

Transcript

Biocon Limited Q1 FY21 Earnings Conference Call July 24, 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. Paul Thomas – Chief Commercial Officer, Biocon Biologics US
- ✦ Dr. Gaurav Laroia – Chief Strategy Officer, Biocon Biologics
- ✦ Mr. Peter Meeus – Head Portfolio & Products, 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
- ✦ Shyam Srinivasan – Goldman Sachs
- ✦ Neha Manpuria – JP Morgan
- ✦ Nithya Balasubramanian - Sanford Bernstein
- ✦ Surya Patra – Phillip Capital
- ✦ Sameer Baisiwala – Morgan Stanley
- ✦ Raj Mohan – Professional Investor
- ✦ Nitin Agarwal – IDFC Securities
- ✦ Charulatha Gaidhani – Dalal & Broacha
- ✦ Tushar Manudhane – Motilal Oswal
- ✦ Yatin Mohane – Iroha Investment Management
- ✦ Vishal Manchanda – Nirmal Bang

Prepared Remarks Session:

Saurabh Paliwal: Thank you, Bikram, and good morning, ladies and gentlemen. I welcome you to Biocon Limited's Q1 FY'21 Earnings Conference Call.

Before we proceed with this call, I would like to take this opportunity to remind everyone that a replay of today's discussion will be available for the next few days about an hour following the conclusion of this call. The call transcript will be available on our website in the coming days.

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

I would like to take this opportunity to remind everyone about 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 may be expressed or implied by such forward-looking statements.

After the end of this call, if you need any further information or need clarifications, please get in touch with me.

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

Kiran Mazumdar-Shaw: Thank you, Saurabh. Good morning, everyone. I welcome you to Biocon's Earnings Call for the First Quarter of FY'21. I hope all of you and your families are keeping safe in these very challenging times.

Let me start with a **"Quick Update on the COVID Situation."**

Starting with operations, we started this fiscal with a skeletal staff through April and started gradually ramping up from May, ensuring strict workplace protocols to maintain a safe and infection-free working environment. I am happy to share that as of June, we have ramped up our manufacturing operations to pre-COVID levels. Supply chain and logistics situation has now fully normalized, and we continue to maintain good safety stocks for key raw materials and finished drug products from a business process continuity perspective. The vertical integration further helps us to have a better control on our inventory management.

In recent weeks, we have seen a huge increase in the number of COVID infections in Bangalore resulting in the state government putting the city under lockdown once again. While the lockdown has now been removed, several industries, including pharmaceutical, manufacturing were allowed to work unhindered and employees were allowed to go to work. This was clearly good news for us, our customers and all the patients across the world who rely on the medicines produced in our various facilities. However, as a precautionary measure, we have asked a substantial number of employees, especially those under support functions, such as Finance, Marketing, HR, IT and administration to work remotely from home. Employees in manufacturing, quality and R&D continue to report at the required strength to our various sites. We are monitoring the situation on a daily basis to ensure that both safety of our employees as well as the continued normal functioning of our operations.

On the research front, Biocon and Syngene have been actively addressing the COVID-19 challenge. While Syngene has established an accredited virus-testing laboratory and has developed an ELISA antibody test kit, Biocon, as many of you would have heard has repurposed its psoriasis drug, ALZUMAb, for the treatment of moderate-to-severe COVID-19 patients who develop what is referred to as the 'cytokine storm'. ALZUMAb or Itolizumab received restricted emergency use authorization from CDSCO on 12th of July and since then the drug

has been extensively used across the country with very promising outcomes. In fact, ALZUMAb is the only biologic with a restricted emergency use approval for CRS in COVID-19 patients. Our US partner, Equillum, is also very encouraged by these results and is planning to initiate clinical trials in the US at the earliest.

Moving on, I will now present the “**Key Financial Highlights for this Quarter.**”

Post completion of our group restructuring in FY'20, the operating segments have been realigned effective April 1, 2020. Branded Formulations business has merged with Biocon Biologics and Novel Biologics has been carved out as a separate business segment. As a result, the four new operating segments are **Generics, Biosimilars, Novel Biologics and Research Services, i.e. Syngene**. You will find us reporting in a very granular way in these four verticals.

Generics is the new name for our Small Molecules segment. It will continue to reflect numbers that pertain to our APIs and Generic Formulations businesses, including our ANDA business.

Biosimilars will include performance numbers for **Biocon Biologics** as well as Biocon FZ, which is Biocon's subsidiary in the UAE. Biocon Biologics business comprises development and commercialization of insulins and insulin analogs, antibodies and recombinant proteins as well as the India-branded Formulations business.

Novel Biologics will be a distinct segment from now on. It will house the P&L for the Novel Biologics assets. Assets in this segment will be those housed under Biocon Limited, which are namely Insulin Tregopil, which is our oral insulin program, Itolizumab and BVX-20.

In addition, our US-based subsidiary, **Bicara Therapeutics** will also be included. Bicara is developing a pipeline of bispecific antibodies, and I am pleased to inform you that its lead asset, BCA101 has entered the clinic in the US.

The **Research Services** segment represents the financials of **Syngene**, and there is no change here.

Now moving to “**Numbers.**”

In the first quarter of FY'21, we delivered a year-on-year revenue growth of 14%, wherein **Total Income** increased from INR 1,483 crores last year to INR 1,690 crores in Q1 FY'21. If you recall, that after the drop in earnings seen in Q4 of FY'20, we had said that Q1 of FY'21 would be a recovery phase. And this is what it is.

We recorded **gross R&D spends** of Rs.142 crores for this quarter, which corresponds to 11% of revenue ex Syngene. Of this, Rs.107 crores is expensed in the P&L while the balance amount has been capitalized. The increase in R&D spends reported in the P&L statement is on account of higher spends in our Biosimilars pipeline.

During the quarter, we booked a **Forex loss** of Rs.4 crores as compared to a loss of Rs.1 crore last year. This amount is reflected in the other expenses line of the P&L statement.

EBITDA for the quarter was down 6% to Rs.432 crores. EBITDA margins for the quarter stood at 26%, down from 31% reported in the same period last year. The reduction in EBITDA margin during the quarter is

attributable to our Biosimilars business that saw greater R&D spend and lower profit share contribution from our partners.

Core margins, i.e. EBITDA margin net of licensing impact of Forex and R&D, stood at a healthy 32%.

Net profit for the quarter was Rs.149 crores. Adjusting impact of discontinuing operation, net stood at Rs.153 crores.

Coming to reviewing “Business Segments Performance for this Quarter.

In terms of our **Generics business**, this reported a very strong revenue growth during the quarter with revenues at Rs.599 crores, up 16% from last year. The segment’s PBT margin for the quarter stood at 17%, up 2% over last year, driven by higher revenue.

The API business witnessed a higher demand of certain key APIs across global markets as customers picked up stocks to ensure continued availability of drugs for patient serviceability. Generic Formulations business also reported strong growth over last year.

We had no impact of COVID on supply or demand of our products as they are needed for chronic therapy.

As a strategy for expansion of our Generic Formulations business, we entered into an agreement with DKSH, a leading market expansion service provider with a focus on Asia, to sell and distribute seven of Biocon’s Generic Formulations in Singapore and Thailand under Biocon’s brand name.

I would now like to give you an **update on NeoBiocon**, our JV in UAE with Neopharma. Given the decision to wind up a large portion of UAE Branded Formulations business, results of UAE operations have been classified as discontinuing operation. Revenues amounting to Rs.22 crores for Q1 FY’21 and Rs.7 crores for FY’20 have been excluded from segment reporting. As part of the winding up process, we are in discussion with few interested buyers to acquire the business, which will include both the brand as well as employees.

Biocon Biologics however will continue marketing its biosimilars portfolio in the UAE.

Now coming to **“Syngene.”**

Syngene reported a flat performance as compared to last year with revenues of Rs.422 crores having been impacted due to the temporary suspension of operations during the nationwide lockdown. During the quarter, there was strong performance in Discovery Services and Dedicated Centers. We expect Syngene to return to growth, Q2 onwards.

During the quarter, apart from COVID-related initiatives, as mentioned earlier in my remarks, Syngene has signed a voluntary licensing agreement with Gilead for manufacturing and supply of Remdesivir in India and 127 other countries.

I will now hand over the section on **Biocon Biologics** to the CEO of Biocon Biologics, **Dr. Christiane Hamacher**.

Christiane Hamacher: Thank you, Kiran, and good morning, everyone.

We are pleased to report that our Biologics business recovered in Q1 in line with what we indicated in the previous investor call. I like to point out that our total quarterly revenues are at an all-time high at Rs.689 crores. This marks a sharp recovery from Q4 of fiscal year '20 revenues of Rs.453 crores. EBITDA for Biocon Biologics is also up at Rs.196 crores from Rs.92 crores reported in Q4 last year.

When we compare performance versus previous year, I like to note that Biocon Biologics profits were particularly high in Q1 last year due to higher profit share from Pegfilgrastim because of increased supply to the US market. Q1 performance of this year is more in line with the average performance of full year fiscal year '20. We expect this to increase in the coming quarters on the back of higher revenues.

While we did capture in Q1 the revenues lost due to logistic challenges in Q4 of fiscal year '20, we have also seen a strong demand coming from Most of the World Markets, in particular, Latin America and the Africa, Middle East region. Growth was driven by Trastuzumab and our Insulin portfolio.

Regarding the US, we have seen a steady but gradually improving demand.

Trastuzumab has seen a positive trend in market share increasing to mid-single digit. The market share of Pegfilgrastim has been maintained at 6%, indicating a solid underlying demand despite increasingly competitive dynamics. For both of these products, we expect that new contracting will further enhance the demand as our partner, Mylan, continues to establish itself in the Biosimilar market.

Furthermore, we are very pleased to have received the US FDA approval of Semglee, our Biosimilar Glargine in June. Semglee is our third product under the Biocon-Mylan collaboration that has received approval for the US. We are convinced that the imminent launch of Semglee in the US will drive increased revenues as we tap into the US\$2.2 billion Glargine market opportunity.

In addition, new launches in EU will contribute to revenue growth in the coming quarters as we expand our presence in the EU, including major markets.

In our ambition to constantly innovate, we are also pleased to announce the global collaboration with Voluntas, a leading player in digital therapeutics. Through this partnership, we will develop and distribute a unique digital therapeutic to support people on our insulin in managing their diabetic condition towards better outcomes, quality of life and thereby a reduction in overall healthcare costs. The exclusive licensing agreement will make Biocon Biologics one of the first insulin companies to offer a US FDA-cleared and CE-certified digital therapeutic to patients across the world.

We continue to set ourselves up in our ambition to strive towards global leadership in Biosimilars with the following progress.

- ❖ The review of our BLA for Biosimilar Bevacizumab by both US FDA and EMA is progressing as per plan.
- ❖ We are on track with the development of Insulin Aspart with our partner Mylan. In addition, at Biocon Biologics, our Recombinant Human Insulin program is progressing well under the 351(k) pathway.
- ❖ Furthermore, our Biosimilar Pegfilgrastim in Europe is in early stage of launch by our partner, Mylan. Also, Mylan expects to launch Biosimilar Etanercept in Europe in the second half of this calendar year. In, Biosimilar Etanercept, Biocon Biologics has shared economics.
- ❖ Our partner, Mylan, received US FDA approval for Hulio, a biosimilar to the world's top-selling drug Humira. In accordance with its patent license agreement, Mylan will be able to launch in US in July 2023. Biocon has shared economics in Hulio.

Overall, we are on track to have at least eight biosimilars being sold in developed markets by end of fiscal year 2022, addressing a market opportunity of approximately up to US\$33 billion. We anticipate that our pipeline will deliver at least three additional molecules between FY'23 and FY'25 after which we expect to launch an average of two molecules per year.

COVID has imposed a lot of pressure on healthcare systems across the world. Therefore, we are convinced that access to affordable biosimilars will play a bigger role than ever before. We are working together with governments, healthcare authorities and international organizations to make our inclusive healthcare solutions available to patients across the world.

I would like to reiterate our guidance of meeting the US\$1 billion revenue target in FY'2022.

I now hand it back to Kiran for her closing remarks.

Kiran Mazumdar-Shaw: Thank you, Christiane. I would like to conclude by saying that we have begun FY'21 on a confident note with both Generics as well as Biosimilars segments reporting strong growth numbers. The performance in Q1 should act as a good setup for the coming quarters where we expect continued and improved traction across our business segments, especially in Biosimilars with the launch of Insulin Glargine, expected shortly in the US. We do look forward to a strong year ahead provided there are no more unforeseen surprises from the pandemic. Thank you.

Q&A Session

Prakash Agarwal: *My first question is on Biosimilars offtake. So the commentary in US, the margin recovery is largely due to recovery in Pegfilgrastim? And the second part to that is, how is the biosimilar offtake now given the hospital setup is still working on skeleton staff and people still do not want to go to hospitals, so how are you seeing the June, July, How it has been in terms of Biosimilar offtake, especially in your large products, Peg and Trastuzumab?*

Christiane Hamacher: Thank you for your question. First, I want to reiterate that also Trastuzumab sees a very positive trend in the market and that we are seeing market shares in the mid-single digit. What we are seeing is that Trastuzumab, Pegfilgrastim are lifesaving treatment for life threatening indications. So we are seeing that patients are coming back to the hospital and we are seeing that clearly these medications need to be given. However, what I want to point out here is that for all medications, we are seeing a higher need for telemedicine and home care across the world. We therefore, are also are very proud that we have the partnership with Voluntis because it will be important in the future that there are solutions so that medications can be given at home instead of being in the hospital and what also means higher cost. Paul, please add to the US market and the specifics.

Paul Thomas: Sure. I think you have covered it very well, Christiane. I think the COVID impact definitely we have seen normalization overall. I think for specific case-to-case things, I think Mylan would have to comment in any further detail. Nevertheless, we see this normalization overall in the market because of the severity of it and the importance for these patients to continue to get treatment. Moreover, the profit impact is broad-based; it is across products and regions also.

Christiane Hamacher: And in this context, we expect that contracting will be back to normal which will also further enhance the demand.

Prakash Agarwal: *My second question is on trying to understand the Trastuzumab scale up better. I mean when I see it versus Amgen who launched earlier, got good market share. Could it be due to bundling? And with our launch of Insulin Glargine coming, would we be also in a position to start bundling given that we are one of the three players in Insulin Glargine, would we be able to bundle other products in the Biosimilar space as well or it does not work that way?*

Christiane Hamacher: So while we are not commenting on specific marketing strategies, it is very clear that a portfolio of Biosimilars plays a major role. When it comes to Trastuzumab, Biosimilars and the other molecules in the US market, Mylan has clearly indicated that they are focusing on commercial execution. The Biosimilar market is new. All companies are certainly observing the market and are having learnings. We are confident that we see continuous increased performance. Therefore, the point on bundling, we do not call it bundling as well when it comes to portfolio. We are in a very strong position because with Trastuzumab, with Pegfilgrastim and the Biosimilar for Glargine, we are having three molecules now in the US market. While a portfolio is important, it is important that for every customer in the US, there are tailor-made strategies when it comes to contracting. Paul, please add some specifics if you like.

- Paul Thomas:** We have our portfolio of biosimilars now in cross-segments also now. In addition, Mylan brings a broader portfolio in existing relationships to build on as well. Therefore, I think we are looking forward to leveraging that with the Semglee launch. It is competitive as we already mentioned, but there is a presence there and it is a payer driven segment that can be centrally driven, there is an unmet need, as we talked about. Affordability is still a space where there is need for improvement in the US market and I think we look forward to be part of that solution.
- Shyam Srinivasan:** *My first one is on the Biosimilars revenue. I recollect historically it used to be EM loaded, in the sense, higher. If you can share us a split of Biosimilar revenue now in terms of geographical split, some kind of EM versus non-EM kind of a split please?*
- M.B. Chinappa:** Last year, we ended with developed markets closer to 60%. This year Q1 we started with very strong growth in the MoW markets and all the rest of the world markets. For Q1, MoW markets is just above 50% of our total revenue.
- Shyam Srinivasan:** *Chini, if you can help understand because the segmentation changed, right, and now we have Branded Formulations in there. So like-for-like, what you are saying is 50% is MoW today, am I understanding it right?*
- M.B. Chinappa:** Just above 50% and it is like-for-like when I mentioned.
- Shyam Srinivasan:** *Yes, Q1 MoW growth versus last year Q1 MoW growth in the new segmentation. So what could be the kind of growth across these two segments? Maybe that is the underlying question actually.*
- M.B. Chinappa:** Q1 MoW growth has been much stronger and that is why the mix has tilted in favor of the MoW markets. As we see the full year play out, we see strong growth coming from both MoW and developed markets.
- Christiane Hamacher:** And we expect that the shift will move to developed markets.
- Shyam Srinivasan:** *In terms of the margin profile between these two, do you think it is blended together very similar or do you think these are widely different in terms of the margin profile?*
- M.B. Chinappa:** We do not give margins by market. US is the highest priced market in the world.
- Shyam Srinivasan:** *Second question is on the launch of Semglee and just the dynamics in the US and the dynamics around substitution versus interchangeability. Is there any updated thoughts you could share?*

Sundar Ramanan: This is Sundar Ramanan, Regulatory Affairs. As you know, the agency has issued guidance for insulins that specifically talked about the pathway that will lead to a faster interchangeability of insulins. For now, we are actively working with the agency. Once we get to know the path, we will be happy to share the details with you. I would like to add interchangeability would certainly help adoption and ramp-up of market share, but not a showstopper for us.

Shyam Srinivasan: *Mr. Sundar Ramanan, is it imminent? Or do you think this is work-in progress, six, 12-months for this to come through? And the launch will be irrespective of this like you were saying. So we should assume it is a more traditional like how we did Pegfilgrastim and Trastuzumab assuming that we are having interchangeability on day one?*

Sundar Ramanan: So once we get clarity on interchangeability, we will be happy to share them with you. As of right now, we are working with the FDA on the fastest way to get to the market to get interchangeability.

Christiane Hamacher: The Insulin market segment is of high interest for us, #1. There is so far only one other biosimilar in the market in the United States. It is a market segment of US\$2.2 billion that we are actually tapping into. Mylan also in the portfolio has other treatments for diabetes. Mylan is very well placed based on the experience in contracting to make Semglee a real success in the United States with the focus now on commercial execution.

Shyam Srinivasan: *On the generics side, if I can understand how Formulations versus API has worked, and there are some qualitative comments on the demand being even better, so, if you can share the qualitative color please?*

Siddharth Mittal: The split between API and Generic Formulations is 80%: 20%, 80% being API. Demand for Formulations has been strong, so has been the demand for APIs because obviously, the customers to whom we are supplying the APIs have seen a good demand for the Formulations that they are selling in these markets. We continue to see a good traction in this business with good underlying demand and a stable pricing environment.

Neha Manpuria: *My first question is on the Biologics revenue. I just wanted to understand your commentary that market share for Ogivri and Pegfilgrastim is improving versus let us say earlier this year. However, you also mentioned that the profit share is lower this quarter. Could you give us some color as to why the profit share even if I look at a performance and the lag is not reflecting the underlying Biologics momentum let us say in developed markets or in MoW?*

M.B. Chinappa: When we mentioned there is a different profit share, we were actually referring to a comparison to Q1 of last year where we had very high profit share consequent to some increased supplies were able to ship to the US markets. When you look at the profit share for this quarter, it is more in line with the average of last year. As we indicated with higher market share of products already marketed and then the launch of Glargine, we expect this to improve going forward.

Neha Manpuria: *Chini, if that is the case, then if I were to look at your EBIT margin at 15% versus let us say even if I were to ignore the first quarter, my margins for the second and third quarter last year was about 25%. I understand that the costs for biologics has increased, but has the cost increased to that extent despite the higher share from Ogivri in US and higher share in Peg, our EBIT margins are not reflecting it?*

M.B. Chinappa: Again, I will point you to the EBITDA margins. Last full year EBITDA margin was 33% where the margin in Q1 was much higher because of this higher profit share. Therefore, I do not want to compare against Q1. I am more pointing to comparing with the average of last year. This year the Q1 numbers on the margin front are slightly soft; at 28% versus the average of 33%, but we see that climbing back to 33% in line with the guidance for the year. We had said that we expect to maintain EBITDA margin at the same level as last year. Therefore, what you are seeing in Q1 is just an effect of multiple things. When you average it over the year, it should play out at 33%.

Neha Manpuria: *As our revenue momentum improves, the profit share therefore, should improve, right? Whatever happened in this quarter or the last few quarters in terms of profit share is not reflective of our underlying Biologics performance?*

Kiran Mazumdar-Shaw: If you remember, we told you that this quarter would be a recovery quarter and the growth will only start from Q2 onwards. We are very confident that starting Q2, you will start seeing better contribution in terms of our margins and our profit growth.

Neha Manpuria: *My second question is on Peg and to some extent on Ogivri. First on Fulphila, at least the secondary data that we have seen that market share is at about 6% for Peg for the last few months and even though volumes have recovered in the month of June, I know it is just one month of data, our market share has been flat. So, how confident are we of improving market share, given, one, we have seen new players come in? And second, we have seen the largest biosimilar player in the market seeing a recovery in market share? Also, if you could comment on your views on pricing given higher competition in both Trastu and Peg?*

Christiane Hamacher: I will start and then I will hand over to Paul. What we have seen with Pegfilgrastim is that 6% of market share was maintained despite the increasing competition. This is the dynamic there. As I stated before, Mylan has clearly said that they are focusing on commercial execution. Therefore, we expect that, in particular, the contracting will further contribute to an increased demand and penetration for Pegfilgrastim in the United States. With Trastuzumab, we have seen a positive trend. In addition, it is important to note that with Trastuzumab and Pegfilgrastim, we have two products in our oncology portfolio. What I expect because it is a Biosimilar market, more disciplined behavior when it comes to price decreases compared to generics.

Paul Thomas: I think the Ogivri trend is really quite a nice trend over the past quarter and so we look forward to that continuing. Pegfilgrastim, I think in the face of competition holding that level has been positive and we look forward to it building from there. The expanded capacities are in place at this point. Payer coverage for both products is strong and there are new contracting starts. We look forward to building on this space going forward. We still are looking for continued growth here.

Nithya Balasubramanian: *So my question was actually on your Semglee approval and launch. You mentioned earlier that Mylan has existing commercial capabilities in diabetes. So, if you can give us a bit of color on what capabilities and commercial infrastructure they already have because my understanding was that they do have a primary care sales force but they will have to invest to start covering endocrinology, so help us understand what their current capabilities are?*

Christiane Hamacher: Thank you for the question. We certainly cannot comment about details of strategic marketing plans or the operational details. However, what we can say is that Mylan also in that area has a strong execution focus and is very confident that they have the necessary capabilities and reach to make an impact when it comes to interactions with healthcare professionals, with payers, and so on. I think Mylan is in a very good position to drive the uptake.

Nithya Balasubramanian: *If I might ask you a follow-up question, I can understand you cannot reveal details, but I tell you where the confusion stems from because right now, you are a "Follow-on Biologics" but in the near future, you are expecting interchangeability. So while we do not have clarity on when that interchangeability is likely to come through, is Mylan likely to make additional investments, which would be required to push through a branded product in the Diabetology space?*

Christiane Hamacher: Couple of comments: One is on interchangeability. What we have seen in the US is that PBMs are willing to switch products without interchangeability. Therefore, that

is very important for the market uptake and to understand this context. In addition, interchangeability for insulins from our perspective and as explained before is not a must-have because switches to other molecules are happening. That is at a payer basis, that is at a PBM basis, and that links back to contracting where Mylan has a strong position with the resources and with the capability.

Nithya Balasubramanian: *If I might, again ask a follow-up question, my question is not whether payers will be able to switch because we have seen that happen in the case of Basaglar as well, right, so I do imagine payers to put Mylan Semglee on the formulary depending on how you are contracting. My question was more towards if additional investment is required in the period between your launching now versus when you get interchangeability, is Mylan making additional investments now, is that something you can comment on?*

Christiane Hamacher: This again has to do with the strategic marketing plan, with the execution on the ground, with the operations. Mylan would be in a best position to answer that, but we are also not revealing the details how we execute and what the strategy is behind including investments.

Paul Thomas: I think I just reiterate that, it is not a black and white is interchangeability or the other extreme, right. You yourself have said there is plenty of payer driven activity here without interchangeability. Therefore, there are many nuances to this.

Surya Patra: *In fact, ma'am, you have indicated that the new contracting would be improving the Biologic revenue going ahead. So just wanted to have a sense that whether the new contracting for the Pegfilgrastim for the 340B program has started and that is now reflective in the numbers? And now having three products in the portfolio for the year, how is the contracting scenario that you are anticipating for the near future if you can just give some color on that front.*

Christiane Hamacher: So the US market for each therapeutic area and products have specific segments for contracting. For oncology, there are huge institutions like Texas Oncology, Tennessee Oncology. There is community oncology practices and there are 340B. For all these segments, specific targeting, contracting approaches are required. Mylan is very well versed in coming up with specific approaches to segments. That is true across our portfolio because every customer needs a targeted approach and with the focus on execution, we are confident that we will see an increased market penetration.

Surya Patra: *On the 340B, have we have already started seeing any benefit?*

Christiane Hamacher: We are not giving any specific comments on any specific segment.

Surya Patra: ***If you can just share your thought process and idea about the Insulia tie-up. How is that fitting to our overall strategy for the insulin for the global market? And what really practically it can mean for Biocon Biologics?***

Christiane Hamacher: I just start with the comment and I will then hand over to Gaurav Laroia, our Chief Strategy Officer. We are proud that we have joined hands with Voluntas because it is a leader in digital therapeutic. Moreover, what a digital therapeutic is, it is a therapeutic intervention that we want to pair with our own insulin portfolio to have a better outcome for patients and also savings for the healthcare system. It is not an app it is a therapeutic intervention. I hand over to Gaurav to guide you through how it works and how we see these strategies evolving.

Gaurav Laroia: Just to set the context of how it works, as Christiane mentioned, it is an FDA-approved CE marked digital therapeutic, which has clinical trial and the world evidence data to show that it can help bring in control the HbA1c levels at a personalized level of a patient. So, it is getting into personalized therapy at a patient level. So, it is a tool given to people with diabetes who are getting on insulin or have uncontrolled diabetes. So how does it fit in? First, I will just say the size of the opportunity. Obviously, 0.5 billion people globally have diabetes. \$725 billion spent on diabetes globally. \$50 billion from 2015 to 2017. The increase in diabetes is projected from now to 2045 is 48% globally. Moreover, 10 million adults added to diabetes from 2015 to 2017. Therefore, the number of people who need help in managing their condition is only growing, right. The second point I would like to highlight is that diabetes called often as a disease of halves. Half the number of people who have diabetes are diagnosed, half the number of people who are diagnosed are treated and half the number of people who are treated reach control. In this situation, with Biocon Biologics having a large portfolio of insulins in the basket and having a paired digital therapeutic that addresses the two parts of this problem of halves. This is how we plan to adopt it as part of our global strategy. So, as I illustrated through the data, huge unmet need, this tool which is a FDA-approved therapeutic actually addresses the problems of the halves and pairing this with insulins can really address the problem that is surmounting with the decision support that diabetics have.

Kiran Mazumdar-Shaw: And I might add to what Gaurav said and saying that when you reach control, it saves the healthcare system a lot of money. Therefore, that is why it becomes very important to use digital therapeutics as a way of adding value rather than just making it a cost proposal.

Christiane Hamacher: I like to reiterate two points. Biocon Biologics is in a strong position when it comes to Biosimilars for the Insulin portfolio, Recombinant Insulin, with Glargine and with the Biosimilar Aspart under development. Second is we mentioned that COVID is changing the world how healthcare delivery is happening in personalized ways. Therefore, telemedicine services delivery to patients is the need of the hour. Our partnership with Voluntas speaks to that as well.

Surya Patra: *Whether it changes the business proposition in terms of realization or in terms of the pricing as a product, all that?*

Kiran Mazumdar-Shaw: Yes, that is exactly what I am trying to tell you that when you normally go and start discussing contracts, normally it all becomes a pricing discussion. But here you can actually have a very different set of discussions and have a value-add which then the contracting companies will actually look at it very differently and you can actually get a premium for what you are asking for.

Surya Patra: *The Production Linked Incentive program of Government of India what now they have revealed. As per that, they are saying that they have identified around 41 whatever the products. So in that, we have a couple of key products. And so far as fermentation which is the focus area of that scheme, so knowing the fact that Biocon is the leading company in terms of the fermentation capability and we are in the mode of creating capacity on those small molecule front as well as the foundation capability what we are having, so on that front, are we participating in a big way or anything that we are trying to get benefit out of the scheme or what opportunities that it throws to Biocon, anything on that if you can add?*

Siddharth Mittal: So most of these 41 or 52 molecules are legacy molecules. If you look at the PLI scheme details, it is for new CAPEX investment. The decision we will have to make is whether to invest that capital in new products, future products or to invest in the legacy products. Obviously, the return on investments will be lower if you invest on these molecules. This is despite of getting an incentive from the government. Moreover, when you look at the main product that we have in that list is Atorvastatin, for which we already have adequate capacity.

Kiran Mazumdar-Shaw: So I would say, Surya, this is not for companies like Biocon. I would suggest that these are opportunities for smaller companies who are CAPEX crunched. I think they are the ones who should be actually availing of these benefits. I do not think Biocon is in that kind of category.

Sameer Baisiwala: *Just on the industry side question for both Pegfil and Trastu, I would imagine that the Biosim adoption is now close to 35% or thereabouts. So is the low hanging fruits taken in now for industry to go 35% to 50% to 60% going to be harder? And second is, for your own products, I know Mylan is your commercial partner, but when do you expect to hit mid-teen sort of market share, is it realistic to expect sooner or is it going to take some time?*

Christiane Hamacher: Couple of comments. We have seen with the market dynamics in the US as well as in Europe that double-digit market shares in the mid-teens are possible, even higher in the 20% and 30%. We have seen that in the oncology arena with a couple of players as an example. We are not commenting specifically how we see our market share uptick and revenue uptick for the quarters to come. In addition, the Biosimilar market segment is still a market that is being shaped, particularly in the US but also in other parts of the world. So whether it is harder now to reach higher market share of 20% or 30%, depends on each and every market segment and the dynamics there, the number of competitors, the time between the entry of competitors, but it is still a wide open playing field. Therefore, I do not expect that it is harder to achieve this market share where we have an advantage with our product. We are in the first wave of Biosimilars if you look at our molecule for the segment.

Sameer Baisiwala: *I am not sure whether my question was answered about the industry adoption going to 50%, 60%, all players put together. Is it going to be harder here on and the lower hanging fruits being taken?*

Christiane Hamacher: No, it is not harder for the industry adoption. As I have said, it is a field where the Biosimilar players are now starting to come in and Biosimilar companies overall can move to 30%, 50% market share or even higher has been seen in several markets of the world. The potential and the possibilities are there and this will play out over time.

Sameer Baisiwala: *Are we on track for Aspart filing in this 2020?*

Christiane Hamacher: As I have mentioned in my commentary, we are on track with the development for Aspart together with our partner Mylan.

Sameer Baisiwala: *For the three products that you are planning to launch fiscal '23 to '25, when do you expect them to enter Phase-III clinicals just working backwards?*

Sundar Ramanan: We are working with the agency on scientific and regulatory pathways for these molecules. As we get further clarity, we will share them with you.

Raj Mohan: *In the Biosimilars space, are the price corrections post increased competition still in the range you had anticipated or are we a little more aggressive?*

Peter Meeus: We see the price corrections or the discounts in line with our expectations. There may be slightly more aggressiveness and some discounting in some areas specifically for markets, but overall we see it the same as Christiane highlighted. We also see that this will be less aggressive than in generics. Thirdly, with the interventions such as Insulia that we are planning to do, we think to stand out and getting price premium is possible when we negotiate contracts with payers.

Raj Mohan: *Based on your current assessment of the evolution of the Biosimilars market through the competition entering the space, of this \$33 billion market opportunity by FY'22 that you envisage, how many players do you broadly expect to be operating in this market?*

Peter Meeus: We expect several players in this market. I will not go into the specifics because it is still a dynamic market, but it is competitive obviously but we are in a good position to be amongst the first to launch the products.

Raj Mohan: *Would it be like sort of per product you will be having with four, five kind of players?*

Christiane Hamacher: The number of players will be different in the market segment. The number of players is important. What is more important is that players have the right business model and have specific targeted approaches to all the different customer segments and that is what we are looking for. What is also important is where companies in when it comes to the different wave are. It is important to be in the first wave because we are seeing dynamics starting to play out in the Biosimilars market. Companies that are in the first wave have an advantage to be a strong player. This is not about a fair share across biosimilar players; this is about the right business model, the focus on execution and being in the first wave.

Kiran Mazumdar-Shaw: I think you will also understand that given the investment required in developing Biosimilars, the matrix that you are likely to see is going to be very, very different to what you see in generics. So you have to look at it molecule-by-molecule and then pipeline-by-pipeline and timing-by-timing. So there are three things that we are tracking in terms of competition. So you might find different competitors and different molecules. And then if those competitors are one-off, then they do not have the kind of advantage that we have.

Christiane Hamacher: And in addition to that, we actually pointed out that it is important to have a portfolio. As we have stated before, we are very well positioned in the Biosimilars space. We have a platform of 28 molecules with our partners that will allow us to capitalize on what we are currently developing and what is currently in the market. Portfolio plays a major role because healthcare systems are looking for savings. Now with COVID, I am absolutely convinced that the demand for Biosimilars as well as generics will be higher than ever.

Raj Mohan: *Though you have clearly spelled out the market share in Fulphila and Ogivri and Mylan's strategy to drive further commercialization, post the creation of Viatris in this Mylan-Upjohn merger, is there a possibility of expansion in distribution capabilities and consequently driving market shares up more rapidly? If so, by when can we see material gains?*

Christiane Hamacher: Mylan is best positioned to make any comments on Viatris. What is clear from the announcements made is that they are combining their strengths across the world. Upjohn with its headquarters in China is very well placed in Most of the World markets. Therefore, we are very excited about this merger because of the combined strength of both of the companies and the focus on commercial execution.

Nitin Agarwal: *Siddharth, this is for you. On the Generic business, now on the Formulations side, we are a relatively small business at this point of time and with the market dynamics being what they are, how are we looking at this business over the next three to five years? And what kind of investments are we looking to make in this business?*

Siddharth Mittal: Nitin, we have started to build a portfolio of our Generic Formulations products. This journey started four to five years back, was a slow journey. When the entire generics industry faced headwinds in the US, we had slowed down. We are now picking up pace again, we are building capabilities in terms of adding R&D infrastructure, adding manufacturing infrastructure, adding right skill people to work on this pipeline and we are going to start ramping up our pipeline which will be under development and the filings for which will happen over the next few years. So, I definitely expect, when you look four to five years from today, this business will contribute a much larger number, both in terms of absolute revenue as well as percentage of the segment revenue. However, it would take some time because even though we have some approvals and tentative approvals, we cannot launch those molecules because of settlements or because of ongoing litigation.

Charulata Gaidhani: *I have two questions; one pertaining to the recent Voluntis agreement. Do you have competition in the similar area?*

Gaurav Laroia: As I mentioned to you, it is a unique proposition when we provide this because what we provide is a portfolio of Biosimilar Insulins along with a digital therapeutic, which addresses two halves of the problem. Therefore, we feel we are uniquely positioned because we are as Christiane mentioned earlier, the only biosimilar company to be able to provide a value proposition that encompasses a portfolio of insulins with a digital decision support tool, which allows for health system cost savings and therefore interesting contracting opportunities.

Charulata Gaidhani: *Is there a limitation because the focus is on type-2 diabetes which is more on oral solids?*

Gaurav Laroia: The numbers as I mentioned 500 million people most are type-2 and even if you take a small percentage to be on insulin, the numbers are huge. And as we mentioned, the consequences of not achieving control in the Insulin segment is deterioration to other co-morbid situations which affect the heart, the kidney, the eye and may result in amputation, right. Therefore, there is a clear pharmacoeconomic benefit of this intervention to a population segment. So huge attraction in terms of the unmet need for patients. And when paired with a Biosimilar, it offers a very strong proposition and which is large enough given the volume of patients.

Kiran Mazumdar-Shaw: Charulata, let me tell you that in this world now that is evolving, this kind of digital therapeutic is not a nice to have, it is a must have.

Charulata Gaidhani: *My second question is on the R&D spend. How much are you planning to spend on R&D over the next two, three years?*

Kiran Mazumdar-Shaw: So as you know, our entire growth depends on how much we invest in the R&D pipeline. This is something that has happened over the years and it will continue to happen. We are a science-led, research-led business and we have to continue to invest in research and innovation if we want to grow at an exponential pace. I think that is what is very clear. You can see that the investments we have made in Itolizumab over the years will now become a very large opportunity for us going forward. So that is what we are actually focusing on. I think people must understand that it is only research and innovation-led companies that can actually start showing non-linear growth.

Charulata Gaidhani: *But how much will be the spend?*

Kiran Mazumdar-Shaw: So roughly at 11% to 12% of our non-Syngene revenues. So it can go up to 14%, 15% as well. But it is that kind of a range that we have been presently spending at.

- Siddharth Mittal:** So the two different ranges that Kiran mentioned -- one is at the net level and the second is at the gross level. So at a gross level roughly 14%, 15%, and at a net level in the P&L around 11% to 12% excluding the research services revenue.
- Tushar Manudhane:** *Just would like to understand on the CAPEX side. Given that we have spent considerable amount particularly on the Biologics side, so how do we see capital investment over the next three, four years now?*
- Siddharth Mittal:** I think Tushar, we had mentioned in the last earnings call as well that we will be investing \$200 million per year for the next two years, split equally between Generics as well as Biosimilars. We cannot guide anything beyond that. It does not have numbers from Syngene. In addition, if you had heard Syngene's earning call, they would have indicated their CAPEX requirements there.
- Tushar Manudhane:** *So when you have said the Syngene part and even the generic formulations, so \$100 million-odd kind of annual run rate. Given that the products now are into the commercial phase, and for which the CAPEX is already done, so just wanted to understand whether there will be some amount of pause for this capital investment or that would continue for the foreseeable future?*
- Siddharth Mittal:** For the currently commercialized products, CAPEX has already been done. The new and ongoing CAPEX is for the future products. Right now, I can give you clarity for next two fiscal years, FY '21 and '22 of \$100 million each year for Generics as well as for Biosimilars.
- Tushar Manudhane:** *Secondly, on the effective tax rate for full year '21?*
- Siddharth Mittal:** Take 25% at a group level. It can fluctuate by 100 to 200 basis points.
- Yatin Mohane:** *Just wanted to quickly check, what is our dependence on China for procurement of raw materials?*
- Siddharth Mittal:** For Biosimilars, we have very little dependency on China. However, we do have a large dependency in Generics business, roughly 60% of our procurement is dependent on China, though we do have multiple sources within China where we source from. We are also working on a very aggressive plan to qualify vendors outside of China.
- Vishal Manchanda:** *I have a question on Itolizumab approved for COVID condition. So, wanted to check what are the existing capacities in terms of patient population that you can cater to? And what are the expansion plan on this? And how long the expansion can take?*

Kiran Mazumdar-Shaw: That is a good question. Actually, this is a very important opportunity that we are addressing. As you can understand, it was an unexpected opportunity. Therefore, ramp up will take two to three months. We have internal capacity that is available to us for actually addressing a very large global demand that is beginning to rise and therefore, we are focusing on this. Starting in three months' time, we will be able to have a very large capacity that we can actually address in terms of catering to the rising demand.

Vishal Manchanda: *Would you need to file for approval in other geographies or would this kind of can happen automatic route through your clinical trials in India?*

Kiran Mazumdar-Shaw: Look, these are very early and unexpected opportunities. Therefore, we are mapping out the whole situation. I think by the next quarter, we will be able to share what is happening in which territory.

Vishal Manchanda: *And would it be fair to kind of assume about 5% of the COVID diagnosed patients would need a therapy of this kind like immunomodulator type of therapy?*

Kiran Mazumdar-Shaw: At the moment, I think it is about 10% of the patients who can actually fall into this category that result in these, what they call "Cytokine Storms." Therefore, we are actually addressing this particular section of the COVID population.

Vishal Manchanda: *One more on Semglee, wanted to check if the promotion expenses that Mylan would incur, before you get your profit share, would those promotional expenses be deducted or the profit share calculated at the gross level, so the realization minus the cost of supply?*

M.B. Chinappa: Sorry, we cannot reveal those kind of details on the contracting with our partners.

- Ends -

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