay to a ceiling, that's the intent behind the two products.

Tushar Manudhane: **Even in manufacturing the authorized version?**

Shreehas Tambe: Yes.

Tushar Manudhane: **Biocon will be manufacturing authorized version?**

Kiran Mazumdar-Shaw: Yes.

Tushar Manudhane: **And secondly, would like to also understand while we have a good pipeline of insulin Glargine, Aspart and Bevacizumab, would like to share the other potential molecules for a FY23, FY24 and may be FY25.**

Shreehas Tambe: We've talked about a bunch of products which are insulin and insulin analog. We've also shared that we will be looking to bring in our recombinant human insulin which is right now approved in over 40 countries of the world, to those in the US as well. And we look forward to adding that to our portfolio shortly so, in addition to the basal insulin which is Glargine, we will add a rapid acting analog in Aspart which is with Viatris, and then we will also bring in our own recombinant human insulin.

Tushar Manudhane: **Got it. And just one last one, on the Generics side. While there is intense pricing erosion but at the same time, if I look Quarter-on-Quarter, the PBT margin has improved by 300-350 bps. So, if you could just explain that point.**

Indranil Sen: The quarter-on-quarter margin is largely improved product mix.

Nikunj Mall: Thanks, Tushar. The next one is from Ankush Agrawal from Surge Capital.

Ankush Agrawal: **Hi good morning, everyone. Just one broad question, on the whole biosimilar business. Biocon has been an early mover, right from identifying the opportunity early on, getting into partnerships, getting into product development and getting the approvals. But how do you think Biocon has fared on the commercialization part of it, given the challenges that we have faced through our end or from our partner Viatris' end or from a market development perspective. How do you think we are going to change our strategy going ahead?**

Shreehas Tambe: I think the important piece is to see the way we have developed these products and brought them to market. These are long gestation opportunities, as Kiran talked about. The way we brought these products first in the emerging markets and then to the developed markets. So, to broadly bucket this opportunity, let me talk about how we brought them to the US first with our partner Viatris and I think it's been a fairly successful launch. If you look at when we brought in Fulphila, it was the first biosimilar to have been launched in the US market and it was probably the most successful launch of a biosimilar ever in US. Since then, we've also been able to value maximize that opportunity in the US and continue to hold high single digit market share by preserving balance for us. In terms of how we've progressed with Trastuzumab, you know we were stated for a risk-free launch until Amgen did jump in with the at risk launch. So, we worked with Viatris, which was caught by surprise by that but it hasn't taken away from how we have gradually inched our market share towards double digits now in the period since we have launched. Again, here we have preserved value, we've preserved margins, the markets remained same. There was this insulin Glargine launch and approval that we got. The timing of that approval in the US meant that we would miss the formulary cycle for CY22 because that was approved in July and October period. Since our approval happened, subsequent to that formulary discussions and negotiations, our CY21 has essentially been in the retail space, but now that it's opened up for CY22 you can see that Viatris is really made good progress and gotten us listed into the preferred status in one of the biggest PBMs. So, I would say we've had a fairly successful approach in probably the largest market in the world, and with the products that we brought to the market, there is no switch that will certainly bring market share, which takes time to build.

I think there was a previous question, asking why can't we build suddenly and sustainably, is pricing the only lever that you have. Pricing is one of the levers and we are very competitive on that, as I responded to Shyam. But I think beyond that there are several other factors to be commercially successful, which is the order of entry or the payer strategy, payer access and importantly what is the cost of acquisition of that portfolio and the particular customer. So, Viatris has balanced all of this very well. If you look at how that business has increasingly grown, and let me say, that entire portfolio is now about 50% or 60% of what we were, since the time we brought these products into the market, the split between develop and emerging product. So, overall we have progressed well in a gradual but steady pace. In the emerging markets, where our teams have commercialized the product through partners, I think we've seen phenomenal progress there as well, whether

it is the markets of Latin America, where our Trastuzumab brand through partner Libbs is the largest brand in the country; or in Mexico, where our partner Pisa for our recombinant human insulin; or in Malaysia, where we have over 60% market share, in that market to a distributor model. So we've changed models to different markets, including how we get access to patients over time. So its a longish answer to your question, but I think the commercialization has been through different avenues, which is successful in the market, which works best in the market that we're operating in and that's really the summary of how we have gone about getting our products to patients.

Ankush Agrawal: **Thanks that was already a very broad answer to it. But do you think the market conditions have shaped, what has been our expectations, say, 5-6 years down the line, and do you think that based on this current status, you will modify your expectation for the future products that we're going to launch?**

Kiran Mazumdar-Shaw: I think what I'd like to respond by saying is, please don't cut and paste the generics model with the biosimilars model. I think we have to build the biosimilars business, just as the way Shreehas has described. It is a very important business which requires a different set of factors to address. I think we are very confident that we have understood what it takes to build a biosimilars business. And we remain very confident that this will be a very large and significant business for the group for Biocon Biosimilars. We certainly believe that Biologics is going to be a very successful business going forward. But I think you must understand that you need to build a very strong foundation before you really start getting a good uptick in terms of what you're trying to do. So, I don't think we are disappointed, I think we know what to expect and we're addressing these expectations very meticulously.

Ankush Agrawal: Thank you.

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

Sameer Baisiwala: **Hi, good morning, everyone. Thanks for giving me a chance. So, the first question is on your virtual PAI that has been done for oral solid in Bangalore. Can you give some color on that, in the sense that, typically, it would be for a first generic complex high value product, you know, is that it the case with you as well?**

Siddharth Mittal: Sameer, it is for a product where there are very limited number of players in the market. So that would have prompted FDA to oblige us with this remote inspection evaluation.

Sameer Baisiwala: **Is it a large market in dollar terms?**

Siddharth Mittal: Not very large, I would say. Abhijit, maybe you want add some context.

Abhijit Zutshi: It's not a very large market. It's upwards of US\$ 500 million with limited competition.

Sameer Baisiwala: **Okay, great thanks and the second question is on Semglee, have you had any advantage on the vial side, because I think you are the only player on that. And are**

the commercialization contracts, both for pen and vial go hand in hand. The second is, would it be a fair expectation that you get to a double-digit market share over next 12-18 months so your thoughts on that?

Shreehas Tambe: I think the opportunity with the Express Scripts formulary listing that Viatrix has secured is for pens and vials both, so in that sense we would be the only one outside of Lantus which had that. So, it clearly creates a unique positioning and we see an uptick in that particular SKU clearly. So, that's different from what other products have to offer, particularly based on that listing. On the second question, do we see our market shares moving up, I couldn't specifically comment on what that would be, but you know it's fair to assume that they will move north from where we are.

Kiran Mazumdar-Shaw: It is safe to say that, certainly, the aim is to be in the double-digit growth market share category.

Sameer Baisiwala: **Okay that's great and just one or two more, can you update us on the pipeline of new biosimilars entering phase three. There was expectation that they would be couple of them in this current fiscal and second is for Aspart, what's a realistic timeline that you think you would be able to get the approval and launch the product?**

Shreehas Tambe: So far for Aspart as Kiran said in her opening remarks, that we have hosted inspection where FDA has visited us. We did receive a Form 483, and we have those six observations, which we are very confident about and we've responded to those observations with solid CAPA actions, which we believe the FDA will find acceptable. So, we are looking at an approval at some point in time sooner than later. So that's about Aspart. In terms of your other question which was more related to products coming to the clinic this fiscal, we are on course to deliver on that and we should be discussing them and the progress of our pipeline with you as we get on to more discussions like this.

Sameer Baisiwala: **Shreehas, would you say Aspart is for Q1 2022, is that a realistic expectation calendar?**

Shreehas Tambe: From an approval standpoint, yes, I think, launch strategies would depend on how Viatrix sees this and how we position it, I think Viatrix would also has to view the formulary cycles like we did in case of Glargine, so we'll have to be mindful of that as we bring Aspart also into the market.

Sameer Baisiwala: Okay, great. Thank you so much.

Nikunj Mall: Thanks Sameer. The next one is Prakash Agarwal from Axis.

Prakash Agarwal: **Hi, thanks for the opportunity again. My second question was on the cost aspect. So, we've been hearing a lot of increase in raw material prices, solvent prices, as well as power costs. As a company, what are we witnessing now and how well are**

we positioned for the next six to twelve months from a raw material as well as operating costs like power, etc.?

Kiran Mazumdar-Shaw: Shreehas and Siddharth, can you take it?

Siddharth Mittal: Sure. So, from a power cost perspective, we do not see any impact. In fact, we are looking at rationalizing our power cost as we move to green energy, with more dependency on wind and solar, which are the new conventional energies where we definitely see a benefit coming in. As far as the raw materials are concerned, I think more than the raw materials, it is the solvents where we have seen the prices go up over the last 6-9 months and that's definitely impacted our margins. With the KSMs and raw materials, we have not really seen any drastic upward or downward movement, coming in from China or even other vendors in India.

Shreehas Tambe: I think you've covered it Sid on that part, I think the only nuance to the Biologics business would be specifics, where you would need single use materials or specific media components, where we've seen supply slowdown I would say, and that's been something where our supply chain team is really working hard at preserving. We do not see any major concerns to our ongoing operations and we've not seen anything that we are really overly concerned about at this point.

Prakash Agarwal: **And how do we read the increase in inventory, I mean is that, to protect the future increasing prices, or is it to protect the supply chain, or would we consider both?**

Shreehas Tambe: It would be a mix of both, and I will let Chini comment on it, but it is a mix of both, clearly there was a lot of anxiety in months which were leading up into the pandemic and there was a requirement to stock up on a lot of these things. We see that easing up overall supply chains, world over has started relaxing a bit. We also are looking at product launches, so we will see some of that building up, so you are fair to say its little bit of both, but Chini, if you'd like to add something.

M.B. Chinappa: You have covered, it is mostly the supply chain aspects Prakash and with the buildup for H2.

Prakash Agarwal: **Okay, you mean the launch or the market share inch up that we expecting across markets, it could be because of that as well?**

M.B. Chinappa: Yes, generally, we are expecting to see sequential growth quarter-on-quarter and set up nicely for FY23. So, part of inventory buildup is towards that.

Prakash Agarwal: Okay got it. Thank you and all the best.

Nikunj Mall: Thanks Prakash. Next one is from Surya Patra from Phillip Capital.

Surya Patra: Thank you for this opportunity. I was trying to understand, whether you have seen any kind of advantages in terms of gaining better or expansion for your other products, like inclusion in the various incremental formularies for the older product, given the benefit or advantage of interchangeability what we have seen in case of Glargine. Let me reframe the question, see we have seen interchangeability and approval for Glargine, so now, this would be a demanded product from us so whether this is giving any advantage to the other old product in terms so penetrating faster with new contracts or new customers?

Nikunj Mall: I think Surya you're asking if there are synergies between the commercialization of interchangeable Glargine and the other oncology products which we have. And does an improvement in Glargine also supports the improvement in Fulphila and Ogivri, is that your question?

Surya Patra: Yes.

Shreehas Tambe: If you look at our current relationships that Viatris has with some of this major formularies, Fulphila is listed with some of these PBMs. In some way we have those ongoing relationships. But, of course, you know this kind of a preferred listing with a formulary as large as Express Scripts will have positive knock on effects, not just on other products in our portfolio, but even potentially with other customers. These are things which we can't necessarily comment on, on how those will play out but basically some of these things will have synergistic or positive knock on effects overall. But to really say that this is what will happen, I think, would be very difficult.

Surya Patra: Okay, then similar question on let's say Fulphila what we had seen last quarter that US FDA highlighting that the artificial volume gain, what the innovator has witnessed over the years because of the Onpro kind of marketing. So, after that did you see any kind of advantage in terms of better penetration for Fulphila?

Shreehas Tambe: We certainly have always maintained that the device itself doesn't probably offer any meaningful benefits to patients, that's one thing that has always been of the view. Clinically doesn't offer any benefit, there's certainly some benefit on the convenience and it certainly did held on to a longer market share during the pandemic but you are seeing that come off now and you are seeing that erode so we certainly feel that the syringe market will overall benefit, which is where we are currently operating in. So, certainly we see some positive effect of that.

Nikunj Mall: Thank you, the next question is from Charulata Gaidhani from Dalal & Broacha.

Charulata Gaidhani: My question pertains to the difference with Adalimumab getting interchangeable status, how does it change the market dynamics and what kind of volume growth, you can anticipate in the market?

Shreehas Tambe: We wouldn't necessarily want to comment on competition here but you know the Adalimumab biosimilar interchangeable approval that Boehringer has been able to secure. Of course, they have been ahead of the pack in terms of what is publicly available in terms of dates. So we certainly feel that this is a positive development overall, in terms of how it will improve and widen access of the product. But if you really look at Humira, it is a large opportunity overall, and we believe that it will only get better in terms of how this will be explored by all the biosimilar players, including Viatrix who is a large player there. So we see this as a positive development in terms of acceptance of biosimilars in general.

Charulata Gaidhani: **Okay, and my second question pertains to the Serum deal by when do we expect completion and the funds moving into Biocon?**

Kiran Mazumdar-Shaw: There are no funds moving into Biocon but we expect to see this partnership realizing revenues for Biocon Biologics in the second half of next fiscal.

Charulata Gaidhani: Okay. Thank you.

Nikunj Mall: Thanks, Charulata. The next question is from Kunal Dhamesha.

Kunal Dhamesha: **Thank you for the opportunity, I have just one question what would be our gross block for the Malaysia biologics facility and what would be its capacity?**

M.B. Chinappa: We have not revealed the capacity but in terms of investments it's around \$350 million.

Kunal Dhamesha: Sure, thank you.

Nikunj Mall: Thanks, Kunal. The next one is from Harith Ahamed from Spark Capital.

Harith Ahamed: **Good morning, thanks for taking my question. On insulin Aspart, one of your comment that the form 483 in the pre-approval inspection doesn't impact your commercialization timelines, just trying to understand if there are any entry barriers, other than the compliance status of the facility? So I would have imagined if the inspection had gone well, we would have had an approval by now and launched sooner. So, are there any patents or something else that's blocking?**

Kiran Mazumdar-Shaw: I think you should be corrected in your perception of what you just said. Okay, first and foremost, as you know, the inspection was not possible because of COVID all this time and we were able to persuade them to come and do an inspection at the Malaysia facility which they did in September. Yes, if they had been able to come earlier for the inspection, we could have got an earlier approval but there is no linkage to the inspection and approval timeline. Approval post PAI inspection takes a specific period of time, and that is why I think even Shreehas confirmed to Sameer that we expect approval in the first quarter of next calendar year, which does not necessarily mean that we will immediately see an uptick in terms of commercial opportunities because it is all linked to contracting cycles. If we are able to enter into a contracting cycle in that period of time, obviously, it means that we can

immediately start with our commercial entry into the US market. If, for some reason we have to wait for a few quarters, so be it, but I think your perception that the inspection is delaying approval is not correct. The inspection had to take place, yes, it could have taken place earlier, but COVID did not allow travel and that was the only reason why the inspection was not done till September this year, and that, too, we persuaded them as a special request saying, please come inspect and they agreed.

Harith Ahamed: **All right, thanks for that. My second question is on Bicara Therapeutics. So, we've talked about the plans to raise funds at that entity. So, any updates there? And do we still maintain our guidance of no more funding from Biocon beyond the US\$ 40 million, that we've already done?**

Kiran Mazumdar-Shaw: They are in the process of raising funds, and we will provide some basic funding to keep their operations going but beyond that, we are not funding them at such a large level.

Harith Ahamed: **Thank you and last one from my side there's an exceptional item related to modification of the optionally convertible debentures of a PE investment in Biocon Biologics. So, can you give more color on this, what exactly this is about?**

M.B. Chinappa: Yes, there's been a modification in the terms, no change in the equity stake, but because there's a modification in the terms, an unamortized cost with respect to the investment has to be expensed off in line with the accounting standard. No change in equity stake that it will convert.

Harith Ahamed: Thank you.

Nikunj Mall: Thanks, Harith. Next, one is from Vipulkumar Shah from Sumangal Investments.

Vipulkumar Shah: **My question is to Kiran ma'am, this is regarding our deal with Serum for vaccines, so is it an admission on our part that we're seeing the growth saturation in biologics business and we don't see any meaningful growth prospects for biosimilar business, how should we read it, ma'am?**

Kiran Mazumdar-Shaw: No, I think let me explain the whole rationale behind the Serum Deal. As you know, the objective of Biocon business is to make global impact on global healthcare. And I think all this time we were only focused on non-communicable diseases which certainly has a huge unmet need. I think nobody had really looked at communicable diseases as an area where, there was a huge need globally to handle global healthcare, I think the pandemic brought the attention to the huge impact of viruses and other microbes in terms of disrupting global healthcare which we ourselves felt was very important, if we wanted to be a comprehensive player in terms of making impact on global healthcare. We felt that this was also a good adjacency for us because of the fact that vaccines can be a very good bolt on business to us. And that is the reason why we believe that this is a very good alliance which gives us an entry into this business. There is also a huge need for developing antibodies for infectious diseases as well and that's why we believe that this was a very good partnership

and alliance. But it doesn't take away from the fact that you need biologics for many, many unmet needs in non-communicable diseases. So, I hope you understand that it is not a way to take away from non-communicable diseases, but to make sure that we also have communicable diseases in our portfolio as something to address because both these areas do have unmet medical needs which are being served by biologics and also now with vaccines. So, for a long time, I think the vaccine space was stagnating because there was no need for addressing any of these kind of viral diseases. But today the spotlight on viral diseases and its disruptive impact is being felt and we felt that we also needed to be there.

Vipulkumar Shah: **So ma'am, are we open to venture into manufacturing of vaccines at a future date also?**

Kiran Mazumdar-Shaw: Well, I think we've already mentioned that in our alliance that Serum Institute and Biocon Biologics will enter into research programs for next generation vaccines.

Vipulkumar Shah: Thank you and all the best.

Nikunj Mall: Next question is from Tarang Agrawal from Old Bridge Capital.

Tarang Agrawal: **Hi good morning and congratulations on getting the interchangeability status and approval to Express Scripts. Actually, I have three questions but I'll just probably start with one. You know what proportion of the overall glargine volumes in North America would be currently driven through the Express Scripts signal network?**

Shreehas Tambe: Roughly we are in the region of about a fifth or a fourth, somewhere there.

Tarang Agrawal: **Okay, can I just phase in one more please.**

Nikunj Mall: Sorry Tarang, we want to give the opportunity to everyone, and we can take this question offline if that's fine.

Tarang Agrawal: Sure.

Nikunj Mall: Thank you. The last one is from Sonal Gupta.

Sonal Gupta: **Good morning, and thanks for taking in my question. I just want to understand like Humira we have seen Boehringer has done interchangeable switching studies. So, I just want to understand what would be the cost, if you were to pursue something similar, for your mAbs, where you have interchangeability? What would be the cost of doing a switching study?**

Shreehas Tambe: Each one of these studies will be different, depending on the product you're trying to do it for. It would vary depending on which reference product, you are generating the study for, the period for which that you are conducting the study, the number of switches that you would need to conduct before you can claim the absolute switchability. So, it would change

from product to product for all these chronic therapies. But more importantly, you will have to see, given the current guideline status that it's only with the first one to make it past the line, who can really benefit from it, given the one year exclusivity period that they will enjoy. And this particular study was known for a while. This was obvious that if they were to make the cut then really everybody else conducting a similar study would probably not benefit from that anyway because there could be an exclusive status that the first one pass the line would enjoy. So, in that context we would need to do these studies.

Sonal Gupta: Okay, thanks a lot.

Nikunj Mall: Thank you everyone, I think there were a few more questions, but request you to reach out to Aishwarya Sitharam or I and we can help you with the responses given we are over time with that we'd like to conclude the call and we look forward to seeing you again next quarter. Have a good day. Thank you.