Transcript

Biocon Limited Q2 FY21 Earnings Conference Call
October 23, 2020

Participants from Biocon's Senior Management Team

- Dr. Kiran Mazumdar-Shaw – Executive Chairperson, Biocon Limited
- Mr. Siddharth Mittal – CEO & Managing Director, Biocon Limited
- Dr. Christiane Hamacher – CEO & Managing Director, Biocon Biologics
- Mr. M.B. Chinappa – Chief Financial Officer, Biocon Biologics
- Mr. Shreehas Tambe – Chief Operating Officer, Biocon Biologics
- Mr. Paul Thomas – Chief Commercial Officer, Biocon Biologics US
- Mr. Peter Meeus – Head Portfolio & Products, Biocon Biologics
- Ms. Finn Doyle – SVP, Commercial, Biocon Biologics
- Mr. Sundaresan Ramanan – Vice President - Regulatory Affairs, Biocon Biologics
- Mr. Saurabh Paliwal - Investor Relations, Biocon Limited

External Participants during Q&A session

- Prakash Agarwal – Axis Capital
- Damayanti Kerai - HSBC
- Nithya Balasubramanian - Sanford Bernstein
- Neha Manpuria – JP Morgan
- Shyam Srinivasan – Goldman Sachs
- Sameer Baisiwala – Morgan Stanley
- Surya Patra – Phillip Capital
- Vinayak Mohta - Augmenta Research
- Rajamohan V – Professional Investor
- Harith Ahamed – Spark Capital
- Ankush Agarwal – Stallion Asset Management
- Nitin Agarwal – IDFC Securities
- Pankit Shah - StockAxis
- Charulata Gaidhani – Dalal & Broacha
- Vrijesh Kasera – Mirae Asset Management

Prepared Remarks Session

Saurabh Paliwal: Thank you, Steven. Good morning everyone. My name is Saurabh Paliwal from the Biocon Investor Relations team, and I welcome you to the Earnings Conference Call for the Second Quarter and Half Year of FY'21.

Before we proceed with the call, I would like to remind everyone that a replay of today's discussion will be available for the next few days about 60 minutes post the conclusion of the conference call. The transcript shall be made available on the website in due course.

To discuss this quarter's business performance and outlook, we have the senior leadership at Biocon, comprising Dr. Kiran Mazumdar-Shaw, our Executive Chairperson, and other colleagues from the management team.

I would also take this opportunity to remind everyone of the Safe Harbor related to this conference call. Today's discussion may be forward-looking in nature based on management's current beliefs and expectations. It must be viewed in conjunction 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. At the end of this call, if you need any further information or clarifications, please do get in touch with us.

With this, I would like to hand over the call to Dr. Kiran Mazumdar. Over to you, Kiran.

Kiran Mazumdar-Shaw: Thank you, Saurabh, and good morning, everyone. I welcome you to Biocon's Earnings Call for the Second Quarter and Half Year of FY'21. Let me start by wishing everyone Shubh Navratri and a Very Happy Diwali ahead of time.

We are all anxiously awaiting the vaccine, and I do hope that you and your families are keeping safe.

Let me start today's earnings call with some "**Key Management Updates**"

As you know, Siddharth Mittal, who used to be the CFO of Biocon, was elevated to the post of MD and CEO.

I am now pleased to welcome **Mr. Anupam Jindal** as the new **Chief Financial Officer** at Biocon Limited. Anupam will head the Finance function at Biocon and be part of the Executive Leadership Team reporting to Siddharth Mittal. Anupam joins us from the Vedanta Group of companies where he worked for 22 years and held a position of Group Chief Financial Officer at Sterlite Technologies since 2006.

I am also pleased to announce the appointment of a **Group Chief Information Officer, Mr. Atanu Roy**, who joins us with a vast experience in the pharma and tech sectors with Sun Pharma, Dr. Reddy's and HP.

Now, coming to "**Highlights for the Quarter**"

- **Tata Capital Growth Fund** invested **US$30 million (Rs.225 crores)** in Biocon Biologics for a **minority 0.85% stake**, valuing it at an **equity valuation of US$3.5 billion**.
- **Semglee**, co-developed by Biocon Biologics and Mylan has been **commercialized in the US.** It is a third product launch in the US market under the joint collaboration after the successful commercialization of Fulphila, which is Pegfilgrastim and Ogivri, which is Trastuzumab in 2018 and 2019 respectively.
- Our partner, Mylan, also launched **Biosimilar Etanercept in Europe**, in which Biocon Biologics has an economic interest.

- **Equillium**, our US partner for our novel drug Itolizumab recently received positive feedback from their pre-IND meeting with the US FDA. It is advancing along the regulatory pathway in preparation for initiating a **global Phase-III** clinical trial in Q4 of calendar year 2020.

- We have also initiated **Phase-IV** clinical trials **in India** following a consent from the Drugs Controller General of India in **September 2020** for our drug, **Itolizumab**.

- Syngene commenced manufacturing **Remdesivir** in Bangalore as a part of its voluntary license agreement with **Gilead**. As you would have heard the news this morning, USFDA has given a final approval to Remdesivir as an anti-viral drug for COVID-19.

Moving on, I will now present the **Key Financial Highlights for Q2 FY'21**.

This quarter we delivered a year-on-year revenue growth of 10%, wherein **total revenues** increased from Rs.1,606 crores last fiscal to Rs.1,760 crores in Q2 FY'21.

Revenue from operations stood at Rs.1,745 crores, up 11% due to stable performance in generics which was up 8%, Biosimilars, which was up 11%, and a return to growth in Research Services which was up 12% year-on-year.

We recorded **gross R&D spends** of Rs.165 crores this quarter which corresponds to a 13% of revenues ex-Syngene. Of this, Rs.148 crores is reported in the P&L while the balance amount has been capitalized. The increase in R&D expenses is primarily due to higher spends to develop our biosimilars pipeline.

During the quarter, we booked a **FOREX loss** of Rs.18 crores compared to a gain of Rs.16 crores last year. This amount is reflected in the other expenses line of the P&L statement.

EBITDA for the quarter was Rs.407 crores, which was down 8% from last year. **EBITDA margins** stood at 23% against 27% reported in the same period last year. The reduction in the EBITDA margin this quarter is a result of higher R&D spend, higher staff cost, FOREX loss and other expenses.

When it comes to **core margins** i.e. EBITDA margin, net of licensing impact of FOREX and R&D, this stood at a healthy 32% compared to 33% last year.

Lower EBITDA coupled with higher depreciation and amortization costs results in **PBT before exceptional item** being down to Rs.223 crores.

Net profit for the quarter was Rs.169 crores. Adjusting for impact from discontinuing operations, net profit stood at Rs.174 crores with **Net profit margin** at 10%.

Now, coming to reviewing Business Segments Performance for this Quarter

The **Generics** segment reported 8% growth over last year with revenues at Rs.599 crores primarily driven by the Generic Formulations business. Segment's PBT margins for the quarter stood at 12%, down 6% over last year due to increase in staff cost, higher R&D and FOREX loss.

API business growth was largely driven by the Immunosuppressants portfolio, supported by sales of specialty APIs. The Generic Formulations business reported strong growth with our products maintaining mid-to-high-teens market share in the US.

There was no significant impact of COVID on supply or demand of products in the generics segment.

Looking forward, we expect **Generic Formulations to continue to drive growth for the Generics segment** based on new launches in the US for the products that are currently under regulatory review. We have also received licenses from MHRA, UK to import and distribute products in the UK. This is in line with our plans to commercialize our formulations directly in the UK.

Novel Molecules, as I mentioned earlier, our partner, Equillium, is making rapid progress in taking Itolizumab global. Apart from advancing along the US regulatory pathway in preparation for initiating a Phase-III study for COVID-19, Equillium continues to make good progress on earlier initiated studies with Itolizumab. In the **EQUATE Phase-1b study**, I am pleased to share with you that complete response to the drug has been observed in a large number of patients by day-29 in the first two cohorts, and Equillium has proceeded with dose escalation in the third cohort as planned. Additionally, Equillium continues to advance this **Phase 1b EQUIP and EQUALISE studies** in uncontrolled asthma and lupus nephritis respectively.

In terms of "**Research Services**", **Syngene** reported 12% year-on-year growth with revenues of Rs.520 crores in Q2 with **good performance in the Discovery Services and dedicated R&D centers**. After the impact due to COVID-19 in Q1, operations in Syngene have restored to near normal capacity.

Coming to "**Biosimilars**", I now hand this over to my colleague, **Dr. Christiane Hamacher**, MD and CEO of Biocon Biologics to discuss the performance.

Dr. Christiane Hamacher: Thank you, Kiran, and good morning, everyone. For Biocon Biologics, let me dive straight into the **factors that influenced our performance in Q2**.

After strong recovery in Q1, we have recorded a modest 11% top line growth versus Q2 last year and 2% decline versus Q1. While in Q2, we continue to see increased demand for our products, we have not been able to fully capitalize on the opportunity because of some operational challenges that have been further amplified by COVID-19. This has resulted in some supply constraints thereby impacting our top line. We are working to mitigate this and be back to maximum operations in the coming quarters. Moreover, on the back of COVID-19, there have also been some challenges in the already stressed health care systems, affecting regular patient flow, particularly in critical care segment, such as oncology.

Moving on to "**Profitability**." In Q2 fiscal year'21, Biocon Biologics had an **EBITDA margin of 27%** Vs 30% last year and **PBT of Rs.81 crores** Vs Rs.107 crores last year. The reduction was primarily on the account of the operational challenges, leading to lower than expected sales, FOREX losses and higher R&D cost.

Our **R&D spends** for last quarter was Rs.82 crores Vs Rs.46 crores last year due to investments in our strong pipeline.

We have seen growth in revenues from developed markets including the **US**. **Ogivri**, our Biosimilar Trastuzumab, shows a 6% market share with 4% in the 150 mg segment and 10% in the 420 mg segment. In Australia and Canada, we continue to be the leading Biosimilar for Trastuzumab, and in Europe, Ogivri has double-digit share in three markets.

Fulphila, our Biosimilar Pegfilgrastim, had 15% of the US prefilled syringe market in Q2 fiscal year '21.

Semglee, our Biosimilar Glargine in the US, has slowly started gaining market share. We are confident that Semglee will have a long revenue stream, addressing a business opportunity of US$2.1 billion with limited competition.

In **Europe**, we are seeing encouraging market penetration for Semglee in certain parts such as Slovakia and Croatia. Semglee has also been launched in Spain in Q2, which is the third largest market in Europe by value.

Our partner has also launched **Etanercept in Europe** where we have economic interest.

Moving on to **Most of the World Markets**, where we see a good demand for Biosimilars. In Q2 FY'21, we launched Biosimilar Trastuzumab in Argentina. As a result, we also have started strengthening our commercial infrastructure by building up direct presence in selected countries like Brazil, Malaysia, UAE and Saudi Arabia, which should allow us to further improve our most of the world's business both from a revenue and profitability perspective.

Branded Formulations business in India recorded a sequential growth of 13% versus Q1.

As a part of our initiatives to make recombinant human insulin available for less than 10 cents per day in low and middle income countries, we have signed two memorandums of understanding with two municipal governments in the Philippines for a long-term integrated diabetes management program.

On the **Regulatory updates** front, the BLA and marketing authorization submission for **Insulin Aspart** is under review with **FDA and EMA**.

Concerning the rest of our pipeline, we continue to make good progress. We are in the process of completing the integration of our recently acquired **R&D site in Chennai,** which further solidifies our R&D infrastructure. We are also working on ramping up our manufacturing capacity and are developing a network strategy to improve our supply chain further. The **new antibody manufacturing facility** at Bangalore is expected to be ready for commercial operations in fiscal year '23.

Additionally, we expect to commission a **third monoclonal antibody facility** which should be operational in fiscal year '24.

We also continue to invest in improving our productivity and efficiency including **digitization and digital transformation** efforts.

Finally, to conclude, we expect continued improvement in performance in fiscal year '21 with full year revenue from Biosimilar Trastuzumab in the US and good contribution from ramp-up of Biosimilar Glargine in the US. Biosimilar Pegfilgrastim and biosimilar Trastuzumab in several most of the world markets will further aid the performance.

We continue to be on track to build Biocon Biologics as a **leading global pure play biosimilar company** through the exciting platform built over the last 15-years, reaching our US$1 billion milestone by the end of fiscal year 2022.

With this, I hand over back to Kiran.

Kiran Mazumdar-Shaw: Thank you, Christiane. Let me now come to the **Outlook**. While dealing with challenges posed by the COVID-19 pandemic on our operations across different business segments in the first half of the year, we have delivered a 12% revenue growth on a consolidated basis, which is below par. However, we are confident the coming quarters will see stronger performance.

COVID-19 has strained healthcare systems globally. This has brought sharp focus on access and affordability, creating a strong demand for Generics and Biosimilars. Biocon is in a good position in both these areas, which bodes well for us in the long-term.

Whilst uncertainties may persist during the rest of the year, we expect the Biosimilar segment to continue to lead overall revenue growth for Biocon.

With this, I would like to open the floor to question-and-answers.

Q&A Session

Prakash Agarwal: ***The first question on actually the Biosimilar business. So, we have seen QoQ flattish performance despite some market share gains in our Peg and Trastu and Glargine launch. So just trying to understand sales of Glargine would have been booked or we would see the bookings from next quarter? And similar commentary on the PBT margin which has been lower. So, if you could help us understand?***

Kiran Mazumdar-Shaw: Yes, you are right. This quarter does not reflect the full launch of Glargine in the US market. And we believe that you will see the greater impact of Glargine in the US market in the coming quarters.

Prakash Agarwal: ***By that statement, I understand some launch impact should be there, right? So, still it is flattish. So, what are the other things which have actually been muted or declined if that color would be possible?***

Kiran Mazumdar-Shaw: Well, as you heard from Christiane's comments, I think many of these segments are still constrained by COVID. A lot of the hospital treatments and hospital services are impacted by COVID. So we are not seeing the kind of growth or uptick that we normally would have expected, but I believe that things are improving now. As you see, the hospitals now becoming free of COVID cases, I think the rest of the disease segments are opening up to more patient traffic. That is what is now giving us the signals that we will start to see resumption of business as usual thereby we will start seeing increased traction in all these biosimilars. Whilst on one hand our operations have not been affected by COVID to such an extent, I think our ability to increase market share

in the developed markets has not had the same good fortune because I think COVID still has dampened the hospital-based treatments. I think that in the coming quarters you are likely to see an uptick.

Dr. Christiane Hamacher: Yes, it is not unusual what we are saying. Many other companies have reported the same that we are seeing the challenges as Kiran has alluded to in particular, in critical segments such as oncology. There is a clear interruption in regular patient flow. It is now coming back. There are stressed healthcare resources. What is important for us to see is that the pressure on the healthcare system in terms of cost is massive. The need for biosimilars at this moment from our perspective is very, very high because of all the cost constraints and the cost pressure. We are expecting and we actually see traction on our molecules in last weekly updates that are publicly available for our molecule Pegfilgrastim and Trastuzumab Biosimilars in the US who are further gaining the uptick. So we are seeing this now in the last weekly updates that we further get traction.

Prakash Agarwal: ***Second question is on what we are seeing now with Glargine having launched more than a month, so how has been the traction, and you mentioned you expect a slow traction, but just trying to understand like how do we see the traction in terms of reaching above 10%-plus market share, how is the acceptability at the channel, if you could give some color?***

Dr. Christiane Hamacher: When it comes to Glargine in the United States, so it is very early that we have Glargine in the US market. I think it is important to understand that Semglee like the other biosimilars in the US, are going for more than US$2 billion opportunity in the market alone. There is limited competition so far. And if you now look at the market in the United States and how the biosimilars have ramped up in terms of market share, we are very confident that we will see a steady growth of Semglee in the US, and not only in the US, but also in Europe. I just referenced the launch in Spain. We expect Semglee to be a key contributor to our success in the United States with our partner, Mylan.

Damayanti Kerai: ***So continuing on Semglee, just wanted to understand like when we go for such critical launches, what kind of inventory we keep ready during the market launch? And related to that, since now Semglee is launched in the US and in other markets also, what kind of utilization level has picked up at the Malaysia plant, if you can provide some update here?***

Dr. Christiane Hamacher: So I will start on the inventory. Like with each and every launch, when you launch in a key market in the US, there is sufficient inventory to go for launch to make it successful. That is a foundation and we do that together with Mylan. We have very experienced partners to do so.

Damayanti Kerai: ***So any quantitative numbers, say like you go with six months, nine months kind of inventory or any color on that will be helpful?***

Dr. Christiane Hamacher: We have sufficient inventory for our launch as required. Level of inventories depend on market, depend on the launch plans, and are always between three to six months.

Damayanti Kerai: ***And update on the Malaysia plant utilization?***

M.B. Chinappa: So just one clarity. Yes, of course, with the launch, we do build up inventory. Today, more inventory is lying at our end that has not translated to sales. And if you have seen our segment assets, you will see that increased reflecting high inventory at our end. This applies to both our facilities across. So in Q1, when we ramped down production, and then post that we have been ramping up. So now we are back to near normal. But overall, during this period, we have lost some production days, and as such it has impacted our sales despite a very strong demand for the Biosimilars. Malaysia, as we started ramping up, the profitability is near breakeven. And if you take off R&D, that breaks even, so we are starting to see improved performance from Malaysia which will further improve in the coming quarters.

Damayanti Kerai: ***So in next quarter, we should be seeing a profitability breakeven for Malaysia plant as you said we are almost there?***

M.B. Chinappa: That is right, yes.

Damayanti Kerai: ***And a broad question. As of second quarter, if you can split your biosimilar sales between developed market and emerging market, that will be helpful?***

Dr. Christiane Hamacher: The split is now roughly a 50-50 split. What we expect to see is that this will move further towards the developed markets over time.

Nithya Balasubramanian: ***I had a couple of questions on Semglee. So I understand that you have launched it at a 65% discount to the list price of the innovator. We do know that rebates are very high in this space to the extent of 80%. So, can you throw some color on what would be the discount that you are offering on the net price and not just the list price?***

Dr. Christiane Hamacher: Thank you for your question. I hope you understand we are not commenting on the specifics for the prices.

Nithya Balasubramanian: ***If you are not commenting on the specifics, can you throw color on is there a significant discount or a decent discount, any color on how competitive Biocon's product is in the market?***

Dr. Christiane Hamacher: Certainly very important question and that would reveal a lot of business and competitive intelligence. So I cannot comment further.

Nithya Balasubramanian: ***The other related question was on interchangeability. I think the press release noted that you have a file with the FDA, which is under review. So, if you can give us some color, will this be treated as a new application or a supplementary application, when do you expect to hear back from the FDA on interchangeability?***

Sundaresan Ramanan: This is Sundar. As we have discussed with the agency, we have made the submission to the agency for the requirement. As you know, as per the new guidance, if analytical similarity package is very strong, then that could be sufficient for both biosimilarity and interchangeability. And that is exactly what we have done. We have made the submission and we are confident of a successful review and approval. Once we get more clarity on the time lines, we will be happy to communicate them to you.

Nithya Balasubramanian: ***But to my first question on, will this be treated as a new application because you are now submitting it in the 351(k) pathway or would this be treated as a some sort of supplementary approval because you already have an approval?***

Sundaresan Ramanan: So, we are not commenting on it at this point in time. We will communicate that to you at an appropriate time.

Nithya Balasubramanian: ***I just had one more on R&D expenses. So given that you are continuing to work on newer molecules in your pipeline for the Sandoz partnership as well, will these elevated levels continue or are you expecting this to move up further in the future?***

M.B. Chinappa: Nithya, see, as an absolute number, we have seen R&D cost increase, and it is more in this quarter, particularly, it has gone up to 12% against a normal high single digits. For the year, we expect R&D cost to continue to increase, but as a percentage of sales remain in the high single digits for this year. We have not yet given guidance on the coming years on the net R&D spend, i.e. net of partner share and capitalization.

Siddharth Mittal: And at a consol level, the R&D ex-Syngene revenues would be in the 13% to 15% range.

Neha Manpuria: ***My first question is, I think in the opening remarks, you mentioned some sort of a supply (Inaudible) 30:33 your top line. If you could give more color on that? And if you could quantify what was the impact because of the supply constraint?***

Dr. Christiane Hamacher: For biologics, there are actually two components and Kiran has already alluded to one in particular. So the challenges we faced were partly also due to COVID as we have

discussed with challenges in critical care segments like oncology based on patient flow. In addition, we faced some operational challenges. We are a fast growing company and what we have seen and experienced is some CMOs had limited capacity for overall supplies what impacted us so that we were not able to service the demand, and that was mainly affecting the Most of the World markets. So internally, we are also further sorting out our operations as a learning and fast growing company. These are not major topics. While it has impacted us, we will be back on track to our full operations in the coming quarters.

Neha Manpuria: ***I am not sure I understand that. When you say limited capacity to meet a higher demand, given our expansion in Peg and available capacity for Trastuzumab, which I am assuming are the two largest products and insulin, if you could just give a little more understanding better, what gives us the confidence that this will get resolved in the coming quarters?***

Kiran Mazumdar-Shaw: So let me try and answer that. What we are saying is that the supply/demand that we need to cater to, I think one of the big challenges we have is that there are a lot of logistics disruptions at this time. And very often, we find it difficult to basically to ship it off in time. So that is the kind of issues we are trying to tackle at this point in time. It is not to do with the inventory, it is not to do with the demand, but it is to do with a lot of logistics kind of operational issues. So that is what we are trying to fix at this point in time.

Neha Manpuria: ***And Chini, could you quantify what in your assessment would be the impact because of this, and by when do we expect this to normalize?***

M.B. Chinappa: I was reflecting on your question. To quantify it is difficult, but we see a pickup from Q3 onwards.

Neha Manpuria: ***My second question is while I understand that COVID has impacted patient flow into hospitals. If I were to look at data for some of our competitor products in both Peg and Trastuzumab, they seem to be showing a positive momentum in terms of market share. While we have seen it in Fulphila and Ogivri, is there any reason, just wanted some color on what is making the ramp-up slower despite having additional capacity, despite our competitors still seeing greater market share?***

M.B. Chinappa: Yes, as you have noticed, we have picked up market shares in both Trastu and Peg in the US. When we talk about lower footfalls, it is largely the whole MoW markets, the India business, it is not particularly targeted at the US.

Neha Manpuria: ***Any reason why our market share ramp-up in the US has been gradual… or to rephrase the question, how is it tracking versus our expectation after the additional capacity approval?***

M.B. Chinappa: It has picked up. I mean the last one that has just come out - October 9th weekly data shows that overall market is 8% and of the PFS is 17.5%. I mean, of course, you cannot rely just on one week's data, but definitely on an upward trend.

Shyam Srinivasan: ***Just the data point in the opening remarks on the EBITDA margins for Biocon Biologics. If you could give us the numbers again, last year maybe Q1 and Q2?***

Dr. Christiane Hamacher: So Biocon Biologics, we had an EBITDA margin of 27% versus 30% last year and PBT of Rs.81 crores versus Rs.107 crores last year. And as explained, the reduction was primarily on the account of operational challenges that led to the lower sales, FOREX losses and higher R&D costs while we are investing in our strong pipeline.

Shyam Srinivasan: ***What is Q1 number? I am curious about that.***

M.B. Chinappa: So Q1 was 28%, Shyam. It has dropped to 27%. In this 27%, as we already indicated that we have had higher R&D cost. That has taken off 5%. Last year Q2 was at 7% net R&D spend. This year, it is at 12%. And then we had a 2% impact of FX, Rs.13 crore loss versus Rs.5 crores profit in Q2 last year, that together comes to 3%, this year, it is 2%.

Shyam Srinivasan: ***Chini, just trying to understand from a profit share with our partner, I know this could be volatile across quarters, but have you seen anything shared during the first half or it is an ongoing process and from an outside analyst perspective, you think we can never find it out? If you recollect, in the past, we have had EBITDA margins close to 37%, which clearly were not normal, right? So we knew that there is some element of profit share coming through. But do you think that as the portfolio becomes larger, will that be more streamlined in terms of what the margin that is being reported?***

M.B. Chinappa: Yes, see, today, it is a bit lumpy, it is not flowing through on a steady state but moment inventory levels at our end, inventory levels at partners' end and inventory levels and market with the wholesalers steady, then you will see this thing play out in a steady manner. Of course, new launches, etc., will keep moving things up and down. But it will start to normalize at a higher level than where we are today.

Shyam Srinivasan: ***My second question is on the Novel Biologics. I thought we would start booking some revenues starting 2Q, maybe Itolizumab, maybe some of the other portfolio. We have seen like zero revenue. So is it subsequent now, is it going to be coming in the upcoming quarters?***

Siddharth Mittal: So Shyam, the revenues for Itolizumab in India is booked under Biocon Biologics since Biocon Biologics has commercialized it. Exports for Itolizumab, have not started. We expect to start exports in this fiscal year. Obviously, it is subject to registration in the

emerging markets. Once those revenues start, we will see revenues in the Novel Biologics.

Shyam Srinivasan: ***And my last question is on the generics piece. Siddharth, maybe just in terms of the trends that you are seeing, what is the formulation absolute number in the generics piece? I used to remember Rs.100 crores quarterly run rate. And two, in terms of general API, anything that you have been picking up, because our number, if I back out, like Rs.100 crores number, I am just assuming, has been flat. So, are we seeing any pickup in APIs, especially our immunosuppressant portfolio?***

Siddharth Mittal: The generic formulations number is roughly Rs.120 crores, and we have had a growth in our API business as well, mainly because of immunosuppressant and specialty API, which is primarily Fidaxomicin. So in terms of trend, obviously, the growth is now dependent on new launches in the US because our current capacities on APIs are maxed out, and we await the commissioning of the new Greenfield site in Vizag which would happen in '22 and the commercialization would start sometime in '23. Till then, we will only get few incremental capacities and new launches for API. However, the biggest growth driver would be the formulations in the US and we have a couple of launches over the next 12-months.

Sameer Baisiwala: ***Is there any update on Bevacizumab regulatory update? I understand that our target action date was somewhere in December if I am not wrong.***

Sundaresan Ramanan: So we remain confident about the target action date, and we will continue to give you update as we get more information.

Sameer Baisiwala: ***A little bit more specifically. Has FDA been able to come down to audit manufacturing for that? And is the COVID-related travel restrictions going to impact our approval timelines?***

Sundaresan Ramanan: So we are in discussions with the agency and it could have an impact. As of now, we continue to remain confident about previous communication.

Sameer Baisiwala: ***And second question is on US Glargine. When you say it is $2.1 billion or thereabouts target market, is this indexed to your pricing or at what pricing is this indexed to?***

Peter Meeus: This is indexed at the prices that are available, the net prices we know in the US from the reports that are issued by the related companies.

Sameer Baisiwala: ***There are only two companies; one is innovator and the other is Basaglar. So what are you suggesting?***

Peter Meeus: That is correct. It is basically the reports that you can read from in this case Sanofi.

Sameer Baisiwala: ***So it is on an innovative pricing basis, right, that is what you are trying to say?***

Peter Meeus: It is an innovative net pricing update based on their annual reports.

Sameer Baisiwala: ***And the third question is on Itolizumab. Just if you can give us some timelines for COVID-related trials that a partner is going to do, what would be the sort of patient size, what are key milestones, and also, why are we doing Phase-IV in India? I assume this is for COVID and not II and III.***

Kiran Mazumdar-Shaw: No. First, let me first answer your last question. As you know, Itolizumab is an approved product in India. So in India, it is a repurposed approved drug. This has already gone through Phase-I, II and III for approval for Psoriasis. Therefore, from that point of view, what we have done is a proof-of-concept study for another indication, on which we have emergency use approval for COVID. The regulator has asked us to do a Phase-IV study because of this accelerated approval that they have given us for a short study to capture the safety and efficacy data on 300 patients. Therefore, this is what is required in terms of the regulatory requirement. There is no regulatory requirement to do a Phase I, II and III for COVID the way you are suggesting.

The US on the other hand does not have an approved drug in the US. This is under trial right now. They are actually doing Phase-Ib studies in GVHD and in lupus nephritis and in acute asthma. Therefore, I think from that point of view, they are required to do a Phase-III study. In fact, they have been given a unique opportunity to jump into a Phase-III study, which is under the present circumstances, it is actually a very good opportunity for Equillium to do a Phase-III study and get approval for this drug. Therefore, I think that is what augers well for Equillium. Moreover, they have actually had a very good pre-IND meeting with USFDA. They have submitted their IND and they expect to commence the trial fairly soon. In addition, it all depends on the recruitment of the patients, which will then determine how quickly they can complete the studies.

Sameer Baisiwala: ***I am not trying to compare US and the India studies. They were two separate questions. But just coming back to India studies, so once approved, would it be only for emergency use or could you then sell it on a broader basis to everyone for COVID indication?***

Kiran Mazumdar-Shaw: So for COVID, basically you are allowed to sell it to anyone, I mean, basically, by consent you can actually sell it to any patient. Initially, because of the capacity constraints, we have already marketed this product or sold this product to over 2,000 patients in the country.

Sameer Baisiwala: ***Is it possible for you to break your developed market Biosimilar revenues by US and non-US? Some qualitative color is fine.***

Dr. Christiane Hamacher: We are giving a split between developed market and emerging markets, and that is currently at 50:50. The US market is certainly the biggest component when it comes to our US$1 billion revenue target and the split between developed and the emerging markets will move from 50:50 more towards the developed markets when molecules in those markets start getting traction.

Surya Patra: ***I am just starting with a couple of book-keeping questions like what is the FOREX loss that you have mentioned, could you please quantify that? And also about the R&D spend particularly for the Biocon Biologics what you have mentioned in the current quarter and the corresponding previous quarter, if you can also mention for the first quarter?***

M.B. Chinappa: I will take the question around biosimilars first and then Siddharth can give you the overall company numbers. For the quarter, we have booked an Rs.13 crores FX loss, that is reflected in our segment margins of 27%. From R&D, it is 12% for the quarter, Q1 was at 9% and last year, it was 8%.

Surya Patra: ***And this FOREX loss is just on Biocon Biologics front or on the consolidated number front, is there any separate number or how is it sir?***

Siddharth Mittal: I think it was there in Kiran's opening remarks that for the quarter there was Rs.18 crores of loss at the consolidated level. There was Rs.13 crores for Biocon Biologics, Rs.13 crores for Biocon Generics, and there was a gain in Syngene, which offset some of these losses. So the net at the consolidated level was an Rs.18 crores loss.

Surya Patra: ***On the biologic progress front, could you give some idea about the contracting cycle for Biosimilars in the US, what is the timeline? I am trying to ask this question because I think during last December or so for Pegfilgrastim, we tied for this 340(b) program and all that, but the contracting cycle generally is somewhere in June, July like that. So obviously, the tie-up would not have really helped us so far on the Pegfilgrastim front. So same would be the case for other Biosimilars also, like the recent launches of Trastuzumab and all that. So if you can give some idea about the contracting cycle and how can that progressively benefit us?***

Paul Thomas: Surya, thanks for the question. I think it is product-by-product. It will make a difference. And I would say it is a customer-by-customer process. I think Pegfilgrastim and Trastuzumab, the oncology products operate in a different space than Glargine on the pharmacy benefit, PBM-driven side. So those are two different animals. And so as you talked about Pegfilgrastim, where that kind of contracting is more on a customer-by-customer basis and less on an annual formulary cycle, whereas I think you would say

the pharmacy benefit side where Glargine operates more on an annual cycle] as complexities relate to that which have been referred to.

Surya Patra: ***At least for 340(b) program for Pegfilgrastim, so if you can give some idea when should we start getting the benefit of this tie-up?***

Paul Thomas: I would not tie that to a specific July cycle or something like that and rather it is a process that will play out with customers over time.

Surya Patra: ***If you can provide some sense about the key CAPEX project say we know that, okay, this immunosuppressant project is on the generic side that is likely to be commissioning soon, then the Greenfield API plant that is there to be commissioned next year. We have also talked about the third monoclonal antibodies biologic plant separately and also something on the Biocon Biologics side. So the key projects that is there to be either commissioned or in the process of construction, if you can give some sense, that would be useful.***

Siddharth Mittal: Let me start with the generics CAPEX. We have already stated that the Greenfield plant in Vizag, the Phase-1 of that plant has been commissioned, which is a much smaller unit. However, we have a much larger immunosuppressant facility under construction that is expected to be commissioned physically by calendar '22, and then the work on regulatory approvals will commence after that. For this plant, we are investing almost Rs.600 crores. The second is a peptide API facility, which is going to start commissioning in Bangalore. This will take almost two years to commission. In addition, we have a large synthetic block coming up in Hyderabad, which again the construction would start early next calendar year. Then we have a couple of other facilities, including expansion of our R&D infrastructure and quality infrastructure in Bangalore that again the work would all start in the coming days. Apart from this, one CAPEX that we are looking at is on our injectable facility, which again, we are in the final stages of determining the location and the sizing and the specifications for the plant, and work would start in calendar '21.

Surya Patra: ***What is the cumulative CAPEX for the generics?***

Siddharth Mittal: It would be around Rs.2,000 crores over the next three years.

Surya Patra: ***And separately for the Biocon Biologics, as you have mentioned I think already?***

M.B. Chinappa: I will give you some color. So far, the gross fixed assets is about $450 million, and our net block would be closer to $200 million. As we scale up, for a billion dollars and beyond, we are investing quite heavily into CAPEX, as we have already covered in the opening statements. We have a large monoclonal antibody facility coming on stream, which will go commercial in FY'23. The second plant is expected to go commercial in FY'24. We are expecting to trigger an investment of expansion of our

insulin capacities. Altogether, we would look to take the asset block to above a billion. That would be the total thing now. Of that, net of partners' spend and spends that have already been made because we have already invested $200 million towards the new upcoming projects, net-net, we are looking at about $400 million of cash flows over the next four years starting FY'21 to FY'24.

Surya Patra: ***Just last one question on the Insulin Aspart front. Is there any goal date that is available with us?***

Sundaresan Ramanan: The application is under review with both the US FDA and EMA. Once we get further information, we will share them with you. We remain confident about the successful review.

Vinayak Mohta: ***I just had a question more of towards the financial end since you are looking to have some heavy CAPEX going for the next two to three years in expanding your capacities, and currently also I can see that you have taken a new borrowings to the tune of Rs.700 crores. So out here, how are you looking to use the funds -- are you going to be more leveraged or is it going to be a mix of accruals and leverage or totally accruals, if you could just throw some light about what is your comfortability level with the borrowings out here?***

Siddharth Mittal: So at a group level, our net debt is Rs.1,000 crores and all the CapEx will be funded through a combination of internal accruals, as both our businesses, biosimilars and generics, are obviously going to generate cash this year and going forward. We will also take on more debt, but the most important source would be the private equity fund raise that is currently in works in Biocon Biologics and eventually an IPO for Biocon Biologics.

Rajamohan V: ***My first question is on Semglee. You did mention about the difficulty to mention pricing strategy on Semglee. With the original pricing discount feeling alarming, wanted to understand, are the discounts at the net level in line with other biologics like Fulphila and Ogivri? Also, by when do you anticipate double-digit kind of market share based on your initial assessment?***

Dr. Christiane Hamacher: So again, when it comes to pricing of Semglee in the US, we do not give details. The business model of Biocon Biologics is built on its global scale, high quality products and cost competitiveness. Moreover, we are able to play either price- volume or value maximization. Therefore, with Semglee, we will be in a position to be very, very competitive.

Kiran Mazumdar-Shaw: To answer your question, Rajamohan, I think what you should understand is that these are two segments. The insulin segment is very different to the biosimilar antibody segment. So obviously, there are very different discounting norms in each segment. Therefore, I do not think you can compare one with the other.

Rajamohan V: ***To the second part of my question, if you could tell us, by when do you anticipate double-digit kind of market share based on your initial assessment of the market in Semglee?***

Kiran Mazumdar-Shaw: I think we are quite confident that it will happen in the coming future because Mylan is very confident that it will garner good market share by the end of this fiscal and beyond. Oviously, the aim is to garner maximum market share. When will we get the 10% market share is a question of many factor. Whether there are any impediments caused by the market dynamics right now in terms of COVID, is it going to be easy for us to garner market share because of COVID, these are questions and answers that Mylan is trying to address? I am sure you will see the performance of Semglee in the next two quarters.

Rajamohan V: ***Next, coming to Ogivri, though you have indicated to 6% market share in the market from 5% last quarter. Mylan in a recent presentation has indicated to gaining 3% to 4% market share in the months of August and September of 2020. Specifically they mentioned this. So are you now closer to the double digit market share in Ogivri, and is this trend accentuating? Could you mention similar latest weekly market share data as you did for Fulphila?***

Kiran Mazumdar-Shaw: So actually, if you look at the two presentations of Ogivri, you can see that in the 420 mg presentation, we are at 10% market share. Moreover, the last week's market share performance overall is 7.8%. As you can see, we already have some traction over the previously reported 6% to 7.8%. Therefore, there is a good traction and uptick of Trastuzumab. And as I said, in one of the presentations, which is the dominant presentation, we are already at 10%.

Rajamohan V: ***Finally, Kiran ma'am, this question comes back to the subject of Biologics listing. I wanted to understand as a shareholder, is there also a thought process within to have a preferential offer at issue price for existing Biocon shareholders so that it becomes mutually beneficial, the existing shareholders get fixed shares without being diluted by oversubscription and the company also does not dilute its receipts in the process.***

Kiran Mazumdar-Shaw: So all we can say is that we will definitely be very sensitive to all these comments that our shareholders of Biocon are making, and we will try and see how fair and equitable we can be to Biocon shareholders when the time comes.

Harith Ahamed: ***My first question is on your Insulin Aspart filing in the US. Are we seeking interchangeability designation for this filing at this point?***

Siddharth Mittal: Yes, we are seeking interchangeability and we remain confident.

Harith Ahamed: ***And is there any timelines that you could share on your rh-insulin filing plan?***

Sundaresan Ramanan: The development is progressing very well. As we get closer and we get firmer dates, we will be happy to share them with you at appropriate time.

Harith Ahamed: ***My next question is on the capacity front. If I heard you right, the new facility in Bangalore is going to start commercial production from FY'23. So from the perspective of our $1 billion sales guidance for Biocon Biologics in FY'22, do we have sufficient capacities from our existing units at Bangalore and Malaysia?***

M.B. Chinappa: Yes, we believe we largely have the capacities. Some networking strategies to fill small gaps here and there, but broadly, the answer is yes.

Harith Ahamed: ***And last one on Itolizumab. I believe there was a comment that the drug has been administered to over 2,000 patients in the COVID indication. So is that a major contributor to our Biocon Biologics revenues for the quarter?***

Kiran Mazumdar-Shaw: No. This is not a major contributor. I think to the 2,000 patients the drug was offered at a very affordable price point. Therefore, you can understand that this cannot be such a major contributor. Even if you just look at the price of the product, you can calculate for yourself that this cannot be a major contributor. It will be a major contributor going forward once we get the US in a successful place.

Nitin Agarwal: ***Christiane, as the Biosimilar market is now beginning to open up with more sort of follow-on approvals coming through across different products, what is your sense in terms of how important is the first mover advantage in your assessment in these products or given the nature of these products, that is not going to be a relevant force from a market share sort of structuring perspective in the coming quarters, I mean, as we go forward with it?***

Kiran Mazumdar-Shaw: Very good question. I would say that first mover advantage is very important, but at the same time, depending on the presence of companies like ours who are already in the market where we have had a so-called first mover advantage; it obviously helps with the products that we are bringing to the market. What we have seen is that certainly companies like Mylan and Biocon are very competitive in the marketplace. Therefore, that also helps a lot. However, as far as the first mover advantage is concerned, you can see that it has helped many, many companies with market share. We have had unfortunate tipping to the post, as they call it, with Trastuzumab because we had the first approval, but unfortunately, we had Amgen basically launching at risk and they had the first mover advantage as a result of that which got them a lot of market share. Nevertheless, I think we are now in a position to catch up slowly in whatever way we can.

Nitin Agarwal: ***And secondly, on the emerging market biologics business, have you seen any different dynamics versus regulated markets? Is it easy to scale up products in***

these markets versus what US and Europe have sort of experienced over the last few years of their initial biologics experience?

Finn Doyle: You know, our past performance, which has really witnessed sustained business in line with our strategy, we have had accelerating success adding on new launches, specifically, we refer to the new launch in Trastuzumab in Argentina, and we expect to launch many more products over the coming quarters and years. Therefore, the rest of the world market is extremely important of our goals. Our vision is to grow the market size in these high value markets. Biosimilars have gained excellent traction in these regions, and our base in emerging market for Trastuzumab, Insulin and Glargine continues to be an important contributor for our business. In addition, we are present in most of the top-20 rest of the world or MoW markets. Geographic expansion, introduction of new products and increased volumes and products already being marketed should really help with the continued growth in this very important pillar of growth for Biocon Biologics. As you know, we have gained additional approvals across Latin America, AFMET and CIS, and we expect to drive further growth in the coming quarters in addition to our historically strong regions in Brazil, North Africa and Southeast Asia. Moreover, as you may remember, Christiane referred to, we have opened up commercial offices in key strategic markets, such as Brazil, Malaysia, UAE and Saudi Arabia, and we do plan to expand further. So thank you for your question. I hope that addresses it.

Nitin Agarwal: ***That is helpful. Quickly, if I can add on to that, in the developed markets, is bulk of the business which comes from biologics, tender-driven or is it essentially a lot of distribution or B2B, B2C-driven business?***

Finn Doyle: So it is actually a mix. We have a lot of tender business but what we are also actively doing is we are also addressing the non-tender or retail business because it is very consistent and also there is differential in pricing opportunities. Therefore, we are addressing both tender and non-tender, but the tender business is a significant part of our business, and we are having more success in that area.

Kiran Mazumdar-Shaw: Yes, there is a large element of a tender business, but there is also a non-tender business, which is obviously at a higher price point. Therefore, we, as a company want to address both opportunities.

Pankit Shah: ***My question is that in the past that we have seen, whenever there is a new launch in biosimilar space, we have seen a good ramp up in the initial month itself. But the similar stuff we have not seen with Semglee. So I think what went wrong or how should this be looked at?***

Dr. Christiane Hamacher: So when it comes to Semglee, Semglee is very very early in the US market. And Semglee has limited competition. So as the next quarters are important, and we have already expressed that we are confident that Semglee will gain traction in the United

States, there is a high need for low cost insulins and insulin and analogs. Therefore, for Semglee, the numbers will emerge over time, over the weeks and months to come. In the next two quarters, as Kiran has already mentioned, we expect to see the market penetration ramping up. Nothing went wrong in the market in terms of any operations or strategic approaches.

Pankit Shah: ***One more thing I know is that you cannot disclose more on competition, but wanted to understand that how has been the reaction of the other two players, and have they been aggressive on pricing front, any color would be helpful?***

Dr. Christiane Hamacher: So when you look at the Biosimilar market, it is not only about pricing. Pricing is one element to enter the market. There are many other operational tactics that are important. The Biosimilar market is a market where we see some segments with steeper price decreases, but overall, the pricing decrease discipline is much, much higher than in the generic segment. And so far, we are well-positioned to compete on price. As I mentioned before, price volume or value maximization, both is possible.

Pankit Shah: ***I know that we are very competitive on pricing front, but I wanted a color on the competition that how has their reaction been and whether they have also slashed their prices, is there anything -- some sort of…?***

Kiran Mazumdar-Shaw: I think when you have less competition; you are not likely to see sort of a price destroying kind of tactics. When you get more and more players coming into Biosimilars, price is going to be important. So right now, we are not seeing aggressive responses to our entry in the market. But if you look at what happened to us in say Trastuzumab, I think the aggression comes from launching at risk and those kinds of methodologies. But certainly, yes, we have seen sort of an aggressive price response in many markets in Europe for instance.

Pankit Shah: ***And I just wanted some color on margins. So is it fair to assume that margins on Biosimilar will remain impacted at least for this fiscal as we are doing the initial supply where the margins would be lower as compared to when the secondary sale happens and the second leg comes in?***

M.B. Chinappa: We will see margins trending upwards. As I said, the moment it normalizes between inventory at our end, at partners' end, and with the wholesalers, the profit share or overall business profitability will probably get distributed. Right now, there is a bit lumpy here and there.

Pankit Shah: ***I wanted to understand that how important is interchangeability status for our $1 billion revenue target?***

Dr. Christiane Hamacher: So when it comes to interchangeability and the US$1 billion target, we have to look at the different therapeutic segments. Interchangeability in oncology will not play a major

role. When it comes to, say, insulins, what we are seeing is that interchangeability is being discussed and Mylan and we are discussing with the FDA. It is not a major success factor. What is happening in the market? We are seeing at a pharmacy benefit manager level that products are being switched from one product to another without interchangeability. It is a factor good to have, but it is not a critical success factor for success and market penetration for insulins.

Pankit Shah: ***So is it safe to assume that we are confident of $1 billion even without the interchangeability in Semglee?***

Dr. Christiane Hamacher: As it is not a critical success factor, the answer is yes.

Ankush Agarwal: ***My question was regarding the margins on the overall business. I mean we have been talking that biosimilar business as a whole has been more profitable compared to other business segments of generics or say research services. But till now the margins have been quite volatile for the Biosimilars business. That I understood would be because of the lower scale of business compared to what kind of opportunities we are chasing. But given that over the next one, two years, we are chasing a target of $1 billion, so do you think that at that scale, there would be some kind of stable scale margins that you are looking at, at that scale also, it would be a little difficult for us to achieve a stable scale margins?***

M.B. Chinappa: As I said, right now, the margins are impacted because we have lower sales than what we planned for. That is really the biggest play. Then as a result, R&D costs are looking higher as a percentage of revenues, and there is the impact of FX losses. As we scale up on our business, we will expect to see improved margins. In addition, as business stabilizes, it will also remain steady and would not be as lumpy as we have seen in the last few quarters.

Ankush Agarwal: ***So just understanding would be at $1 billion kind of sales, you expect the Biosimilar business to have a stable scale margins because one comment that you recently made is you expect normalization when the business as a whole has inventory level normalized at the Mylan level, at the market level, at your level. So, at $1 billion kind of business scale, do you expect that thing to happen?***

M.B. Chinappa: That is right, because $1 billion is the FY'22 guidance. I just want to caution that look at margins pre-R&D. We have not yet given guidance around the R&D spends.

Nithya Balasubramanian*:* ***Just a quick one on Copaxone. So any color you can give us on when do you expect to file back? What could be revenue timeline?***

Siddharth Mittal: We expect to file back in the next few months. Since it is a major CRL, we expect FDA to take anywhere between eight months to a year to review. Nevertheless, we expect to respond back within this fiscal.

Nithya Balasubramanian: ***As in the next quarter, right, you would be able to…?***

Siddharth Mittal: Yes.

Charulata Gaidhani: ***My question is for Aspart, have you got a target date?***

Sundaresan Ramanan: We will share the target date at an appropriate later time.

Charulata Gaidhani: ***Then secondly, in terms of the CAPEX over the next two years, could you give me the segment-wise breakup in terms of biologics how much, generics and Syngene?***

Siddharth Mittal: I think we have said in the past give or take $100 million per year per segment is what you should consider.

Charulata Gaidhani: ***And a last question on Remdesivir. Are we looking at exports to the large market?***

Kiran Mazumdar-Shaw: Yes, we will look at all opportunities.

Charulata Gaidhani: ***But the current agreement is only for LMIC, right?***

Kiran Mazumdar-Shaw: Yes, that is what I mean. LMIC are over 100 countries. I think that is a large market to look at.

Charulata Gaidhani: ***So US does not look likely?***

Kiran Mazumdar-Shaw: No, we do not have. I mean, Gilead has given the license based on a certain number of countries, and, of course, it excludes US, Europe and LATAM as well.

Vrijesh Kasera: ***Just a clarification. Quarter-on-quarter drop on the biosimilar sales, you did mention much of it was because of external issues, be it COVID-related or logistical issues. But I just trying to understand if I see Q1 versus Q2 across the globe there has been a substantial opening up of economies and month-on-month across businesses we are seeing normalization happening. So it is kind of difficult to understand why in Q1 we reported a better quarter with Rs.690-odd crores and this quarter there has been a drop because of these external issues that you alluded to. So if you could just help me understand was it some internal issues as well that we faced which led to a drop?***

Kiran Mazumdar-Shaw: So I mentioned earlier that it was operational logistics issue, which prevented us from getting product out of Biocon. So I think there was a demand, but we were not able to cater to that demand. So I think that is what we are fixing now and we have fixed it. It will reflect in the coming quarter.

Vrijesh Kasera: ***So it was nothing related to any like earlier last year when we faced Pegfilgrastim capacity constraint. Now we do not have those kinds of constraints, probably some technical issues in getting the product manufactured, delayed the decision?***

Shreehas Tambe: This is Shreehas here. So let me just quickly explain that topic. I think if we just look at what we have done in Q1, we voluntarily ramped down certain aspects of our activities which given the long biologics manufacturing cycle, some of it flowed through into Q2. As we look to ramp up our output into Q2, we have seen restrictions, particularly in personnel travel which has affected us from ramping up our operations in this particular quarter. So you are seeing us build the inventory, you are seeing us having the product, but not necessarily having that product leave our site in this particular quarter. So yes, you will see that settle down and see more improvements in the coming quarters.

Vrijesh Kasera: ***So if I have to just take this forward, so can we see some lost sales that we had this quarter coming back to us, say, next quarter or quarter going forward?***

Kiran Mazumdar-Shaw: Yes, your understanding is right. It is a timing issue and it is a lag issue. So I think if you look at that, then I think you will make up in the coming quarters. It is not a loss of sales in that sense…you have not lost business.

Vrijesh Kasera: ***Just a clarification regarding the regulatory landscape. Of late, we have been witnessing that a lot of these developed markets, specifically US and Europe, are trying to reduce the clinical requirements and the development timelines required for developing a Biosimilar. So basically, the newer entrants would kind of spend less on the biosimilar development compared to what we have done. So, how do you going forward, say, two, three years down the line, see this landscape changing in terms of competition and incremental competition coming through in Biosimilars because the return requirement for these companies would be much lower, so how do you think that would impact our business per se in these markets where the products we have already launched?***

Kiran Mazumdar-Shaw: So that is an excellent question. Let me answer it by saying that this is how any new segment will open up. If you remember, when generics started, this was the same kind of challenge that the early companies had. They obviously were at a disadvantage when it came to these kinds of abbreviated pathways, but they opened the path. So we have done that. Now I think we will also benefit from the abbreviated pathways

because obviously developing a biosimilar is complex even before getting to the clinical path. Therefore, I think from that point of view, it allows us to get to the market even faster than others. Whilst others do have an opportunity and advantage of developing biosimilars cheaper and faster, I think it will also allow us to develop many more biosimilars faster and cheaper and keep us ahead of the curve.

- Ends -

Note: The contents of this transcript contain edits to improve accuracy and readability. It may include corrections to statements/ numbers.