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Biocon Limited Q3 FY21 Earnings Conference Call Transcript

January 22, 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. Anupam Jindal** – Chief Financial Officer, Biocon Limited
- # **Mr. M.B. Chinappa** – Chief Financial Officer, Biocon Biologics
- # **Mr. Shreehas P Tambe** – Chief Operating Officer, Biocon Biologics
- # **Mr. Paul Thomas** – Chief Commercial Officer, Biocon Biologics
- # **Mr. Sundaresan Ramanan** – Vice President - Regulatory Affairs, Biocon Biologics
- # **Mr. Ankit Gupta** – Head-Investor Relations, Biocon Limited
- # **Mr. Nikunj Mall** – Head-Investor Relations, Biocon Biologics

External Participants during Q&A session

- # **Prakash Agarwal** – Axis Capital
- # **Keshav Botda**- Professional Investor
- # **Damayanti Kerai**- HSBC
- # **Neha Manpuria** – JP Morgan
- # **Shyam Srinivasan** – Goldman Sachs
- # **Nithya Balasubramanian (Nithya B)** - Sanford Bernstein
- # **Sameer Baisiwala** – Morgan Stanley
- # **Harith Ahamed** – Spark Capital
- # **Tushar Manudhane**- Motilal Oswal
- # **Manoj Bahety**- Professional Investor
- # **Bharat Sheth**- Quest Investment
- # **Mitesh Shah**- ICICI Direct
- # **Shrikant Akolkar**- Ashika Stock Broking
- # **Charulata Gaidhani** – Dalal & Broacha

Prepared Remarks Session

Moderator:

Ladies and gentlemen, good day, and welcome to the Biocon Limited Q3 FY'21 Earnings Conference Call. As a reminder, all participant lines will be in the listen-only mode, and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal the operator by pressing '*' then '0' on your touchtone phone. Please note that this conference is being recorded. I would now like to hand the conference over to **Mr. Ankit Gupta** from **Biocon Investor Relations**. Thank you, and over to you, sir.

Ankit Gupta:

Thank you, Janis. Good morning, everyone. I'm Ankit from Biocon Investor Relations team, and I welcome you to Biocon's Earning call for Q3 FY'21. To discuss the Company's Business Performance and Outlook, we have today with us 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 the **Safe Harbor statement**. Today's discussion may be forward-looking in nature based on management's current beliefs and expectations. It must be viewed in concurrence with the risks that our business faces, which could cause our future results, performance or achievements to differ significantly from what is expressed or implied by such forward-looking statements. After the end of this call, if you need any further information or clarifications, you can contact me or write an email to ankit.gupta@biocon.com

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

Kiran Mazumdar-Shaw:

Thank you, Ankit, Good morning everyone and welcome to Biocon's Earning call for the third quarter of fiscal 2021

Let me begin by wishing you and your families a healthy and prosperous 2021. 2020 has been one of the most challenging years humanity has faced. Countries, communities and businesses the world over have been tested on multiple fronts. While the global scientific community stood up to the challenge of developing vaccines and therapies to control the pandemic, the damages caused to societies and economies has been devastating.

Let us aim to reboot the world economy in 2021. Now that the vaccine deployment has been initiated let us hope that normalcy is restored.

I will start this call with the main highlights of the quarter:

- ❖ Biocon Biologics has received **USD 150 million investments** from **Goldman Sachs** and signed an agreement with **Abu Dhabi based ADQ** for **USD 75 million investment**
- ❖ These investments from marquee global investors validate our capabilities and is an endorsement of the scale that Biocon Biologics has built as a Global pure-play, fully integrated biosimilars company
- ❖ Biocon Biologics has **cumulatively raised USD 330 million** in the **last 12 months** and has now achieved a **post-money valuation of USD 4.17 billion**. These funds will enable us to make prudent investments in R&D, high-quality manufacturing, establishing a global commercial footprint and redemption of preferential shares invested by Biocon Limited, which will be deployed to fund our generics business expansions

- ❖ In our **US generic formulations business**, we launched Tacrolimus; a complex immunosuppressant capsule integrated with our API
- ❖ The Malaysian Government has extended its contract with **Biocon Biologics for one year** to supply rh-Insulin under its **Off-take Agreement (OTA) initiative**
- ❖ **Syngene, our research services business**, entered into a collaboration with **3DC (Deerfield Discovery and Development) for providing integrated drug discovery projects**, from early target validation to preclinical evaluation; 3DC has awarded four antibody discovery projects to Syngene in areas of oncology and autoimmune diseases.

I will now present the financial highlights for Q3FY21

This quarter, we delivered year-on-year **revenue** growth of **7%**, wherein the Total Revenue increased from **₹1,753 Crore** last year to **₹1,879 Crore** in Q3 FY21.

Our **Revenue from Operations** in the quarter stood at **₹1,851 Crore**, up **8%**, mainly driven by research services (up 13%) and Biosimilars (up 11%). We reported a muted performance in generics (degrowth of 3%)

We recorded **Gross R&D spend** of **₹183 Crore** for this quarter, which is an increase of **18%** over last year and corresponds to **14%** of revenue ex-Syngene. Of this, **₹171 Crore** is **reported in the P&L** while the balance amount has been capitalized. This **increase in R&D expenses** is primarily due to higher spending in developing our biosimilar pipeline and continued investments in novel programs and generic pipeline.

We also recorded a **Forex gain** of **₹6 Crore** versus a gain of **₹15 Crore** last year during the quarter.

EBITDA for the quarter was **₹427 Crore**, down by **11%** from last year. The EBITDA margins stood at **23%** as against **27%** reported in the same period last year. The quarter's decrease in EBITDA margin mainly accounts for additional spends of **₹108 Crore** on R&D and employee costs. **Core Margins** (i.e. EBITDA margin, net of licensing, forex and R&D) stood at 31% compared to 34% last year. A lower EBITDA combined with higher depreciation and amortization resulted in **PBT (before exceptional items)** being **26%** down to **₹236 Crore**. The **net profit from continuing operations** stood at **₹169 Crore** with a **Net Profit Margin** of **9%**.

Let me now turn to a "Segmental Review" of our business

Generics

Our **generic business** reported a muted performance with a **3% degrowth** over last year and revenues at **₹561 Crore**. The PBT margin for the quarter stood at **10%**, down by around 600 basis points over last year due to increased spending on employee cost, R&D and Forex losses. Our API business which did well in the first half of this fiscal saw a subdued performance in the current quarter. We believe this was mainly due to lower off-take by customers as inventory is coming back to pre-Covid levels, compared to the temporary spike we witnessed during the peak of this pandemic.

As mentioned earlier, we received **approval for Tacrolimus**; an immunosuppressant used to treat organ transplant patients. This product bodes well with our strategy of developing a strong portfolio of complex generic formulations integrated with our APIs. We believe this will augment our competitiveness in the generics market. We launched Tacrolimus towards the end of December and expect a ramp-up in the coming quarters.

However, other approvals, for our products under review, were impacted by the deferment of inspections by the USFDA due to Covid restrictions. As we look forward, we continue to invest in infrastructure, including at Vizag and build a robust pipeline of technology-intensive molecules for future growth.

Novels

The novel business remains an essential strategic pivot in our journey as a global company known for path-breaking research.

Equillum, our US-based partner, is making steady progress in Phase 1b clinical trials for Itolizumab in the first-line treatment of acute graft-versus-host disease (aGVHD). The overall Phase 1b top-line data is expected during the first half of 2021. As you know, aGVHD has a vast unmet need, and we believe that Itolizumab is well-positioned to address this need.

Itolizumab, under the brand name **ALZUMAb-L**, has also been commercially launched in India to treat **cytokine release syndrome** in **moderate-to-severe Acute Respiratory Distress Syndrome (ARDS)** experienced by COVID-19 patients.

We are progressing well with the **already announced Phase 4 studies** in India and have **enrolled more than 100 patients of the 300 required**. Under the Emergency use, over **2000 patients in India** have benefitted from Itolizumab administration. We will also explore potential opportunities for this asset across other emerging and developed markets as an effective ARDS treatment.

Research Services (Syngene)

Led by sustained growth across divisions, Syngene reported ₹585 Crore revenues in Q3 this fiscal, up 13% year-on-year. During the quarter, Syngene also expanded its Hyderabad facility and added capacity for an additional 90 scientists. Syngene has built strong business fundamentals around dedicated centers, discovery services and bio-manufacturing. The way forward for the business is integrated discovery and development services, and this quarter alone saw four IDD projects for us. Syngene is well poised for sustainable growth in the future.

Biosimilars (Biocon Biologics)

I will start with the news that **Dr Christiane Hamacher**, Managing Director and CEO, has stepped down from the Board of Biocon Biologics effective January 20, 2021. She will leave the organization on completing a two-year term on February 28, 2021. Differences between Christiane and myself on key strategic matters have led to a mutually agreed separation agreement.

The Board has appointed **Dr Arun Chandavarkar**, former CEO and Joint Managing Director of Biocon Limited as **Managing Director of Biocon Biologics** with effect from January 21, 2021.

Further, I will now assume the **Executive Chairperson of Biocon Biologics**, where previously I was a non-executive chairperson. I believe that between Arun and myself, we will bring the business back on a steady growth path.

Turning to the Business Discussion for Biocon Biologics

Our Financial performance in Q3 has recorded a **top line of ₹769 Crore**, a year on year growth of **11%** and a **14%** sequential growth. Our **EBITDA margins** during the quarter were **27%**. **Profit Before Tax** stood at **₹111 Crore** in Q3 with **37%** sequential growth. This strong financial performance is on the back of **increased supply of Senglele (Insulin Glargine)*** for the US market and a **modest increase in market share of Ogivri (bTrastuzumab)*** and **Fulphila (bPegfilgrastim)*** in the US, despite a challenging environment.

**Partnered with Viatrix*

Besides, our products have continued to perform well in other markets too. For example, **Ogivri** continues to be the leading biosimilar in **Canada** and **Australia**. We have also **received approvals for bBevacizumab and bAspart in Malaysia** where we have a direct commercial presence.

We have also **partnered with the Christian Social Services Commission (CSSC)** to enable affordable access to insulins for diabetic patients in Tanzania under **Mission 10 cents**. The program will serve up to **10,000 patients over the next two years**. We have several other discussions ongoing to broaden access to our products globally.

On the regulatory front, **bBevacizumab** has received a positive nod from EMA. However, there is a **delay in approval** from the US FDA due to a site inspection which has been on hold due to the ongoing pandemic. At present, there are no further technical data requests from US FDA outstanding, and we have answered all questions received to date. As you might be aware, there have been similar issues faced by other companies, where the FDA has not been able to conduct site inspections even in the US.

We continue to make significant investments into R&D, manufacturing and commercial infrastructure. I firmly believe that Biocon Biologics has been built on robust science and strong business fundamentals, making it **one of the unique global integrated pure-play biosimilar players with several "first-in-class" achievements to its credit**. While the long-term success for Biocon Biologics in the global biosimilar market remains unmatched, we believe that the impact of COVID-19 on our business across the value chain has **not allowed the acceleration to be in line with our expectations**.

As we had mentioned last quarter, we have been facing market-related challenges on the back of COVID-19 across the value chain. There has been a **reduction in patient footfall** in hospitals leading to lower consumption, for example, Pegfilgrastim market volume in the US was down by 7% in Q2FY21. It has been more challenging for commercial teams to switch customers to biosimilars and enter new markets. Tenders have been delayed amongst other reasons.

Besides, our internal operations, including R&D, manufacturing, and commercial functions, have also been slowed down. Our facilities are not running on full strength due to COVID-19 related safety measures; procurement of some raw materials has taken longer than usual; it has been challenging to get shipments of finished products out on time; resolving operational issues is taking more time given travel restrictions; etc.

Against this challenging backdrop, we believe that **COVID-19 has dampened our ability to achieve our aspirational billion-dollar revenues by FY 2022**. We will reassess the timeline required to accomplish this target after evaluating all possible opportunities once business normalcy returns. We continue to believe that this is a short-term impact not related to the **overall biosimilar opportunity**. **We reaffirm our pursuit to make Biocon Biologics a global leader in this large emerging business segment. We have seen healthy growth in the business over the last few quarters but not the acceleration we were hoping for**. We continue to develop a rich portfolio of biosimilar molecules, aggressively scale-up manufacturing capacities and set up our direct commercial infrastructure in global markets. We are confident that the fundamentals of our business and the biosimilar market remains solid, and we remain committed to delivering on the long-term growth potential.

So, let me conclude by saying that amidst the uncertainties and business environment challenges, our consolidated performance in Q3 led by Research Services and Biosimilars has been better than the first and second quarter of fiscal 2021. We remain confident of the opportunities that lie ahead of us, and we are determined to deliver on our commitment to our partners, patients and all other stakeholders.

With this, I would like to open the floor to question-and-answer. Thank you.

Q&A Session

Prakash Agarwal: **Ma'am, on Glargine, nothing has been talked. I mean we at a four-month kind of launch. Bloomberg data in terms of market share still shows under 1%. So how are we ramping up there, what is the outlook for that product, any colour would be helpful.**

Kiran Mazumdar-Shaw: Sure. I will get my colleague Shreehas to give you more colour on this thing because as you know, it has just been launched in September last year.

Shreehas Tambe: Thanks, Kiran. Hi, Prakash, Shreehas here. So, as you know, we've launched Semglee at the end of the last calendar quarter of 2020. Our partner, Viartis, has already made a statement that they see a long-term revenue stream on this with a slower than usual ramp-up for these products. You've also seen that other similar products in the market in the first 12-months have had a single-digit market share. Then as you get to preferred or exclusive formulary status, the market share substantially increases.

We are quite confident about the way the US market will shape up. It's a substantial market, and we see that fiscal 2022, we believe that these numbers will favourably move in our direction.

Prakash Agarwal: **What I understood is it will see a slower than usual ramp-up, and it's calendar '22 is where you see the reasonable market share, would that be correct understanding?**

Kiran Mazumdar-Shaw: Yes. I think this whole business is very much dependent on formularies and contractual ramp-up. And this is expected to start now happening because this is a process-driven contract. So, we believe that these contracts will be drawn up, and that is what, I think, Mylan/Viartis has also shared. And once our product enters formularies, the ramp-up is likely to be much faster.

Prakash Agarwal: **And entering formularies is a function of interchangeability, and when do we expect that?**

Shreehas Tambe: So typically, entering formularies is a matter of timing as well, Prakash. So, as we get into the next calendar year, which will get opened up for review, we will see how those discussions will progress. A favourable formulary coverage will certainly work in getting a higher market share in the next fiscal.

Prakash Agarwal: **And the second question on Bevacizumab. Here, we have mentioned that we are waiting for the FDA, but if you could give some colour on the dialogue, if the dialogue is on, and have they given any timelines of the visit or given COVID, it is still uncertain?**

Sundar Ramanan: Prakash, our conversation with the FDA has been pretty fruitful, and as we mentioned, all technical items as of right now stand closed. No technical issues are outstanding with the FDA; the only component is the FDA's COVID-related ability to inspect our facilities.

When the FDA communicates with us, we will be ready to share that information with you appropriately. We're waiting for the FDA to show up at our door and inspect us at this point.

Prakash Agarwal: **And lastly, on the IPO plans, are we still on track with 12-18-month timeframe or there's a rethink there?**

Kiran Mazumdar-Shaw: It all depends, Prakash, on how quickly things come back to normalcy. It's difficult for us to forecast that because as you know our business also has been hit by COVID, and we want normalcy to return as soon as possible. As soon as normalcy returns, we'll be able to ramp up our business in a much more accelerated manner, and that will help us assess the timing of the IPO. But at this point, I don't want to comment on the timeline, but we are still aiming to do this in the next 18 to 24 months.

Keshav Botda: **Only one question what I had is currently on the manufacturing capacity of insulin, are we expecting any ramp-up? And what is the turnover we expect from insulin alone for the next two years, if you can give a tentative idea on that?**

Kiran Mazumdar-Shaw: As far as the capacities are concerned, we have capacities both in India and Malaysia. We can support the businesses that we are addressing both in the developed and emerging markets. And we believe that we are the only company in the US with both vial and cartridge approval for Glargine. And of course, as you know, we are also focusing on the insulin 10 cents opportunity. As far as all these opportunities are concerned, I think the capacities we have right now are adequate to support the kind of business we are addressing. But looking forward, of course, we have plans for a Phase-II expansion in Malaysia that will augment our capacity even further.

Keshav Botda: **How much turnover we can expect?**

Kiran Mazumdar-Shaw: No, we will not share the revenue information, but suffice to say that it's a very big opportunity.

Damayanti Kerai: **Kiran Mam, you're coming back in the executive role and Dr Arun taking over as MD of Biocon Biologics, what will be your initial priorities, and which are the areas which you believe were earlier not addressed and you should be doing that for a better pickup in the biosimilar sales?**

Kiran Mazumdar-Shaw: So right now, of course, we will focus on business opportunities in emerging markets in a very aggressive manner. We will focus on cost-cutting and cost containment as you know costs have increased significantly. So, we will be looking at some of these aspects

of the business. Of course, the most important thing for us to make sure that our R&D pipeline delivers on time.

Damayanti Kerai: **Regarding the normalcy in operations, we have seen the impact of COVID on our business for the last few months. So, at this point, we are almost reaching the end of January, how much we are back on normal operations compared to say if there was no COVID, and how fast do you believe we can go back to normal operations?**

Kiran Mazumdar-Shaw: So Damayanti, you know that some of the issues are associated with social distancing, zoning, etc., Now in our Bangalore campus, we are doing aggressive testing, and we are seeing that our test positivity rates are coming down, which helps us get back to normalcy much faster. In India, in general, the numbers are coming down, and of course, the Government has started vaccination. So, we are hoping that by the end of this fiscal we should return to pre-COVID kind of operations levels, setting us in a good position for next fiscal. However, in Malaysia, we continued to have challenges given the stringent Malaysian regulations. For instance, early December or late November, we had a few people testing positive in certain departments and whole departments needed to be shut down for at least two weeks. And that disrupted some of our product releases. So, these are the kind of issues we are facing in terms of logistics and supply chain. Now that vaccination is starting to be deployed, we believe the normalcy should return by the next fiscal year.

Damayanti Kerai: **And my last question is regarding the formulary gain for Semglee. So, if you can share more like what factors could help us in gaining formularies? Also, the challenges if a new player tries to gain formularies for their product in the market, some information about that will be helpful.**

Paul Thomas: As Shreehas and Kiran both mentioned, there is a process of working through the formulary cycles in different parts of the market viz. the Medicare segment, commercial segment, and PBMs also have a role. There is a negotiation process discussion of the value that Semglee can add in the various context. That's a customer-by-customer process, and there is an annual cycle to these formularies with some other review processes during the year. And discussions are going on. We do expect these to come on as we go through the year.

Damayanti Kerai: **The majority of the formulary contracts will be up for discussion in the calendar year 2022 or 2021?**

Paul Thomas: Based on the timing of the approval of Semglee, there were formulary decisions that were already made for calendar 2021. But we expect that some opportunities depend on the segment of the market and the type of customer. There are remaining opportunities in 2021 and more opening in 2022.

Neha Manpuria: Kiran ma'am, based on your comment that we will reassess the timeline on the \$1 billion targets for biosimilars and the fact that we are focusing on the business opportunities in emerging markets, should I read into this as the US and Europe will probably not contribute or not see a significant ramp-up from here? How should I look at the incremental ramp-up in the biosimilar revenue over the next year?

Kiran Mazumdar-Shaw: No, not at all. I think the US and Europe will be contributing to this in a very important way on a go-forward basis. We are saying that many of the emerging market (EMs) growth story was also baked into our \$1 billion targets, and that is what we have fallen short of during the last few quarters. We believe we need to address EMs in a very robust and aggressive way. So, it's not about the US and Europe growth story that we are focused on, we are also focused on the emerging market opportunity.

Neha Manpuria: What impacted the emerging market opportunity -- was it purely COVID? Or do you think there were certain issues internally that we need to address, either by way of logistics or capacity at the Biocon end?

Kiran Mazumdar-Shaw: No, we have also mentioned that many emerging markets are dependent on tenders. And I think a lot of these tenders have been delayed in the sense that I just mentioned. Even we benefited from that, for instance, the off-take agreement was extended by a year. Normally, it would have been again brought back to a bidding process, but this was extended. Most governments preferred to extend the tender contracts rather than opening up new tender contracts during COVID. That has affected us in a big way. So, we expect all this to open up, which will help us build this business very aggressively.

Neha Manpuria: And on the margin trajectory for Biologics, as the revenue ramps up, when should we expect inflexion in the margin profile of the Biologics business, or do you think that will probably be lower than the revenue ramp-up because of the investment?

Kiran Mazumdar-Shaw: No. I think if you've seen our numbers in the past, it's all linked to a very good revenue line. And today I think we can get back to those margin numbers if our revenues are much higher. So, it's all about economies of scale, it's about getting much higher revenue lines, which falls to the bottom line quite fast.

Shyam Srinivasan: If you could help us understand the Biocon Biologics' split into MoW and developed for the quarter? I recollect that \$1 billion targets had to be 60:40. Now hearing your commentary, Kiran ma'am, I'm just trying to see where do you think this will now change, right, forget the \$1 billion target, looking at your efforts to improve emerging market contribution, how should we look at that, right? Since it's more tender like you're saying, should we now kind of structurally expect lower margins for the Biocon Biologics subsidiary?

Kiran Mazumdar-Shaw: No. Our estimate for the \$1 billion compositions of developed and emerging markets remains the same. I think you should look at the 60:40 split. I think right now we've just gone through a little bit of a blip the business has been affected by a contribution from the developing markets or the emerging markets in a way that brings down the top line significantly. So, I think that's what has affected our performance.

Shyam Srinivasan: **The second question is on the agreements with Mylan and Sandoz. Maybe some of them are on track, but just trying to understand from a forward path perspective are changing how we would be dealing with the partner?**

Kiran Mazumdar-Shaw: No, not at this point at all.

Shyam Srinivasan: **And my third question is on the generic business. We have had certain operational issues as you highlighted but just wanted to get some comfort. It's been starkly different from how the rest of the guys have performed both on formulations and API. So, if we could get the split of API and formulations like we do every quarter. And has there been any divergence in those two businesses for the generics, please?**

Siddharth Mittal: Shyam, the split remains to be like in the previous quarter 80% revenues from API and 20% from formulations. I think more than the operational challenges, what we said is that we saw a good H1 because when the pandemic had just hit, there was a lot of supply chain disruption, especially in China. Many of our customers bought additional inventory to ensure that they are not out of stock on their formulations. Now we see normalcy and the inventory level is going back to pre-COVID days. So, our API revenues have come down this quarter compared to the run rate in the first two quarters.

On the formulations side, we are looking at it as a growth driver. However, we faced challenges related to delay in new approvals because of Covid-19 restrictions. We have had a couple of products under review, which we could have launched had FDA visited and inspected our facilities. We do not have any pending information request or Complete Response Letter (CRL), just the facility has to be inspected, and hence, we cannot launch these products.

As we have said in the past, generics' growth will fundamentally come on account of our formulations business. The API will show growth once we have our new immunosuppressants facility, which we are setting up in Vizag and shall take anywhere between 12 to 24 months.

Shyam Srinivasan: **Are we reevaluating CAPEX given probably delay in some of our approvals, if you can highlight us or the updated CAPEX outlook?**

Siddharth Mittal: Well, fundamentally, there is no change in terms of the CAPEX projects. We will invest because it is essential for our growth for all our businesses.

However, the timing might get deferred a bit as we've seen some of our existing Capex projects delayed by 3-6 months because of COVID.

In terms of overall guidance, we have given at group level, it might just get deferred by a year or so, but not going to get reduced.

Kiran Mazumdar-Shaw: As you know, most of our CAPEX in our Biologics business has been already invested. We have very little CAPEX to invest in apart because we will look at the Phase-II investment in Malaysia soon.

Nithya B: **My question was on the price erosion you witness in biosimilars in the US. So, if you look at CMS data, we see prices erode almost 10% every quarter the data is published. So, is it trending along expected lines, is it higher, any thoughts on how this is likely to shape up in the future and the impact it's likely to have on Biocon's gross margins?**

Kiran Mazumdar-Shaw: I think, Nithya, this is in line with expectations. I don't think this is anything which is out of line. We have baked this all into our projections and our calculations. We are concerned about these kinds of price discounts.

We believe that this is a market that is still very nascent at this point, and there are very large opportunities. I believe that Biocon Biologics is well poised to capture a large part of this market going forward. I think Viatris also remains very confident. We've had a temporary setback because of all the challenges I spoke, but we believe that we will be far more aggressive once normalcy returns.

Nithya B: **If I may ask a follow-up on that. But do you see a bit of short-term stress because your older products in the market, Pegfilgrastim, Trastuzumab, Semglee are likely to continue to see price erosion? But your newer products, unfortunately, are delayed because of the pre-approval inspection delays. So, is there likely to be a few quarters of stress?**

Kiran Mazumdar-Shaw: No, I think we mentioned that the ramp-up of Semglee is likely to take us into the next fiscal because, as you know, this is a very formulary-driven business.

Getting us into those formularies is a process-driven activity and, we need to get into those formularies which Viatris is already working in. And as you remember, we had just launched the product only a few months ago. So, I think it takes time to get into those formularies, and that's why I said that the ramp-up would only start happening next fiscal. Right now, it's an early entry into the market which has been very well received by the way.

In the future, we have a very comprehensive portfolio of products in the offering. As you know, Aspart also has received a positive nod from CHMP, and we expect the USFDA also to approve this product during this calendar year. We think that we will have a very

comprehensive product offering in the insulin segment. And I think you also are aware that Biocon also has recombinant human insulin, which it is pursuing with the USFDA, which will also come into play in the next calendar year. So, I think with all this; we are very, very positive and confident in the way we are going about the insulin segment.

Nithya B: **On Copaxone and your generics business, any update on whether you've refilled, and what is the progress on that CRL?**

Siddharth Mittal: We're working on responding to the CRL. We expect to respond over the next few months.

Sameer Baisiwala: **Kiran, is it possible for you to talk about your pipeline beyond bBevacizumab and bAspart? I remember, earlier the expectation was that there would be three more launches in fiscal '23 to '25 timeframe.**

Kiran Mazumdar-Shaw: We would like to do as soon as we enter the clinical phase, which is going to be very soon, at this point, we have at least three programs that should be entering the clinic very soon.

Sameer Baisiwala: **And would these three be all the Sandoz-partnered products or any of these would be your solo product as well?**

Kiran Mazumdar-Shaw: I cannot comment on that, Sameer. Please be patient.

Sameer Baisiwala: **Just on the Semglee comments for the US, are all the comments equally applicable for vial form and the pen form because, for a vial, you are the only player in the markets or are you getting any advantages over there?**

Kiran Mazumdar-Shaw: I think this is a question that Mylan/Viatris should answer, but certainly it should give us some advantage, but I think I would defer to our partner to answer that question.

Sameer Baisiwala: **And Kiran, what are the low-hanging fruits for the emerging markets?**

Kiran Mazumdar-Shaw: I think we have a large number of opportunities, for instance, our Trastuzumab and Glargine have just been approved in Saudi Arabia, we have had Pegfilgrastim approvals in a few of the developed markets. And I think there are several regulatory approvals that we've got in emerging markets which now become low-hanging fruits for us, and as you know, these are big markets.

Harith Ahamed: **My question is in the context of Christiane's departure and other changes you've announced at Biocon Biologics. So, over the past 18-months, significant time and effort have gone into giving Biocon Biologics a separate structure, a separate leadership team. You've announced a potential IPO and a \$1 billion sales target for FY'22. So, in the context of Christiane's departure and other changes, will there be a disruption to some of these efforts? And then this abrupt change in**

leadership, how much of an impact it will have on some of these initiatives that we've started over the last 18-months?

Kiran Mazumdar-Shaw: So, let me answer this question in two ways; one is, of course, that we don't see any abrupt disruption of leadership because we are seamlessly transitioning to a very old and mature leadership between Arun and myself. We understand the business very intensely, so I don't expect any disruption in leadership. We are looking at the global business and how it is being approached. And, as I mentioned earlier on, we are very committed to accelerating growth. This is something which Arun and I will be very focused on to address. We don't see any disruption in what we are doing and all the efforts because, as you know, this is a very R&D-driven effort, and it's a very commercial-driven effort. And we have two parts to our commercial strategy; one that is being directed by Viatrix; and one that we have control over in our own emerging markets. We will be making sure that we focus on unlocking all the business potential from our emerging market opportunity. And we will, of course, work closely with our partners to make sure that we also get the maximum benefit from the developed markets. While we've seen a temporary setback from COVID, I am very confident that even though we may not hit the \$1 billion target by FY'22, we remain very committed to seeing how quickly we can address that \$1 billion target.

Harith Ahamed: **My second one is related to my first question and sorry for pressing a bit on this point. Given the biosimilars business's nature, how important is it to have someone with a global biopharma background lead Biocon Biologics eventually? I understand the company is in safe hands for now. But eventually, would you be looking at a CEO who comes with a global biopharma background? And in the context of this abrupt departure of Christiane, would it be difficult for you to attract global biopharma talent into a CEO level at Biocon Biologics, your comments on that, please?**

Kiran Mazumdar-Shaw: Well, first and foremost, I think the biosimilars business is very different from a biopharma business which is being driven by the innovator companies. As you know, this is a very, very different business. So, I don't think it is necessarily true that you need a big pharma person to come and run this business. So, I think these are some of the things that we are looking at, and we will, of course, take the right decision at the right time. We believe that we understand the business, its challenges and competitiveness very well; we will make the right decisions to make sure that the business performs very strongly.

Tushar Manudhane: **Would like to know on the Insulin Aspart side also, is the site already inspected, or will it come under inspection as a part of the review?**

Sundar Ramanan: As you know, we are currently under the agency review, and the review is going very well. When the agency lets us know of the site inspection at an appropriate time, we will come and inform you of that as well. As with all programs, regardless of whether

they are located outside the US or inside the US, the agency as they come out of COVID will start inspecting the facilities as well. Prior approval inspection is part of the approval process. Therefore, we anticipate that the agency will inspect the facility at some point in time within the review cycle.

Tushar Manudhane: **Secondly, in terms of this formulary and then subsequent contracts, typically, these contracts renew at what frequency and when in the part of the year?**

Paul Thomas: Primarily, there's an annual formulary cycle of new formularies launched in January of the year, but there are mid-year reviews, and something like Medicare has more rigid timelines and fixed timelines whereas commercial formularies have some more flexibilities. But it's overall an annual process with some mid-year reviews.

Manoj Bahety: **I have a couple of questions. First one- these are early days for biosimilars considering the big opportunity ahead. Just wanted to understand the emerging competitive landscape. I just wanted to understand whether innovators reactions in terms of biosimilars coming to the market in terms of the pricing reduction. And also in this light, if you can give some colour like \$1 billion aspiration vis-à-vis sacrificing some margin if you have to take that call, how do you see this, whether this \$1 billion kind of aspiration will come at the cost of some margin?**

Kiran Mazumdar-Shaw: First and foremost, you are right; these are early days of biosimilars. As it happened in generics, the biologics originators will react aggressively by preventing biosimilars from encroaching their market share. So, they will start reducing their pricing. However, pure-play biosimilar companies like Biocon Biologics are aware of these kinds of pricing aspects. We have already baked in many of these assumptions about how much the discounting could be for us to reach our \$1 billion targets. I don't think any of that will change substantially.

Unfortunately, COVID came and stopped us in our tracks. If it hadn't happened, I think we would have seen a much faster ramp-up and a far greater accelerated pace of growth. In terms of competition, yes, we do anticipate competition from other players in the coming years. But as you know, early movers do have a great advantage of getting higher market share, and that's what we're focused on. And as soon as the COVID crisis is over, the strategies we had developed to gain greater market share will quickly kick in. So, I don't think you should view this \$1 billion opportunity as a commoditizing opportunity. I think we have baked in a lot of the pricing that we expect over the next five years, we have baked in a lot of the costing advantage that we have, and we have baked in the kind of margins we can realize based on the pricing that we have worked out to compete in the marketplace.

Manoj Bahety: **Overall dilution which shareholders can expect in Biocon Biologics Limited with private equity and the prospective IPO we are targeting, whether it will be 20% or 25% maximum dilution which will suffice our growth aspiration?**

Kiran Mazumdar-Shaw: I think we expect to go down to 75% for sure when we go for an IPO. Right now, we are at around 90%. So, I think going forward, we have factored that we will have to reduce to 75%. As you know, in a company like Syngene, we are at 70%. So, I think that's the kind of ballpark you can look at.

Bharat Sheth: **Kiran, just want to get your sense on entry into China with now Mylan, I mean, already forming a new company with Upjohn who have a presence in China. So how that will play out for us in the coming time?**

Kiran Mazumdar-Shaw: You're right, Bharat Bhai, that it's a big opportunity for Biocon, not just in biosimilars, but also in generics. And I think Mylan is well-positioned through Upjohn to get an entry into the Chinese market. And I think they are looking at this opportunity very seriously. And as soon as we get some regulatory colour on how soon that can happen, we will certainly share it with you.

Bharat Sheth: **Do we expect that somewhere in FY'22, I mean, first half or second half, that could be a probability?**

Kiran Mazumdar-Shaw: I would say it's a very big medium-term opportunity. I don't think I can call it this fiscal or next fiscal opportunity. It might happen, but I think we are looking at it as a sort of a medium-term opportunity, which is like three to five years.

Bharat Sheth: **What is the potential size for our addressable business in China?**

Kiran Mazumdar-Shaw: Right now, we really can't assess it accurately, but the Chinese market itself could be a \$1 billion opportunity.

Mitesh Shah: **My question is regarding the generic APIs. Apart from the COVID challenges, can you see the competition increase, especially since China is back in the market?**

Siddharth Mittal: Well, in the short term, we don't see any major change because to qualify our new source is not easy; it's time-consuming. All our customers have one or two options because they qualify one or two sources in their ANDAs and then buy from these one or two sources.

Fundamentally, we have not seen any market shift where either customer who has been buying from China have started buying from India or vice versa. There was some bit of rhetoric in between when COVID had just started where people were looking at derisking from China and sourcing from India. Even then, we believed that this would be temporary, and once the pandemic is nearing an end, things will return to normalcy.

Again, India does not have that large infrastructure on API manufacturing; the costs are higher; the regulations are quite stringent. It's going to take a long time to have a structural change. And we know the Government of India is working in bringing a lot of scheme and focus on local manufacturing. But again, these things will take time.

Mitesh Shah: **My second question is regarding the \$1 billion targets of the Biologics. Assuming the next year would be normalized, is it fair to assume that our target would not be postponed more than one year?**

Kiran Mazumdar-Shaw: Yes.

Shrikant Akolkar: **I would like to know based on the FDA's discussion have you received the next review date for Bevacizumab?**

Sundar Ramanan: The inspection hasn't been announced yet. And so, once we get clarity on it, we'll be happy to share.

Shrikant Akolkar: And we also have a couple of more biosimilar products. So, are we expecting any delay on those, for example, insulin Aspart rh-insulin?

Sundar Ramanan: At this point, no. We are on track, and things look as stated before.

Shrikant Akolkar: **On the small molecules business, last quarter, we said that our capacities are running at full utilization, but now that inventory is going back. So how should we look at the growth rates in the future at least for FY'22?**

Siddharth Mittal: I think I had mentioned earlier and even in the past that for our API business, we expect a mid-single-digit growth level, and for our formulation, we expect growth in high-teen levels. Overall, we will look at growth between 5% to 10% over the next one to two years for the segment.

We've also stated in the past that we are rebuilding this business. Our focus obviously for the last many years was on biosimilars business. And as we start to reinvest in this business in terms of the pipeline and the capacity, it will take time. The rebuild takes a couple of years, and we should start seeing good growth starting in the next two years or so.

Shrikant Akolkar: **And the last question on the Generic Formulations. If you can share some market share of some of our products would help us?**

Siddharth Mittal: We have currently four products launched. We've recently launched Tacrolimus. Again, it's very early days. It's a similar story as Semglee. We need to gain formularies, and the contracting cycles all start this year. But the three products that were launched earlier were the three statins; Atorvastatin, Rosuvastatin and Simvastatin. And for all the three statins, our market shares are between 15% to 20% in the US.

N Balasubramanian: **Just wanted to understand if there are any updates on the interchangeable file you have placed at the USFDA for Glargine?**

Sundar Ramanan: We had a very productive meeting with the FDA, and we are fairly optimistic and confident that we're going to secure that designation fairly soon. The meeting went very well with the agency.

N Balasubramanian: **Can you guide us on is there a TAT date or any particular date to watch out?**

Sundar Ramanan: We don't have it just yet, but once we get clarity on that, we will get that across to you.

N Balasubramanian: **And would this require a pre-approval inspection because this is a site that's already been inspected?**

Sundar Ramanan: At this point, the agency hasn't communicated that this transfer requires an inspection. And so far, we are fairly confident that it's (approval) going to come fairly soon.

Charulata Gaidhani: **My question pertains to the biosimilars, excluding insulin. When do you see a market share ramp-up? In case of Pegfilgrastim, there was approval from Express Scripts, so we expect a ramp-up from 2021. So how is that placed in the current situation? Secondly, whether the Malaysia breakeven has happened or is that also delayed?**

MB Chinappa: I'll answer the second question first and Paul, if you could chip in on the increased market share. Charulata, for the quarter, it's still a loss for Malaysia, but we expect Q4 and FY'22 will be a positive territory.

Paul Thomas: And on the oncology, I'd say, in that institutional market, the role of a PBM formulary like Express Scripts is not material, it's not very relevant in that market. So, I wouldn't look at that. But what I would say is that the shares for both of those products have been holding quite firmly in the face of competition. We have seen some gains, and we've seen a recent week up to 9%, around 7%, those ranges. And so that continues to grow. Viatrix continues to hold a strong position and add new customers. So, I think this will continue over time across segments.

Moderator: **Well, ladies and gentlemen, that was the last question for today. I would now like to hand the conference over to Mr. Ankit Gupta from Biocon Investor Relations for closing comments. Over to you, sir.**

Ankit Gupta: Thank you, everyone, for joining us today. We look forward to seeing you in the next quarter. If you have any follow-up questions, you can reach out to me anytime. Have a good day and thank you once again.

- Ends -

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