Biocon Limited Q1 FY22 Earnings

Conference Call Transcript

July 23, 2021

Speakers and Participants from Biocon Limited and Biocon Biologics

- **Dr. Kiran Mazumdar-Shaw** – *Executive Chairperson, Biocon Limited*
- **Mr. Siddharth Mittal** – *CEO & Managing Director, Biocon Limited*
- **Dr Arun Chandavarkar** – *Managing Director, Biocon Biologics*
- **Mr. Indranil Sen** – *Chief Financial Officer, Biocon Limited*
- **Mr. M.B. Chinappa** – *Chief Financial Officer, Biocon Biologics*
- **Mr. Shreehas P Tambe** – *Chief Operating Officer, Biocon Biologics*
- **Mr. Susheel Umesh** – *Chief Commercial Officer, Biocon Biologics*
- **Mr. Paul Thomas** – *Chief Commercial Officer-US, Biocon Biologics*
- **Mr. Chirag Dalal** – *Head-Investor Relations, Biocon Limited*
- **Mr. Nikunj Mall** – *Head-Investor Relations, Biocon Biologics*

External Participants during Q&A session

- **Prakash Agarwal** – *Axis Capital*
- **Damayanti Kerai** – *HSBC*
- **Neha Manpuria** – *JP Morgan*
- **Surya Patra** – *Phillip Capital*
- **Shyam Srinivasan** – *Goldman Sachs*
- **Harith Ahamed** – *Spark Capital*
- **Nithya Balasubramanian** – *Sanford Bernstein*
- **Sameer Baisiwala** – *Morgan Stanley*
- **Charulata Gaidhani** – *Dalal & Broacha*
- **Sheersh Jain** – *Apex Capital*
- **Masira Vasanwala** – *FSSA*
- **Mitesh Shah** – *ICICI Securities*
- **Tarang Agarwal** – *Old Bridge Capital*
- **Vipul Shah** – *Sumangal Investment*

Prepared Remarks Session

Chirag Dalal:

Good morning ladies and gentlemen, welcome to Biocon Limited Q1FY22 earnings conference call. I am Chirag from the Biocon investor relations team, and I welcome you to the Biocon earnings call for Q1FY22. All the attendees to this call shall be in listen only mode, and there will be an opportunity to ask questions after the opening remark concludes. Should you need to raise questions, please select the raise hand option under the reaction tab of your zoom application. We will call out your name, and then request you to unmute yourself and ask the question. While asking, our request would be to please begin with your name and that of your organization. Kindly note, 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 call is being recorded. To discuss the company's business performance and outlook, we have with us today the Biocon leadership team comprising **Dr. Kiran Mazumdar-Shaw**, our **Executive Chairperson** and other senior management colleagues.

I want 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 risk 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 the call, if you need any further information or clarifications, please get in touch with me or Nikunj.

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

Kiran Mazumdar-Shaw:

Thank you, Chirag. Let me welcome everyone to this earnings call, which is being held on this new format. I would like to start this earnings call by saying that the impact of the second wave of the pandemic has turned out to be far more devastating than we thought. The pharmaceutical industry faced mounting onsite infections coupled with lockdowns, which has posed significant challenges to our operations across our facilities in Bangalore and Hyderabad, particularly at our API plants. As you know, we are a fermentation-based industry, and many of these supply chain challenges included things like oxygen shortage, etc.

We have been impacted this quarter, but we have taken several measures to mitigate the impact of the spread of Covid-19 within our organization. A massive vaccination drive was also undertaken for our employees, their families, and our neighboring communities, wherein more than 20,000 doses of vaccines were administered. We simultaneously ramped up the manufacturing of Itolizumab, which has been at the forefront of our fight against COVID-19, and I would like to share with you that more than 27,000 patients have benefited from Itolizumab thus far. We have received several testimonials of appreciation from patients, family members and healthcare professionals for the number of lives that Itolizumab saved throughout this pandemic.

With the vaccination drive picking up pace and newer vaccines on course to get government approval in India, we are hopeful that the situation will turn better sooner than later. While there are signs of recovery, we cannot drop our guard. We must stay vigilant, ensure that we get vaccinated and stay safe.

I would also like to also with you an important management update. John Shaw, Vice-Chairman and Non-Executive Director of Biocon, will retire from the Board of Directors due to health reasons on 23rd July, that is today, at the conclusion of the annual general meeting. As a key member of the Company's Board and the management team since 1999, John Shaw has contributed majorly to the transformation of Biocon from a small enzymes company to a globally recognized biopharmaceutical company. Over the past 22 years, John Shaw has played an important role in building Biocon and ensuring the highest levels of corporate governance in the Company, as well as contributing to the financial and strategic development of the Group. On behalf of Biocon's Board of Directors and management, we express our

deep appreciation and gratitude to John Shaw for his stewardship and guidance.

I would also like to share with you another organizational update. I'm pleased to welcome Dr. S Vijaya Kumar as Head of Operations at Biocon Ltd to lead the Manufacturing, Projects and EHS functions for the Generics business. He will be part of the executive leadership team. Vijaya Kumar is an industry veteran with more than 30 years of extensive experience across manufacturing and engineering in global diversified setups.

Let me now turn to some business highlights,

- We launched Labetalol tablets and Esomeprazole capsules in the US, further expanding our generic formulations portfolio.
- With Biocon Biologics, we expanded our Biosimilars global footprint with product launches in seven countries in Q1.
- We also received Marketing Authorization Approval for Biosimilar Bevacizumab from TGA, Australia, and MHRA, UK.
- The US FDA has scheduled a pre-approval inspection of our Malaysia facility in Q3 of calendar year 2021 in support of the BLA for Biosimilar Aspart.
- Syngene has signed a five-year agreement with IRV, a US-based non-profit scientific research organization, for manufacturing three anti-HIV monoclonal antibodies for use in Phase 1 and 2 clinical trials.

I will now turn to financial highlights for the quarter.

- Let me start by saying that we delivered a revenue of Rs. 1,808 crores in Q1 this fiscal, versus Rs. 1,712 crore last fiscal, a modest year on year growth of 6%. Our revenue growth was mainly driven by Research Services, which was up 41%, and Biosimilars, which was up 10%.
- We reported a subdued performance in Generics, which saw a degrowth of 22%.
- We largely sustained all our operational, financial aspects of our business
- We recorded a Gross R&D spend of Rs. 136 crores for this quarter, versus Rs. 142 crore last fiscal. This corresponds to 12% of revenue ex-Syngene. Of this, Rs. 120 crores are reported in the P&L, while the balance has been capitalized.
- We also recorded a Forex gain of Rs. 17 crores versus a loss of Rs. 4 crores during the same quarter last fiscal.
- Core margins, that is EBITDA margins net of licensing, forex and R&D, stood at 30% in this quarter. This is on account of subdued performance by Generics that offset the gains of an improved performance in Biosimilars and a strong growth in Research Services.
- EBITDA for the quarter was Rs. 437 crore, largely flat year-on-year, and the EBITDA margin stood at 24% against 25% reported in the same quarter last year.
- PBT for the quarter was at Rs. 166 crore, Rs 166 Crore, down 9% versus 15% (₹249 Crore) in Q1 FY 21, which is largely on account of higher depreciation and amortization and share of loss from a Boston-based associate startup, Bicara. However, if you exclude the share of loss from Bicara, PBT stood at Rs. 224 crores. Novel Biologics is a capital-intensive business and while it impacts our P&L, it is an integral part of our business and future growth. We will explore external venture funding to support clinical development for long-term value creation. This is a high-risk high-reward business, and we believe that these novel programs are important to pursue.

- Our net profit for the quarter stood at Rs. 84 crores versus Rs. 149 crore last fiscal, but if you exclude the share of loss from Bicara, our net profit was Rs. 142 crores for this quarter. This largely points to a sustained financial performance; despite all the challenges we have faced because of the pandemic.

I will now take you through the performance of our business segments during the quarter.

Generics

Generics business revenues witnessed a degrowth this quarter, as I mentioned earlier, largely due to COVID-related headwinds that resulted in operational and supply chain challenges that impacted our API manufacturing. With the number of COVID-19 cases starting to decline, we expect these to normalize in the coming quarter. Additionally, the comparable period in the previous fiscal benefited from customers stockpiling APIs, on account of COVID-related uncertainties. The segment delivered quarterly revenues of Rs. 486 crores. The quarter's PBT stood at Rs. 29 crores, versus Rs. 96 crores in the same period last year. PBT margins also were at 6%, compared to 15% in Q1 last fiscal. Tacrolimus capsules were launched in the US in Q3 FY20 and is witnessing a gradual ramp up in demand. Our statin formulations portfolio in the US, comprising Rosuvastatin, Simvastatin, Atorvastatin, held on to its market share despite continued pricing pressure.

During the quarter, we launched Labetalol tablets and Esomeprazole capsules in the US, in line with our aim to expand our formulations portfolio and establish a strong global presence. Labetalol is used to treat high blood pressure and helps to prevent cardiovascular complications such as heart attack and stroke. Esomeprazole, a proton pump inhibitor, is indicated for treatment of gastroesophageal reflux diseases. IQVIA pegs the market value for Labetalol Hydrochloride and Esomeprazole Magnesium in the US at $63 million and $230 million respectively.

Travel restrictions in the wake of the pandemic continued to delay inspection of our facilities. Consequently, new launches, as well as expansion into some key markets, were affected. However, we are in discussion with the US FDA to see if we can apply the mutual recognition agreement announced in May 2021 between the US FDA, EMA and MHRA. We have responded to the complete response letter issued by the US FDA on Copaxone.

We remain on track to commission our greenfield API facility in Visakhapatnam in FY22. This will significantly expand our immunosuppressant manufacturing capacities, which will come on stream in FY23 post qualification and validation.

We are confident that our strong foundation in fermentation technology, coupled with several initiatives undertaken during the past year, including digitalization, cost improvement and measures to boost operational efficiencies, will help us to significantly improve our business performance in the coming quarters.

Novel Biologics

Equillium, our US partner, had an end of phase one meeting with the US FDA, which confirmed a path to advance Itolizumab into a single phase 3 pivotal study for acute GVHD to support their biologics license application or BLA. The study is expected to commence later this year.

Biocon, which owns the European rights for Itolizumab, would like to report an important milestone this quarter, wherein the committee for Orphan Medicinal Products approved an orphan designation to Itolizumab for the treatment of both acute and chronic GVHD.

Meanwhile, Itolizumab continues to be at the forefront of our fight against COVID-19 in India. We have ramped up our production capacity to meet the growing demand for the product. A second brand of Itolizumab has been licensed to Sun Pharma for distribution.

We have also completed patient dosing in the phase 4 study of Itolizumab, to treat Cytokine Release Syndrome in moderate to severe ARDS patients due to COVID-19. The study report is expected to be converted into a publication

in the near future.

Biosimilars

Biocon Biologics has recorded revenues of Rs. 758 crores in Q1 FY22, a year-on-year growth of 10%, and a sequential growth of 14%. Core EBITDA stood at Rs. 271 crores in Q1 FY 22, versus Rs. 249 crore last fiscal, a year-on-year growth of 9% and 26% growth sequentially from Rs. 216 crores in Q4 FY21. Core EBITDA margins were at 36%, in line with last fiscal and profit before tax stood at Rs. 101 crores.

We have seen a significant contribution from our COVID portfolio in India, predominantly Itolizumab and Remdesivir, in the strong growth delivered by our Branded Formulations India business. Thus far, more than 50,000 patients have benefited from these products. Our non-COVID products have also performed well.

Our biosimilars continue to maintain and garner market share in the US. Fulphila, our biosimilar Pegfilgrastim, maintained a steady market share of around 8.5%. Ogivri, our biosimilar Trastuzumab, increased to over 9% volume share in June 2021 and our biosimilar insulin Glargine is estimated to be at around 2.6%, about 20 basis points higher, month-on-month. We anticipate continued pricing pressure in the US and are taking steps to mitigate this through increased volumes and market share. In addition, we expect our growth to be fueled by regulatory approvals for our biosimilar Bevacizumab and biosimilar Aspart in the near-term, once onsite inspections happen.

In Europe, our sales continue to improve on the back of new market entries and better market share in key countries. The EU launch of biosimilar Bevacizumab by Viatris is expected in Germany, Austria and Poland in Q2 FY22.

Moving on to regulatory topics, the US FDA has scheduled a pre-approval inspection of our insulin manufacturing facility in Malaysia, in Q3 CY21, in support of our Biosimilar Aspart BLA. We believe the BLA is adequate in all scientific aspects and it is only the pre-approval inspection of the Malaysia facility that is pending. However, with respect to our biosimilar Bevacizumab BLA, we are yet to have visibility on the timing of the site inspection in India by the US FDA. We have received approval for biosimilar Bevacizumab from TGA, Australia and MHRA, UK. We expect the US FDA's decision on interchangeability of our biosimilar Glargine by the end of this month. If approved, it will be the first interchangeable insulin approved in the US. We continue to make good progress on our robust R&D pipeline.

To summarize on our Biologics business, we remain confident of the long-term opportunity for biosimilars through improved market penetration, geographical expansion, and further growth from upcoming approvals.

Research Services (Syngene)

During the quarter, Syngene reported revenues of Rs. 595 crores, up 41% from Rs 422 crore during the comparable period last fiscal. PBT for the quarter was Rs. 95 crores, with PBT margins at 16%, in line with Q1 FY21. Syngene's performance was driven by growth across all divisions – discovery, development and manufacturing services, and dedicated centers. Remdesivir was also a significant contributor to the revenues this quarter. The company's Mangalore API facility has also successfully completed ISO 9001 2015 certification audit.

As mentioned earlier, Syngene has signed a five-year agreement with IRV for manufacturing three anti-HIV monoclonal antibodies for use in phase 1 and 2 clinical trials. Syngene will provide an integrated solution encompassing clone selection, analytical methods development, manufacturing process development and cGMP manufacturing of drug substance, viral clearance studies, cGMP manufacturing of drug product, and stability studies. So, you can see that Syngene now has end-to-end capabilities, from clone to market in every possible way.

To conclude, I would like to say that this has been a challenging quarter for all of us. However, we are confident that we can overcome these challenges with all the encouraging developments and opportunities that lie ahead. Business sentiment is favorable for biosimilars, generics and research services. Globally, we see a strong demand for biosimilars and generic drugs, given the growing emphasis on affordable drug pricing.

These are challenging times, and I would like to end by saying let's be responsible. We all need to stay away from crowds. Let's double mask ourselves, maintain proper COVID appropriate behavior, and most of all, I hope every one of you have vaccinated yourselves, like we have at the Biocon Group. Thank you.

I would now like to open the floor to question and answers.

Q&A Session

Prakash Agarwal: **Thanks, and good morning to all. My first question is, I am trying to understand the July end timeline better. So, as per our understanding, what are the things pending if at all, and what is our expectation of getting interchangeability and how does it impact our assumptions for the market share ramp-up, which we have in the past talked about from CY22 only, we will see some, since the buying has already happened as per the last commentary. So, if you could give more color there that would be very helpful.**

Shreehas P Tambe: Thanks Prakash. As Kiran said, we are looking for the interchangeability status, our Goal Date is towards the end of this month and we have reason to remain optimistic that our insulin Glargine would be the first interchangeable biosimilar insulin analog that the FDA would approve. Now, having said that, we have talked about this in the past as well that after the interchangeability status, Viatris would still have to go through the full contracting cycle and secure the contracts - that piece will we have to be completed in terms of securing the contracting piece. But it certainly does provide us the opportunity to then validate the decisions that payers have made in supporting the cost of biosimilars, and building it into the formularies, and more importantly also provide assurance to the patients, prescribers, and more importantly when it can be made available at pharmacy counters in a substitutable manner. Clearly, there is a support to the overall strategy that Viatris outlined, where it stated on its investor day that, it is an opportunity to re-launch Semglee as an interchangeable insulin Glargine, the first of its kind. So, we will certainly be looking at that update in the coming calendar year.

Prakash Agarwal: **So, the contracting cycle that you spoke about, what is the contracting cycle currently, is it ongoing and would it help if we get the interchangeability say on the goal date or it would actually help in the next contracting cycle?**

Shreehas P Tambe: So, the Viatris commercial team is right now in discussions with various payer channels at this point as we talk, and the interchangeability status towards the end of this month is in a way timely because it will aid in these decisions as we make them over the course of the next month or two.

Prakash Agarwal: **Okay, got it and secondly, on the inspections that you have talked about in Malaysia plant for Aspart. So, what I understand is that everything is done, but it would require a physical inspection, or would it be an online inspection? And I don't know what the status is in Malaysia, but has the FDA started visiting other countries and Malaysia? If you could throw some light there and in Bevacizumab is there a chance**

of an online inspection? That's all from my side.

Shreehas P Tambe: Yeah, thanks Prakash. I think there are 2-3 questions in that, so let me respond. I think on the Aspart inspection, for our facility in Malaysia, as Kiran said the agency, FDA, has confirmed that they will visit us at the end of this quarter for a physical inspection on location. So that's something we are working with the agency closely for and that's something the agency has consented to. So, we will be looking to host the agency towards the end of this quarter and the Aspart inspection should be the only step to move us forward into the approval process.

On Bevacizumab, our approval date as you know was the end of last calendar year and we have been working with the agency to enable the inspection. The FDA published a resiliency roadmap where they are looking at international inspections in an expedited manner. We have been engaged with them. We haven't received a firm date on when they can visit us in Bangalore, but at this stage the understanding we have is that there are no technical outstanding questions for the Bevacizumab application. We have submitted a complete package and we look forward to the pre-approval inspection, which is a mandatory requirement for biosimilar approval in the US. So that's the update Prakash on Bevacizumab and Aspart inspections.

Damayanti Kerai: **Good morning. My first question is, can you explain what kind of P&L impact we should continue to see from Bicara; maybe some more clarity like what is spent from our side? What kind of impact can we see on the P&L, say in next few quarters?**

Siddharth Mittal: So Damayanti, I think last quarter we had said that Bicara, which was earlier a subsidiary, would move to being an associate because Bicara is looking at raising funds directly in the US to fund its clinical programs, and the pipeline is under preclinical stage. The investment value that we have for Bicara at the end of June, is roughly $15 million and we expect that till this $15 million of expenses are there in Bicara, it will continue to go through the P&L. However, this would be through the share of loss of associate, which we expect for the next 1-2 quarters.

Damayanti Kerai: **Okay, thank you for that. And my second question is can you provide a current split of biosimilar sales between regulated market and rest of the world market. Also, can you talk a little bit more on what will be the key expectations for the rest of the world market biosimilar sales - what would be key drivers or key markets which you are looking at that part of the business?**

Susheel Umesh: Thank you Damayanti for your question. In the rest of the world, we are looking at the biosimilar space very positively. We have a plan to quickly launch new products, and also increase our products' reach in many more countries versus where we are today. We will do this with our partners and distributors, and we plan to have a very robust growth in excess of 25% over the years.

Damayanti Kerai: **Okay, that's helpful. What is the current split between this regulated and the rest of the world market sales for biosimilars?**

M.B. Chinappa: Damayanti, hi. For the quarter, emerging market is actually above 60%, but if you look on a full year basis, you would see developed markets at40-45% and emerging markets at around 55%.

Damayanti Kerai: **Okay, just to clarify 55% on rest of the world market and 45% for the regulated market.**

M.B. Chinappa: **Yes, that is on a** full year basis. However, for the current quarter, emerging markets is above 50%.

Neha Manpuria: **Thank you for taking my question. Firstly, on the biosimilar business, in ma'am's opening comments she mentioned, there's a COVID portfolio contribution in the quarter. If there is a way to quantify that, just to understand how the base business will look going forward? So just to understand what is the COVID contribution in this quarter please?**

Kiran Mazumdar-Shaw: Well, this was specifically linked to the second wave. Actually, it is just sort of a blip in our BFI sales. We don't expect it to continue at these levels. It has contributed significantly to our Branded Formulation India business, but we don't expect it to continue and contribute at these levels going forward. So that's as far as what I can tell. Branded formulations India have certainly jumped over 50% because of this contribution, but I don't think we can rely on this particular business beyond a few quarters.

Neha Manpuria: **Understood and ma'am in the biosimilars business, if I were to look at quarter on quarter, we have a FX gain, R&D does not seem to have moved too much from what I can see for the biosimilars business, but the costs seem to have been in place. So, is it a reflection of our gross margins being different or lower because of this COVID portfolio contribution and just because ROW sales are higher, so what's driving the margin improvement should have been higher given the FX gain and flattish R&D spend?**

Kiran Mazumdar-Shaw: So, two things, one is you must understand that always quarter one obviously reflects the increments that we give our employees and that's the big impact on costs in the first quarter which gets normalized over the year. Secondly, I think you must also understand that even though we have a contribution from the COVID products, the margins are at a lower level as compared to our other biosimilars business. And thirdly, I don't think you should read into the fact that ROW margins are low. I think ROW is a very good business - many markets with rich margins which averages over the entire business. Overall, the margin impact has been because of the quarterly impact of salary increments, as well as some of the low margin sales that we had in the quarter because of COVID portfolio.

M.B. Chinappa: Just to clarify, there's no FX gains in biosimilars with the core EBITDA margin at 36%, which is a 26% sequential growth. In growth terms, its 26% sequential growth, and in margin terms it is a 36% margin, consistent with last year.

Neha Manpuria: **Yeah, but I was looking at the absolute sales increase, year on year which is pretty significant. To that extent the margin is flat despite R&D pretty much around 60 Crores. That's why I was asking, but ma'am's answer sort of provides colour on that.**

M.B. Chinappa: Revenue growth was 10%, EBITDA growth 10%, core EBITDA growth just about 9%. So, they are all consistent.

Neha Manpuria: **Understood. Siddharth, just on the generics business, given that if the supply chain and operational challenges were not there, what was the impact? I am just trying to understand the normalized performance of the generics business.**

Siddharth Mittal: So, the impact on supplies, because of the second wave was roughly Rs. 75 crores. Else, we would have been very close to our fourth quarter number. I have alluded that we have also seen continued pricing pressure in the US for our generics formulations business and also for our API customers. Unfortunately, we do not have any new approval, because the drugs which are under review with FDA until the inspections are complete, and as such we are not expecting any new launches. The two products which we launched were more in-licensing products. So, these products were approved by our partners, which we in-licensed and launched recently. So, we do expect some growth to come in, but the main point is when we get additional approvals, the continued pricing pressure will continue to impact our generic formulation sales. But the API business, which was impacted in quarter one, as we said that we have seen normalcy now as number of cases in Bangalore have gone down, all our employees are vaccinated, and operations are running on normal course.

Surya Patra: **Good morning everybody and thanks for this opportunity. So, my first question would be on Pegfilgrastim. A couple of days back we have seen a notification from US FDA to Amgen about the claims they used to make about their product Onpro, and FDA has indicated that all the claims of a superior clinical benefit over the prefilled syringe is baseless. So, I think with those claims Onpro was having initially about 60% market share of the total Pegfilgrastim opportunity and now is still having over 50%. So, with this notification, how should we look at it as a potential opportunity for Biocon?**

Shreehas P Tambe: Thanks for the question. I think if you look at our previous commentary on the topic, we have always said that the Onpro device does offer an element of convenience, but we have focused on making meaningful clinical difference through the prefilled syringes, that's been our focus and this, in a way, validates some of the positions we have taken in the past. Over the last one year we saw the effects of the pandemic resulting in the Onpro device holding on to a market share of around 58%. Now we are starting to see that come off, and we have seen that to be about 52% this year, this quarter we just closed in June. So, in a way it does create an opportunity for Fulphila, and we do see that in terms of our market

shares in the last quarter have started to slowly ramp up with 50 basis point increase in the monthly market share. We look at this as an opportunity to really make a difference in the marketplace.

Surya Patra: **Okay. So, I want to extend this question a bit more. The 340B program what you have tied up for Pegfilgrastim and the kind of significant ramp-up in the capacity for Pegfilgrastim what you have already achieved prior to the COVID, and possibly the benefit of all these would not have flown into you. So, given that, with the recovery in the business that end with a favorable notification from FDA, all that considering, should one consider this as a kind of meaningful opportunity in the near-term, or what timeframe you can see that there will be some meaningful progress in terms of penetration, as well as contribution to the earnings?**

Shreehas P Tambe: Just to elaborate on that. I think these are certainly developments which bode well for an increase in market share going forward. But if you really look at it, the factors that will influence these things would be competitor contracting strategies, the regulatory or reimbursement strategies that exist in the marketplace. We certainly see this as a positive development and an opportunity for us. We have the capacity, the product, the approvals and with increased customer focus and commercial attention to this, which Viatris has actually said in their previous calls as well, with a stronger value proposition that we can bring to stakeholders, we really see this as an opportunity in the coming fiscal to really realize a lot of this market share.

Surya Patra: **Thank you, and about the interchangeability approval. So, aren't we expecting the interchangeability approval for both insulins, Aspart as well as Glargine?**

Shreehas P Tambe: Yes, as you know we talked about insulin Glargine a while ago, where we are expecting it towards the end of July, we will expect a decision on our application for interchangeability. The insulin Aspart has been filed as an interchangeable insulin analog under the 351(k) pathway. When approved, we will be looking at that approved as well as an interchangeable insulin analog.

Surya Patra: **Okay, just last one question from my side on Bicara. If you can just help me understand what the earlier entry for Bicara could be, because we know that the first or the lead molecule is at the very earliest days in phase 1 or phase 2. And there is an up-fronting of the spend also which we know. So, if you can just give some sense on that side.**

Kiran Mazumdar-Shaw: Bicara has both the first program in clinic at an early stage of phase 1 development, and it also has a portfolio of molecules, which are preclinical. So, I think from that point of view, it is a growing startup and as Siddharth mentioned, we have basically funded it, and they are on the active stage of looking for external venture funding. I think that is where we need to support them, because the program is very exciting, and some of the early signals are also very encouraging. So, I think we would like to support them until they raise external finance.

Siddharth Mittal: Let me just add, we expect some critical readouts on the first program which is in clinic by the end of this calendar year.

Surya Patra: **Okay. The losses from this share of losses whether that is restricted to let's say current year and every quarter of next year or is it a kind of a continued thing till the time that we see some progression in terms of earnings.**

Siddharth Mittal: Surya, we have roughly $15 million left in the balance sheet out of the $40 million which we had funded, and that $15 million till it gets utilized, will flow through the P&L, unless we fund anything incremental over the next few quarters, till Bicara gets this readout and does the external funding. So, it is expected to be temporary. Definitely, we do not expect it to go beyond this fiscal.

Shyam Srinivasan: **Hi, good morning and thank you for taking my question. Just the first one on the COVID impact going back to the earlier participant as well. Remember branded formulations in there were some Rs. 100 crores, like the way we used to report earlier, maybe I am wrong, and if that has grown 50%, so Rs. 758 crores minus Rs 150 crores is Rs. 600 crores, I am making these numbers up but looks like, then the base biologics or the biosimilar business has declined Q-o-Q, would that be a fair way to think of things?**

M.B. Chinappa: Base biosimilars business is kind of flat versus the last year if we strike out the COVID portfolio, but keep in mind that last year, there was a spillover from Q4 into Q1, which boosted the Q1 FY21 numbers. So, if we strike that out, then you will still see a growth in the biosimilars business, excluding the COVID portfolio.

Shyam Srinivasan: **So, from a market share perspective, Q-o-Q things have improved so I am just trying to understand where the struggle is for the business and you talked about, I think, EM being higher contribution and DM being lower versus how you envisage it to be for the full year. So, what are some of the translations? I remember in fiscal 21 call we had actually said that the profit shares from Viatris is not flown through. So, you know what can ease now, which will kind of help us accelerate this Biosimilar business?**

M.B. Chinappa: We are double counting there when - it's COVID portfolio that caught the emerging markets share about 60% just to clarify, and then the second point, as we start to increase the market share in Glargine you will see profit share from Glargine play out, and you are aware that we have two more approvals lined up for this year, plus a potential increase in market shares on our existing portfolio, that is Pegfilgrastim and Trastuzumab should also play out in improved profit share in the coming quarters.

Shyam Srinivasan: **Second question is on the generics business. Siddharth I think we have seen a kind of subdued performance, you talked about the Rs. 75 crore and this now spans across multiple lines. So, the Rs. 100 crore I remember for Q4 FY20, we couldn't ship things in the Biosimilar line, now its Rs. 75 crores on the generics line. So, from an**

operational and an ability to supply perspective, is the group looking at, you know, what are some of these issues, could these have been avoided, can we do something in the path forward, where these issues don't recur because just looking at peers, we have not seen this kind of like Q-o-Q large volatility in numbers, most of other pharma companies have had it trended upwards. So, I am just curious from our own group perspective, where are the potential misses, and how can we correct it in the path forward.

Siddharth Mittal: Very good question. We do have a BCP and disaster recovery plans, but if you look at the second wave in Bangalore, we all know there were significantly higher number of cases compared to the first wave. Out of 3,500 employees in generics, in the second wave we had almost 500 employees who were positive within a span of two months, and that impacted a lot of the work schedule, the quality releases got impacted. Now, that has been addressed by vaccinating all our employees - 100% of our employees in Hyderabad, Vizag, Bangalore are vaccinated - that's number one. Number two, Kiran had alluded in her opening comments, that if you look at the Biocon API business, it is primarily a fermentation-based business, and for fermentation (these are large scale fermenters), one of the most important ingredients is oxygen. And when there was overall a high number of cases in the country, the allocation of oxygen was being done by the Central Government, where a lot of the oxygen even for industrial use was diverted for medical use, and we were out of oxygen, and hence not able to charge any new batches. Unfortunately, we treat this more as a force majeure, where there is no mitigation plan, we were working with various state and central governments to see how soon we can get the required quantities that we needed, which did happen as I mentioned after 15 years. There were also certain other disruptions, but we do have overall a good plan in place, but an extreme situation like this wave two, I'm not sure if at a very short notice, we were able to address all the issues that came up. In fact, in Q1 last year, we didn't have any of these issues in the generics business, we had a very strong Q1 last year including H1 because, number of cases in the company were still low, we were continuing to manufacture, we had supply chain issues which we addressed very efficiently. So, hope that these issues, at least on the employee front doesn't happen if there is a wave three in the future.

Shyam Srinivasan: **Last question to the team is on R&D spend. So how should we look at it for fiscal 22 and 23, is it the current run rate now or you see a step up happen in terms of R&D.**

Siddharth Mittal: Maybe I will just give a view at a group level - we continue to maintain our earlier guidance of between 12-14% of gross R&D, ex-Syngene revenues.

Harith Ahamed: **Good morning. So, on the generics business - my apologies if this question was addressed previously. On the generics business, after the disruptions we saw in the first quarter, how is the business shaping up now, and how should we think of the second quarter and the upcoming quarters?**

Siddharth Mittal: Harith, I will split this answer into three parts - the operational impact that we had in quarter one is normalizing, so we do expect again our API production to ramp up to what it was in

the previous quarters. We do not have any new plant or new capacities which get qualified this quarter, so there is no growth in our API business. The generic formulations business in the US is undergoing pressure. While we are launching new products, we are ramping up our Tacrolimus drug which we had launched last year, we won some new contracts and we started supplies against those contracts; at the same time, we have lost certain business on statins, and on an overall basis in Q2 I do not expect significant growth because the biggest growth is going to come from the 2-3 products which we have filed and are under review with the FDA. We have a target action date which was in Q1 of CY2021, which FDA moved to calendar Q3, and Q4 of CY21. Now, assuming FDA accepts our request for conducting a virtual audit or consider the UK, MHRA, audit which was successfully conducted in Q1FY22- even if we receive the approval, we expect the launch to happen in the third quarter this year. So, I expect overall business to remain flattish compared to let's say, Q4 of last year. But definitely, we should be much better compared to this quarter's performance in the next quarter.

Harith Ahamed: **And on Bicara how far are we, in terms of our fundraising plans for that entity and who owns the 13% minority stake there.**

Siddharth Mittal: Our funding is actually dependent on the readout. I mentioned that the readouts from the Phase-I clinical trial are expected by end of this calendar year, basis which the funding timing would be decided. The remaining 13% of the company is with the employees in the ESOP pool.

Nithya Balasubramanian: **I just had the one question on the biosimilars in the US. So, we know that CMS offers a pass-through status for the reimbursement rate that's given to 340B hospitals and that's valid only for three years. So, if you look at your Fulphila, you are possibly reaching that deadline in June, and that's likely to happen for some of your other Biosimilars in a later point of time. So, given that the delta between reimbursements is ASP plus 6% to ASP minus 22%, do you expect this to impact your margin profile meaningfully.**

Shreehas P Tambe: Yes, we are seeing that CMS pricing would come up shortly. We have developed strategies to counter that pricing change which will come up shortly. We believe the recent discussion that we just had on the call also in terms of Onpro provide us the opportunity to expand the market. There is going to be increased competition in that space with more players than we started off with when these rebates were fixed. We will certainly have to have the right mix of whether it's just the pricing part or whether it's the reimbursement strategies that we talk about, or the overall mix that we will be coming up with. But certainly, Viatris is aware of this and we are looking at providing a stronger value proposition, overall, to the various stakeholders.

Nithya Balasubramanian **If I may just follow up. Can you throw some color on whether, if you look at your revenue split between hospitals, clinics and 340B, is it possible to provide some color on what's your exposure to 340B?**

M.B. Chinappa: I don't have the exact split, but we have a lower share of the 340B segments which is slightly lower than compared to some of our competitors, but we can't give you specific numbers.

Sameer Baisiwala: **Good morning everyone. The first question is on the pricing pressure that you are seeing in the US for biosimilars Trastuzumab and Pegfilgrastim. Can you please help us what's driving this, you have been talking about this for last six months at least?**

Shreehas P Tambe: So, pricing pressure in terms of the US - you could see that the biggest question around US was whether the US market will be accepting our biosimilars. I think that was the biggest question that we were faced with as we began the fiscal and maybe towards the end of the last fiscal. I think that's been reasonably answered as we've seen good adoption of biosimilars and as competition increases, the natural fallout is that there is going to be some pressure on pricing. We have not seen pricing go down the generics route. So, this is in line with our expectation, when you see different major players enter the space, we expect this to kind of stabilize and we've also seen, you know, more gradual decrease in prices overall, and the ASPs have been more in line with what you would expect in a market where you have 4-5 major players across the portfolio. So, we are not really seeing anything out of line that we had set out in the beginning.

Sameer Baisiwala: **Sure, that's fine, but I am just trying to understand what's the dynamics behind it in the sense that if there is a no new entrant over last whatever six-month period than what forces the price correction? Is one of the incumbents, getting more aggressive or is the payer demanding, what's the catalyst behind the price cuts?**

Shreehas P Tambe: So, pricing is certainly one factor which plays a role in deciding this, but as I was saying before, beyond pricing, there are other factors that play a role as well in terms of how entrenched players are focused on therapy areas, in terms of what the competitor contracting strategies have been, in terms of what the overall deal dynamics are. So, in addition to just the pricing even the reimbursement strategies that have been put together play a role in terms of how market shares get allocated and they are not equally weighted between the various determinants, on how these decisions are being taken. So, pricing is certainly one factor but not the sole determinant of market share allocations between the various players and you will see that change over time, across the various players. Certainly, those who have been in the space in that particular therapy areas to create barriers given their long-standing relations with payers and I think that's an area that Viatris has also said in the past that there is an area for improvement that they have identified, and that's what they will be investing in with a greater focus on their commercial team and they have stated that publicly as well.

Sameer Baisiwala: **Okay, my next question is on the market share for these two products Pegfilgrastim and Trastuzumab in the US. We have been to 6-8% for some time and we do get some 50 basis points up here and there. What's really going to drive this to 15-20% rightful market share and what's holding back? And just to add to that, over time you will see more players coming in and this opportunity would then go away as the**

biosimilars utilization goes up to 65-70-75%. So, we need to act urgently. It's been a long time so, so your thoughts on this.

Shreehas P Tambe: Let me address these questions one by one. Let's talk about Pegfilgrastim to begin with. I think in the Pegfilgrastim space, we have got a steady market share of around 8.5%, that's where it has been trending. As we discussed earlier on the call, we did see Onpro kind of move up in market share over the last one year, given the pandemic situation and the convenience factor that we saw the patients were looking at. So certainly, it held on to the market more than what was expected. It has taken a longer time for all incumbents to move into that share. We have seen that come off as we get into this year and we have seen over the last one year that Onpro market share dropped from 58% to 52%. Certainly, this creates an opportunity for Fulphila to move into that space. In terms of Trastuzumab, I think there again the COVID pandemic has played a role where there's been a reduction in terms of the overall diagnosis, where the screening itself came down over the course of last year. We have held on to that market share steadily over the course of the last 18 months. We have ramped up towards double-digit figures and we are at just under 10% at this point and we are looking to increase that market share. There was of course a disruption that was caused with the market moving from 150 milligrams to 420 milligrams and certainly there is some attribution to that given the higher dose formulation there is lower losses, hence lower requirements. So, in the franchise itself, there is some rationalization in terms of volumes. But we believe that remains strong and as we get into the coming year with the pandemic firmly behind us, particularly in the US, we are starting to see more footfalls in the hospitals and more screenings. We will see that we continue to hold that 150 milligram pole position that we've held. In terms of talking about what has driven this overall franchise, in addition to Pegfilgrastim and Trastuzumab, we are looking forward to getting Bevacizumab join this overall oncology franchise, which we believe will be also another sizable opportunity because Bevacizumab itself has grown year on year 5% in terms of market volume, solely in the US and 26% globally. We believe that there is a long-term play for us in the oncology space with a more complete offering in terms of Pegfilgrastim, Trastuzumab and then Bevacizumab to join it shortly.

Sameer Baisiwala: **When will FDA confirm that it would come for the Malaysian inspection in Q3? Last question because I think Malaysia right now is going through a very bad third wave. I think just 2-3 days back it's hitting almost its highest ever COVID positive cases. So, is there any reason to think that FDA can actually deliver? and second question is, any thoughts on the new biosimilars entering phase three trials?**

Shreehas P Tambe: Let me answer the first one straight up, we have been in constant dialogue with the inspectors who are visiting us on site. You are absolutely right, the third wave of Malaysia despite the lockdown has been more aggressive, or not the third wave, but essentially the current wave, and they are seeing an all-time high in terms of cases reported. But there are clear relaxations that the government has provided in terms of visitors from different parts of the world and those who are coming for visits for 15 days and less. And I think the way we worked with the agency is that they are confident of making the trip to inspect us and be with us on site. At this point, what we have to share with you is those plans are still on

track and they expect to visit us towards the end of this quarter. So that's on the Malaysia Aspart pre-approval inspection at our location. In terms of products getting into the clinic, we have said in the past that our products are progressing very well in terms of the CMC aspects of it. We are currently in the state where we are progressing them towards the clinic and we will be updating you shortly once they get past that stage and are ready to discuss that with you.

Charulata Gaidhani: **My question pertains to the interchangeability for Glargine. After receiving interchangeability what type of market share would you expect to earn in the first full year of operations?**

Shreehas P Tambe: So, we won't be able to comment on specific market shares but as we discussed all through the call, we certainly believe this to be a development in the right direction for us to have more constructive discussions with the payers, but we wouldn't be able to give you specific guidance on what those market shares would be.

Charulata Gaidhani: **But while you are talking to the payers with limited number of competitions in Glargine, would it be reasonable to expect 10% market share in FY23, or it could be higher?**

Shreehas P Tambe: As I said, we would not want to comment on specific market share percentages. But suffice to say that we are looking at building on what we have done so far in the past.

Sheersh Jain: **Thanks for the opportunity. I wanted to understand the cost competitiveness and cost advantages of Biocon in the biosimilars arena, like do we have certain cost advantages in manufacturing biosimilars which other players won't have, because we are manufacturing in India and Malaysia, and do these cost advantages will help us stand in this pricing war that is happening currently in US?**

Shreehas P Tambe: Sheersh if you look at how our focus has conventionally been. In the biosimilar space, price is certainly an important or I would say cost is an important element or important lever to be successful in the market, but the first piece is the scientific aspect and to be able to develop a molecule as complex as a biosimilar, then the ability to get the facilities approved in terms of which markets you want to bring these products to. And then the third aspect will be the ability to price it competitively and to gain market share. So, I think what Biocon has been able to successfully demonstrate - is we have the scientific credibility to bring these highly complex biologics to the market, and not just to emerging markets, where certain players may be operating in, but to all parts of the world. Our products today are approved by all ICH countries – that's the scientific hurdle taken care of. The next piece is the manufacturing scale and the compliance to regulatory standards and that's the other hurdle that we have been able to move on and surpass. But we have always been, you know, even in our small molecule days, very focused on emerging markets, we have always been extremely competitive in that space, that's been our DNA. We continue to be focused on cost at all times. We come from that focus and legacy. So, we don't see cost being a barrier to us to gain market share. But I want to leave you with the thought that it's not the only factor determining success,

Sheersh Jain: **Okay, that helps. Another question is, what is the core growth strategy that senior management is looking at - where is the bottom-line growth going to come from in the next two or three years. What areas are you most hopeful about?**

Shreehas P Tambe: On the biosimilar space, let me respond. I think one of the things that we have got is that we have laid the platform very effectively for an insulin franchise, which is all set to grow. In terms of the US, towards the end of the month, looking forward to the first interchangeable insulin ever to have been approved by the FDA. We are clearly looking forward to that decision. We are hopeful, and we are looking forward to that. So, we are looking at the insulin franchise making a difference. Certainly, we are also looking at a more complete oncology portfolio with Bevacizumab joining the Pegfilgrastim and Trastuzumab franchise. We are also looking at making a difference to patients through our COVID portfolio pipeline where we have products like Itolizumab, which has really made a difference in saving patient lives in this time of crisis. We are looking at growing our footprint in emerging markets, where we've really had great success in different parts of the world as Susheel talked about with the portfolio that we've got. And most importantly, we are looking to bring the next wave of biosimilars to the market as we continue to maintain our lead, in terms of bringing several first biosimilars to the US and to several other geographies. So, I would say that there are several things that we have to look forward to. And we are really looking forward to that with a lot of optimism.

Kiran Mazumdar-Shaw: I would just like to add to that by saying - across the group, we see some very strong growth drivers. I think you just heard from Siddharth, that we have a large number of ANDAs in our pipeline, we are having a lot of capacity expansions that will go on stream. API business, as you know is also a very profitable business for Biocon and if you saw the recent rankings of API producers in India, Biocon is right up there in the top 10. In fact, it's in the top 5. So, I think from that point of view, we are very committed to this business as well, and of course Research Services has a lot of growth opportunities which you also heard. So, I think overall, the Biocon group is in a very strong position to deliver on all fronts, whether it's Biosimilars which is now going to focus on market expansion across developed and emerging markets with its existing portfolio. It's looking at portfolio expansion. It's looking at a strong focus on insulins and I think, in terms of our generics business, both in terms of APIs and formulations we see a huge opportunity for growth in the coming years, and so also in the Research Services. So, I think overall we are in a good place, and we are going to be really focusing on operational excellence, as well as market share in terms of all our products.

Sheersh Jain: **Now one last question from my side. Siddharth, what kind of Capex do we foresee for fiscal 22?**

Siddharth Mittal: I think we had said that overall capex spends were $100 million a year for next three years. We have had some delays in the beginning, in the first quarter. But overall, from a cash spend perspective, I expect around Rs. 500 crores to be the outlay in FY22, but it will pick up in FY23. I am only talking about the generics business - maybe Chinappa can give numbers for the biosimilars business.

M.B. Chinappa: Another $100 million account for biologics. $100 million per year.

Masira Vasanwala: **Thanks for taking my question. I think, first just wanted to understand, with Mr. Shaw leaving the Board, are you thinking of adding somebody else to the Board and what kind of profile are you looking for?**

Kiran Mazumdar-Shaw: Yes, we will look at adding someone to the Board and we will look at someone who comes from a technology background is what our view is.

Masira Vasanwala: **Thanks, and the second question was, six months to a year ago the target for the Biosimilars business was about a billion dollars in revenue. Understandably, some of that has been delayed with FDA inspections being delayed, does that target still stand?**

Kiran Mazumdar-Shaw: Well, the target is there obviously, but it won't happen by FY22. So, I think we are looking at recalibrating that target date, but obviously the billion-dollar target is very much on the anvil for biosimilars, and we hope that we will deliver it sooner than later.

Mitesh Shah: **Thanks for taking my question. I just have one hypothetical question- post interchangeability, if a product is substitutable, can we see similar kind of generic acceptance, like for Aspart and the insulin portfolio?**

Kiran Mazumdar-Shaw: I think Shreehas had mentioned that we have submitted our BLA for Insulin Aspart as an interchangeable insulin. So, I think, going forward. all our insulin submissions will be made as interchangeable insulins, and Glargine was filed under a very different regulatory route, and that's why we had to now request for an interchangeable label, under a very different set of circumstances, but going forward I think we will look at all insulins being submitted under interchangeability.

Mitesh Shah: **My question is mainly because, post interchangeability of the Glargine, can we expect similar response - like generic is having interchangeability currently in the market, or pure generic will be accepted as branded portfolio?**

Kiran Mazumdar-Shaw: Well, you mean for biosimilars in general.

Mitesh Shah: **Right.**

Kiran Mazumdar-Shaw: I thought you were talking about insulin, but right now the guidance given is for insulins because it's a simpler molecule from an identical comparability point of view, but when it comes to monoclonal-antibodies, I think it will take some time before the agency takes such decisions, is our belief.

Mitesh Shah: **Okay. And on the loss of our sales this quarter because of the COVID-related disruption. Can we see some of the recovery in the coming quarters?**

Kiran Mazumdar-Shaw: Well, we certainly expect that to happen because we expect normalcy to return this quarter unless we see a very unexpected third wave. But other than that, I think, since we have vaccinated all our employees, we believe that we are in a safe place to continue with our operations and we hope that things will resume over the coming quarters. So certainly, we expect things to improve. Let me put it that way.

Tarang Agarwal: **Hello Team good morning. Couple of questions from my side - just general questions. One, in manufacturing, marketing partnerships that you have entered with your partner, such as yours and Viatris for your oncology platform, or the diabetes platform in North America, if you could give us some sense on what proportion of value of the product is captured by the manufacturer, and what is captured by the marketer? Without getting into specifics, just wanted to get a broad brush of incentives between the two collaborators. That's number one. And the second question is, given the size of the biosimilars opportunity wave 1, wave 2, wave 3 and maybe wave 4 and, you know the portfolio that you have, whether it's approved or under development, would it therefore not make sense for you to maybe in the medium to long term actually be marketing these products on your own so as to be able to capture the entire value chain? Would that be the right way to look at it or would partnerships be the right way to look at this in the long term obviously, not in the short term?**

Kiran Mazumdar-Shaw: Well, if you look at the way we have developed the biosimilars business, it is exactly along these lines. I think you will know that our partnership with Viatris was extremely valuable, as we initiated our biosimilars development because I think it was important to share the risks, the cost, and the opportunity, which I think both partners have benefited from, and realize the value of entering into such a partnership, where Biocon brought in a lot of R&D and manufacturing capabilities, and Viatris is obviously focusing on the commercial aspects of our partnership. Going forward, as you know in terms of wave 2 and wave 3 programs, we have a partnership with Sandoz, we also have plans to have our own programs. So, we will have a combination of partnerships and programs going forward, depending on what the commercial models are going to look like. So, I don't think we want to completely focus on one or the other. I think it's important to have a very balanced view of what works in a partnership, that could work better on your own. So, I think that's the way Biocon has gone about it. And going forward, we certainly want to have our own programs being marketed by us.

Tarang Agarwal: **Sure, my first question of broad brush in terms of value capture at the manufacturing level and at the marketing level.**

Kiran Mazumdar-Shaw: So, let me put it this way on the collaboration as a whole, we have a very equitable collaboration. I think that's as much as I can say. I cannot really break it down into the share, but I would just say that it's a very equitable partnership.

Sameer Baisiwala: **Thank you for the follow up question. Just a couple of questions - One is on the mutual recognition group with MHRA, UK for Bevacizumab, what's the likelihood that FDA accepts this, and are there any case precedents where FDA has done so.**

Kiran Mazumdar-Shaw: Sameer, to correct you, the MHRA mutual recognition route has been actually pursued by the Generics division. As far as biosimilars or Biocon Biologics is concerned, they have looked at all avenues of trying to get our facility in Bangalore inspected, whether it's virtual, whether it's through mutual recognition, but we are yet to get a positive feedback from the agency. We at least appreciated that they gave us a positive feedback for Malaysia, but India is still not something that we have visibility on.

Siddharth Mittal: I may add in general, there is no precedence on this. I think this guideline came out in May, after that I know that companies have reached out to FDA to get the advantage of this new guideline. The FDA has reached out to us and requested for information which we have submitted, and we await that decision. So, at least I have not heard in the Indian generic context, if any other Indian company has received an approval, using this mutual recognition within MHRA or EMA.

Sameer Baisiwala: **Okay, and just on interchangeability, I'm not so sure it's a very right question, but would this be against the innovator brand, which is Lantus, or also against the other brand which is Basaglar?**

Shreehas P Tambe: This is against the innovator brand. So, this interchangeability is to Lantus.

Vipul Shah: **Any update on the oral insulin program, and what is the progress on our biosimilar joint venture with Sandoz? Any update there?**

Kiran Mazumdar-Shaw: So, in terms of oral insulin we are still in the process of completing the Type 1 diabetes trial and once that is known, we will take a view on the next path ahead for this program. As far as Sandoz is concerned, yes, the programs are under development, but they are still at an early stage.

Vipul Shah: **Lastly, what type of annual loss guidance can we expect per annum for Bicara.**

Kiran Mazumdar-Shaw: Bicara is a startup. So, I would say that you will only get some readouts by the end of this year, in terms of their first program that is in the clinic. And based on that, the company plans to then raise funds, through venture funding. And it also has some very exciting follow-on programs which are preclinical. I am sure you are aware that these kinds of very innovative startups do need to basically focus on one or few programs, that will then establish their capability and their platform technologies.

Nikunj Mall: That was the last question. We thank you all again for joining us today. If you have any additional questions, please feel free to reach out to our Investor Relation teams. We look forward to seeing you again next quarter. Have a good day and stay safe. Thank you.