



Transcript

Biocon Limited Q4 FY20 Earnings Conference Call May 15, 2020

Participants from Biocon's Senior Management Team

- # Dr. Kiran Mazumdar-Shaw – Executive Chairperson, Biocon Limited
- # Mr. Siddharth Mittal – CEO & Managing Director, Biocon Limited
- # Dr. Christiane Hamacher – CEO & Managing Director, Biocon Biologics
- # Mr. M.B. Chinappa – Chief Financial Officer, Biocon Biologics
- # Mr. Shreehas Tambe – Chief Operating Officer, Biocon Biologics
- # Mr. Paul Thomas – Chief Commercial Officer, Biocon Biologics US
- # Mr. Peter Meeus – Head Portfolio & Products, Biocon Biologics
- # 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
- # Dhaval Shah – Girik Capital
- # Dheeresh Pathak – Goldman Sachs Asset Management
- # Damayanti Kerai – HSBC
- # Neha Manpuria – JP Morgan
- # Nithya Balasubramanian - Sanford Bernstein
- # Shyam Srinivasan – Goldman Sachs
- # Sameer Baisiwala – Morgan Stanley
- # Surya Patra – Phillip Capital
- # Aimee Truesdale – Jupiter Asset Management
- # Nitin Agarwal – IDFC Securities
- # Raj Mohan – Professional Investor
- # Charulatha Gaidhani – Dalal & Broacha
- # Bharat Sheth – Quest Investment Advisors
- # Atishra Rahlan – Dawn Capital
- # Yatin Mohane – Iroha Investment Management
- # Vishal Manchanda – Nirmal Bang

Prepared Remarks Session:

Saurabh Paliwal: Thank you, Janis, and good evening, ladies and gentlemen. I welcome you to Biocon's Fourth Quarter and Full Year of Fiscal'19-20 Earnings Conference Call. Before we proceed with this call, I would like 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 made available on the web site in the coming days.



To get started, we have the company's management led by our Chairperson -- Dr. Kiran Mazumdar-Shaw and other colleagues from the senior management team.

I would like to take this opportunity to remind everyone about the Safe Harbor related to today's conference call. The discussion may be forward-looking in nature based on management's current beliefs and expectations. It must be viewed in conjunction with the risks that our business faces that could cause our future results, performance or achievements to differ significantly from what is expressed or implied by such forward-looking statements.

At the end of the call, if you need any further information or have any questions, please do get in touch with me. With this, I would like to turn the call over to Dr. Kiran Mazumdar. Over to you, ma'am.

Kiran Mazumdar-Shaw: Thank you, Saurabh, and good evening, everyone. I welcome you to Biocon's Earnings Call for the Fourth Quarter and Full Year for the Fiscal Year 2019-20.

As you can see, we are living through unprecedented times and, of course, I must say that this is a format which has not changed whereas other formats of communication have. So, I would like to make a couple of points upfront on the broad impact of COVID-19 on Biocon operations and how we have responded in terms of our preparation to sustain our operational performance amidst all this turmoil.

First and foremost, in line with our commitment to provide a safe working environment to our employees, we significantly reduced the number of people in our facilities to only those who were required to carry out manufacturing and quality operations based on planned production schedules. All other employees either stayed back or were working remotely from home.

And I would like to add that the work from home that was put into effect was done so very rapidly with all the sophistication that is required to operate from home on internet in a secure manner.

I am very proud of our employees and want to thank them for their efforts in rising to the challenge and responding positively to the situation. It has helped us maintain our critical manufacturing operations with reduced manpower while we continue to address the needs of medicines and services for patients, partners and customers across the globe. In recent weeks, we have also added to this fleet of people operating at the workplace by getting many of our research workers back to the labs.

Earlier this month, there was some easing prescribed by the central and state governments and we have started to gradually scale up our operations with more employees reporting at site for work with required safety precautions to maintain a safe and infection-free environment. A substantial number of employees still continue to work remotely from home and we are continually assessing the situation and look to normalize our operations to pre-lockdown levels by the end of this month. This is of course subject to the evolving COVID situation in the cities and areas we operate in as per government mandated guidelines.

I am also very pleased to report that Biocon has played a very important role in coming out with workplace protocols along with various industry bodies.

Secondly, the turmoil caused by the COVID-19 pandemic obviously has disrupted supply chain and impaired mobility due to the nationwide lockdown and it did have a bearing on our manufacturing operations. We put into place business continuity plans to minimize this impact. We did experience delays in receiving and sending shipments, but that did not have very big impact, except for the Biologics business.



The logistics situation has now begun to rapidly improve after the relaxation provided by the government in early May which allows for unhindered movement of goods vehicles across the country. We have also seen imports for raw materials gradually normalize and outbound logistics have also now significantly improved.

Having adequate inventory of key raw materials to sustain operations during the period of the lockdown has helped us tide over this challenging period, both for Small Molecules as well as biologics. We are adequately stocked with a few months of inventory to carry out our critical manufacturing operations and are continuously evaluating our requirements to overcome another lockdown kind of situation. In Small Molecules therefore we have decided to discontinue manufacturing of certain products which were sourced from China and were not strategic. The impact of this discontinuation will be made up by repurposing the facilities towards manufacturing strategic products over the long run.

Now coming to our "Performance." After three strong quarters, Biocon has reported a weak fourth quarter. Two of our businesses -- the Small Molecules and the Research Services segment - delivered strong revenue growth amidst these unprecedented times. It was only the Biologics segment that was extremely challenged during the quarter and reported a weak performance. Dr. Christiane Hamacher - CEO of Biocon Biologics, will elaborate further on the Q4 Performance for the Biologics segment later in the session.

Thirdly, spending on medicines across the globe for non-COVID diseases has seen reprioritization with healthcare systems strained due to dealing with the pandemic. In that backdrop, there will be tremendous opportunity for volumes of generics and biosimilars to ramp up as the situation improves and spending returns. At Biocon, we are very well placed in both these areas and expect to come out stronger once things normalize.

In the next quarter, i.e. Q1 FY21, we expect our financial performance to improve over Q4 with uptick expected from Q2 onwards. The US FDA approval for Semglee or Insulin Glargine is expected shortly. This will add to our current portfolio of biosimilars which includes Fulphila, biosimilar Pegfilgrastim and Ogivri, biosimilar Trastuzumab and create a growing portfolio of biosimilars for the Mylan partnership.

On the regulatory front, our biologics facilities both in India and Malaysia have received positive EIRs from US FDA as well as EMA. These approvals will significantly expand our capability to address US, European and global market opportunities with a competitive advantage.

Now moving on, I will present "**Key Financial Highlights.**" I will first discuss the highlights for the quarter followed by the highlights for the full year.

Financial Highlights [Q4 FY20]:

The fourth quarter delivered year-on-year **Revenue** growth wherein revenues increased by 6% to Rs.1,644 crores compared to Rs.1,557 crores in the same period last year.

Revenues from operations stood at Rs.1,581 crores, up 3% driven by healthy growth in Small Molecules which was up 15% as well as Research Services which was up 14% as compared to Q4 last fiscal. The Biologics segment performance was impacted by COVID-19 related to logistics and other challenges while branded formulations also declined 12% as compared to last year.

We recorded **gross R&D spends** of Rs.139 crores this quarter which corresponds to 14% of revenue ex-Syngene. Of this amount, Rs.125 crores is expended in the P&L while the balance amount has been capitalized. The increase in R&D spends reported in the P&L statement are primarily on account of higher spend across biosimilars and insulins.



Given the depreciation of the rupee against the dollar, we booked a **FOREX gain** of Rs.35 crores this quarter as compared to a loss of Rs.7 crores last year. This gain is reflected in the other income line of the P&L statement.

EBITDA for the quarter is down 11% to Rs.382 crores. **EBITDA margin** for the quarter stood at 23%. Reduction in gross margins due to lower sales in the Biologics segment, higher R&D spend, higher staff cost, plus increase in operating cost in Malaysia have led to the reduction in both EBITDA and EBITDA margin.

Core margin, i.e., EBITDA margin net of licensing impact of FOREX and R&D stood at 29%.

Net profit for the quarter was at Rs.123 crores down from Rs.214 crores last year.

Financial Highlights [FY20]:

During FY'20, total **Consolidated Revenues** for the year grew to Rs.6529 crores which is a 15% increase as compared to Rs.5659 crores the previous fiscal. **Revenues from operations** were up 15% at Rs.6,367 crores.

Small Molecules reported revenues of Rs.2,094 crores which is the first milestone of crossing Rs.2,000 crores, which is up 18%, a very strong performance by the Small Molecules segment.

As far as **Biologics** was concerned, they actually had a very strong annual growth of 29%, delivering Rs.1951 crores as against Rs.1517 crores the previous fiscal.

Branded Formulations recorded revenue decline of 18% at Rs.536 crores while **Syngene** also reported a 10% revenue growth at Rs.2012 crores which is also another milestone for Syngene, having crossed Rs.2,000 crores.

We incurred **gross R&D spends** of Rs.527 crores on R&D this year, corresponding to 12% of revenue excluding Syngene. Of this amount, Rs.439 crores is reported in the P&L while the balance has been capitalized. The capitalized amount relates to biosimilars and insulins development expenses. For the full year, we spent higher amounts across biosimilars and insulins as well as ANDA and development programs.

For the full year, we booked a **FOREX gain** of Rs.65 crores compared to a gain of Rs.28 crores the previous fiscal.

EBITDA for the full year was Rs.1765 crores which was up 15% and **EBITDA margin** were at 27% which is very similar to previous fiscal.

Core margin, i.e. EBITDA margin net of licensing impact of FOREX and R&D stood at 33% which was up 1% as compared to 32% the previous fiscal.

Reported **Net profit** for the year stood at Rs.748 crores which includes certain exceptional items. Adjusted for exceptional items and associated tax, Net profit for the year was Rs.760 crores with net profit margins at 12%.

Coming to **Reviewing Business Segments Performance for the fourth quarter and the full year.**

Let me start with **Small Molecules**. The strong performance of the Small Molecules segment during the fourth quarter was led by a further ramp up of our generics business in the US market. For FY'20, the improvement over the previous fiscal was led by a strong performance of generic formulations in the US on the back of



consistent client acquisitions and increased market share for all our products. This was also aided by the API business performance which has been driven by a better product mix and realization over the previous fiscal.

Branded Formulations business underperformed yet again. This business is going to be a strong focus for us to see how to turn it around for a better performance. The business has been challenged with pricing pressure which has led to a decline in revenues and there have been logistics and distribution disruptions in the month of March which has also contributed to a further decline.

I would also mention that our **Branded Formulations business in the UAE** through our JV entity NeoBiocon has not only faced significant business challenges in the last fiscal resulting from mandated price reductions from the Ministry of Health, UAE, but is now facing other challenges wherein our JV partner has come under investigation for governance issues which is likely to have a reputational impact on the JV. As a company committed to the highest standards of governance, we have decided to wind up the JV entity. Going forward, we will plan to market our Biologics products under our own brand name.

Research Services delivered a steady year-on-year growth in the fourth quarter led by a continued strong performance in Discovery Services and a very healthy Q4 performance in Development Services. For the full year, the performance was driven by a broad-based growth across all business verticals and an improved traction in Discovery Services.

Now moving to **Biologics**, I will hand it over to Dr. Christiane Hamacher to discuss the Performance of the Biologics segment.

Dr. Christiane Hamacher: Good evening, everyone. For Biocon Biologics, let me dive straight into the factors that have impacted our Q4 performance. After seven straight quarters of strong revenue and profit growth, we saw a sharp dip in Q4 performance with segment revenues coming down by 21% and segment profits coming down by 84%. The COVID impact was significant. About Rs.103 crores of products that were scheduled to be shipped at the end of the quarter were held up due to logistics issues related to COVID.

In addition, we were impacted by lower profit share contribution from our partners. We take comfort from the fact that market share of our products in the US are maintained at the same level and as such we believe this sharp dip is a one-time effect and we will see a recovery from Q1 onwards. We expect Pegfilgrastim and Trastuzumab sales to pick up with new contracting in the US and gain traction in many markets across Europe and rest of the world. Other recent launches by our partner, Mylan include Pegfilgrastim in Canada and Australia which adds to our Oncology portfolio with Trastuzumab in both countries. Mylan has reiterated that they have strong confidence in their long-term capabilities from physician payer hospital standpoint to fully execute commercially on the growing biosimilar portfolio throughout this fiscal and in the coming years. We are therefore confident to reach our target of US\$1 billion by fiscal year 2022.

Moving on to Regulatory Matters. We received FDA pre-approval for our Malaysia manufacturing facility for Insulin Glargine. We also received a favorable district court decision with respect to our ongoing patent litigation for Insulin Glargine and further IPR decisions remain pending. Through Mylan, we also continue to be engaged in active discussions with the FDA on a viable path to obtain an interchangeable designation. As such, we remain on track for a mid-year 2020 launch. Glargine is a US\$2.2 billion market and we believe this product will be an important contributor to our growth in fiscal year '21 and beyond. In addition, we expect Mylan to launch Etanercept in Europe in the second half of this calendar year. Biocon has shared economics in this program.



Other updates on our Biosimilar programs include the review of our BLA for biosimilar Bevacizumab, both by US FDA and EMA. On the insulins front, we are on track with the development of Aspart. Our recombinant human insulin program is also progressing well under the new 351(k) pathway.

Overall, we are targeting to have at least eight biosimilars being sold in developed markets by the end of fiscal year 2022 addressing a market opportunity of approximately up to US\$35 billion. Our pipeline is expected to continue to deliver at least three additional molecules between fiscal year '23 and fiscal year '25. Thereafter, we expect to launch two molecules per year.

COVID has given us an even larger opportunity to shape the biosimilar landscape. Global healthcare will be compared to leverage both generics and biosimilars to contain healthcare cost and we would like to position ourselves in a leadership league that drives our vision of delivering affordable access to innovative and inclusive healthcare solutions. We continue to see the biosimilar market as a significant opportunity to be played out over many years and across markets globally. All regions show strong promise with high single to strong double digit growth underlining the tremendous potential that biosimilars offer. The total global market of all biosimilar monoclonal antibodies and therapeutic proteins is anticipated to grow from approximately US\$25 billion to-date to US\$55 billion in 2025 based on consensus estimates.

Whilst we are currently focused on developed markets such as US, Europe and Japan through strong partners, we also believe that the demand for biosimilars in rest of the world markets is rapidly increasing. We already have a presence in the majority of the top-20 markets, and we plan to expand our geographic footprint even further.

With 28 molecules in our portfolio covering oncology, diabetes, immunology and other therapeutic areas, we offer one of the industry's largest and most diverse global biosimilar portfolios. We are one of the few fully integrated players with scientific speed and manufacturing scale that provides competitive advantage and uniquely positions us as a fully integrated pure-play global biosimilar company.

We see fiscal year '21 as a step up year with strong revenue growth and steady EBITDA margins. We will be able to provide more color on this guidance in the next earnings call after some of the COVID-related uncertainties recede.

With this, I will hand back to Kiran.

Kiran Mazumdar-Shaw: Thank you, Christiane. So let me conclude by making some comments on the Outlook.

The new financial year comes with a new set of challenges in the midst of the ongoing COVID pandemic; however, we are confident of emerging from the current situation stronger and more determined than ever to deliver on our commitments to our patients, partners and stakeholders. While uncertainties may persist during FY'21, we expect the Biologics segment to continue to lead overall revenue growth for Biocon and steady growth is expected in both Small Molecules as well as Research Services.

With that, I will now open it up for question-and-answers.

Q&A Session

Prakash Agarwal: *My first question is on again the statement which Christiane made on the biosimilar business that there is Rs.103 crores delay in shipment. So how do we think about it, like if we add that, it is flat YoY, but still there is a decline of 20% QoQ, in the past we have said that Biosimilar business would continue to ramp up pace. So what are we missing there, why the QoQ big large dip, a) and b) is on lower contribution from the partner. What is leading to that -- are the primary sales and secondary sales too different?*

Kiran Mazumdar-Shaw: As you know, Christiane talked about two factors that basically gave us this sharp decline in performance this quarter. One, as you rightly said was the Rs.103 crores it is not good enough to show why we did not grow. The second one really was about the COVID impact in the US where I think the movement of inventory to distributor channel was certainly very badly impacted in the month of March which also then directly impacted us as well. So, I think this is what has really led to this very sharp decline. We have seen a pickup of the business both in the US and many other markets and that is why we feel confident that we will see a good recovery in Q1.

Prakash Agarwal: *On the second part ma'am, on the lower contribution from the partner, the EBIT margins are down to 7% versus an average of 25-30%?*

M.B. Chinappa: Yes, Prakash, as you kind of picked up, it is the secondary sales and the primary sales play, secondary sales of course, is the sales from the wholesalers to the hospital and clinics and primary sales is defined as the sales by us to a partner and our partner to the channel. The real measure of performance is of course secondary sales. And as you have seen from the data generally our market share is steady at the prior quarter levels with a slight uptick in Trastuzumab; however, during this quarter, this did not lead to a matching increase in primary sales, thereby impacting both our revenues and profits. Again, as Christiane already mentioned, we see this as a one-quarter effect, and we are confident that when you look at the overall business we will see recovery in Q1 and normalization in Q2.

Prakash Agarwal: *Kiran ma'am said that it is more so due to the impact in the US. So given these are hospital-led products, so we are seeing some improvement. So, the patients have to necessarily come to the clinics or hospitals to get the treatment done or there are some campaigns being done by Mylan, what are the initiatives which are taken in terms of closing the gap?*

Kiran Mazumdar-Shaw: As you know, with the growing COVID pandemic in the US, I think there was a lot of challenges in many of the hospitals to offer the treatments to non-COVID patients as you know and therefore there was a lot of focus on COVID treatments and many of these patients have basically had to defer a lot of their treatment. Now, it is all coming back. So we believe that with these improvements, you are going to see business recovering very rapidly.

Dhaval Shah:

Ma'am, two questions on the Biologics: First is on our billion revenue guidance for FY'23, how would our Biologics balance sheet be like, what would be our capital employed, expected return on capital, just want to get some flavor on that. Secondly, want to understand the entire business economics of the Biologics business, which company's balance sheet should we look at -- Biologics India Limited or the Limited, can you just also give some clarification on that?

Kiran Mazumdar-Shaw:

So let me first correct you, it is FY'22 that is our billion dollar target and we remain committed to that target because you cannot be questioning that target based on one quarter's performance. This is a one-off as we have said before, and we are on the path to recovery and therefore we are not at all concerned about not meeting any of those targets. We are very confident that we will meet the \$1 billion target by FY'22. Coming to the balance sheet, I will request Chinappa to comment.

M.B. Chinappa:

It is actually difficult to create the Biologics balance sheet currently because it is a combo of Biocon Biologics India Limited, there is a UK entity, there is a Malaysia entity and another Malaysia entity also just set up. Now we will in the subsequent quarters actually present to you independent to fully detail P&L for the Biologics segment and the Small Molecules segment. So thereby you will start to see from next quarter onwards full report of the businesses, but for now, it is difficult, and there is a lot of common cost that are getting apportioned and cannot read the full. On the second part of your billion dollar question where you asked what the margins will be, it is difficult to really split margins down into FY'22 because it is also dependent on the R&D cost and really how much the R&D spends are. But for now if we look into FY'21, as Christiane already mentioned, we are looking at steady margins despite higher R&D cost.

Dhaval Shah:

Broadly, we have currently Rs.4500 crores invested as capital employed as per the FY'20 press release. So to achieve Rs.7000 crores top line billion dollar, so how capital employed would move? What are the economics of this business? I understand R&D is a big component of capital employed. But broadly, given it is a two-year period, we would have some sense and what would be the ROCE look like because we are currently at some 10% for FY'20. And also given a lot of our new products are getting launched in US, which are higher margin, so this will broadly give us some idea to us in terms of how should we approach this Rs.7000 crores profitability?

M.B. Chinappa:

I will just give you a directional sense. Today, our total investment is just under \$500 million, if we look at the gross fixed assets, it is Rs.3,300-odd crores. Now from there, we have additional CAPEX that is underway, capital work-in progress plus some additional CAPEX coming up next year. That total investment can support billion guidance.

Kiran Mazumdar-Shaw:

So, I think from an ROCE point of view, we are guiding in the range of around 20% to 23% in the next two years.

- Dhaval Shah:** *So, your current gross block is Rs.3300 crores and which will see an addition in manufacturing facility for the new product?*
- Kiran Mazumdar-Shaw:** Yes.
- Dhaval Shah:** *In terms of the CAPEX guidance, it will be Rs.1000 crores ex of Syngene over the next two years?*
- Siddharth Mittal:** It will be roughly \$200 million per year for next two years – one half for Biologics and another half for Small Molecules.
- Kiran Mazumdar-Shaw:** This is at a group level ex-Syngene.
- Dhaval Shah:** *From this \$100 million would be you said it will be for Biologics and \$100 million will be for...?*
- Kiran Mazumdar-Shaw:** Yes, exactly.
- Siddharth Mittal:** I think in the past I have mentioned that if you look at the segment ROCE Biologics, which has obviously inched up over the last couple of years is at 11%, as you rightly said in FY'19 and FY'20, when you compare with Small Molecules and Research, which is already at 20-22%. The scope for improvement in Biologics is huge because from a profitability perspective, Biologics is the most profitable segment. And what we definitely expect when we are out of the capital investment cycle, the ROCE with a higher EBITDA margin would start going up significantly and will catch up definitely at a group other segment's level.
- Dhaval Shah:** *In terms of the balance sheet to understand this entire business, you said over the next two, three quarters you will be grouping everything under one entity... the entire Biologics business. Do I understand correctly?*
- Siddharth Mittal:** So I think what Chini meant was that we will be reporting segment sales. We will be redoing our segments next year. So, there will be Small Molecules, there will be Biosimilars, no longer Biologics because Biologics also has novel biologics as a part of, there are only expenses. And there is a Branded Formulations India component which is currently reflected under segment revenue, but they are going to be reclassified under Biosimilars. And Research Services will continue as is. So from a segment reporting, you will see segment revenue and segment results in four segments -- Small Molecules, Biosimilars, Research Services and Novel Biologics. The detail P&L for all the entities is uploaded once a year on our website in line with the requirements of the Companies Act. So it will be visible once a year. Now the statutory requirement obviously is to present a consolidated balance sheet and P&L along with segment revenues and segment capital employed.

- Dhaval Shah:** *And sir the money what we raised is under Biologics India Limited, am I correct?*
- Kiran Mazumdar-Shaw:** Right.
- Dhaval Shah:** *The IPO, whenever in the future it comes, it will be for Biologics India Limited?*
- Kiran Mazumdar-Shaw:** Yes.
- Dheeresh Pathak:** *Just a follow-up to the earlier participant's question. Just Biocon ex-Syngene CWIP I am seeing about Rs.1340 crores. So can you just explain the underlying assets for CWIP ex Syngene?*
- Siddharth Mittal:** So Biocon ex-Syngene is up Rs.330 crores compared to March '19, of which significant portion is pertaining to our new Biologics facility which is under commissioning and our new Research Services facility which was acquired in Chennai from Pfizer and certain other capacity enhancements that are underway. But the new antibody facility and the Chennai R&D facility would be the largest component of that increase.
- Dheeresh Pathak:** *This \$200 million CAPEX over two years for biologics, this would be sufficient to...?*
- Siddharth Mittal:** It is \$200 million per year for 2 years.
- Dheeresh Pathak:** *It is split 50-50, right. So in two years, you will spend \$200 million for Biologics for two years that is sufficient to give you enough manufacturing capacity for \$1 billion of sales, right?*
- M.B. Chinappa:** Right yes. So the turnover growth will be higher than the asset growth and we will see improved asset turnover and an improved return on capital.
- Dheeresh Pathak:** *Chini, you also just mentioned that there is a gross block of Rs.3300 crores in Biologics and the asset side is about some Rs.6000-odd crores mentioned in the published numbers. That leaves us...*
- M.B. Chinappa:** No-no, just I think I said gross block, not net block.
- Dheeresh Pathak:** *Yes, but the assets are showing Rs.6300 crores. So even if net block is lower than this, then there is a lot of working capital sitting in Biologics. Am I missing something?*
- M.B. Chinappa:** Yes, obviously it is working capital which represents rest of the investment.
- Dheeresh Pathak:** *But Chini, compared to the scale of the business, it is like more than Rs.3000 crores of working capital for a business which is making Rs.2000 crores...?*

- Siddharth Mittal:** No, it is not Rs.3000 crores for sure. See, you look at the capital employed of Biologics is at Rs.4500 crores. The net block is how much?
- Dheeresh Pathak:** ***Asset size we will have to look at no, because the capital employed is just shareholder equity. I am looking at the assets. Assets are Rs.6382 crores. Maybe I can take it offline?***
- M.B. Chinappa:** Yes, take it offline. There is a big CWIP also sitting in there.
- Dheeresh Pathak:** ***So that Rs.3300 crores did not include the CWIP?***
- M.B. Chinappa:** Yes, what I meant is what was deployed as assets and there is a CWIP component. I will walk you through the numbers.
- Damayanti Kerai:** ***So, recently your partner, Mylan in their March quarter call mentioned that they are shifting to execution and strategic performance for a biosimilar franchise. So if you can update us on how your commercialization and marketing strategy has changed since you launched your first product in the US, so that will be helpful? How this is in line with your target for \$1 billion sales from biosimilars by fiscal year 2022?***
- Dr. Christiane Hamacher:** So thank you for your question. Question regarding marketing strategies and operations, Mylan is in a best position to state that. But as I have already said, Mylan has expressed and we have a strong confidence in their capabilities, because what we expect is an expansion of the Pegfilgrastim business; and you are aware that Trastuzumab was just launched end of last year in December, we expect the market trajectory there, and we are looking forward to the upcoming launch of Glargine in the US. Certainly the US is the biggest component for reaching the US\$1 billion mark. So we remain very-very confident. Mylan has clearly expressed focusing on commercial execution and with that we also predict the new contracting in the US for all our products will come through.
- Damayanti Kerai:** ***You just mentioned expansion of Pegfilgrastim opportunity will be critical towards our \$1 billion goal. So how much progress we have made in new segments, say 340B hospitals and how has the new ramp-up capacity has helped in reaching out to newer markets or newer segments?***
- Kiran Mazumdar-Shaw:** I think this is a question better posed to Mylan because they will be able to give you some visibility on these kind of questions. I do not think it is right for us to comment on their behalf.
- Damayanti Kerai:** ***How much of your operating cost is flexible in nature? And if the COVID situation goes on for a bit long, how much headroom you have to manage cost in near-to-medium-term?***

- Siddharth Mittal:** If you look at the fact sheet the expenditure section - Power cost, Staff cost and more than 50% of Other expenses would be fixed in nature. What is variable is obviously the material cost, part of R&D cost and other half of the Other expenses.
- Damayanti Kerai:** ***So Siddharth, most of our costs are fixed in nature. And as you mentioned, some are flexible which we can manage if situation persist longer.***
- Siddharth Mittal:** Yes, that is right. So you look at the gross margin, I think gross margin is the best indicator; 61% is the gross margin for the quarter and gross margin is at the material and the power level. And if you look at the net margin at 8% which would mean that you will have around 20-30% to as the fixed cost.
- Neha Manpuria:** ***My first question is on the Biologics business. You mentioned that FY'21 should see a stable EBITDA margin in Biologics. Could you give us some color on what could be the R&D spend -- could it be significantly higher which will lead to this stable margin? And also just related to that question, what have you seen in pricing for Ogivri given we have seen multiple players come through in the quarter?***
- Kiran Mazumdar-Shaw:** So let me answer by saying that, obviously, competition is factored in when they look at projecting what their outlook is going to be. And I think Mylan has already projected that they are very confident of a good performance in FY'21 and beyond. So, I think if you look at that aspect, then I think it is not that competition is something that was not factored. Secondly, I think as far as we are concerned, when you look at stable margins, obviously, we do realize that there is going to be increased R&D spend, there will be a factoring of some of the capital investments that have been made. So considering all that we still expect to sustain these kinds of margins that we are seeing in FY'20. So I think that is the way it has to be looked at, saying that despite large increases in R&D spend, we are likely to still maintain stable margins.
- Neha Manpuria:** ***Siddharth, in that case, can I ask you what is the guidance for R&D is for FY'21 -- is it still 15% of sales ex-Syngene?***
- Siddharth Mittal:** No, I think the range will be 12-14% at a gross level. The absolute number while it will go up, but the revenue growth in Biologics will also increase the base.
- Neha Manpuria:** ***Given we will have three products contributing in FY'21, even with the higher R&D, large part of our cost increase had come in through in FY'20, should we not be seeing some margin improvement in FY'21, what am I missing here?***
- Siddharth Mittal:** There are obviously the three products from a commercial perspective, but there are many other products which will be in development stage and will be advancing to the next stage of development. So, the expenses would be required to continue to fund the pipeline in both our businesses.

- Kiran Mazumdar-Shaw:** And remember, this is at a consolidated level. So you are going to see even the ANDAs and the biosimilar pipeline being developed plus the novel programs that we are developing. I think you are missing the point that it is not just the Biologics business on a standalone basis.
- Neha Manpuria:** ***My second question was on the fundraising in Biologics. After the first tranche, given the current COVID environment, a) do you see delay in the subsequent round? and b), in case there is a delay, could this for whatever reason impact our ability to fund our growth plans for the next year in Biologics?***
- Siddharth Mittal:** So Neha, let me take the second question first. We do have enough leverage on our balance sheet to take money. So, even if there is some delay, we do not anticipate an issue because all the investments which are being planned, we already have a plan to fund those CAPEX. And obviously the business as it grows into next year and generates the kind of margin that we indicated will also generate operating cash.
- Kiran Mazumdar-Shaw:** Neha, I would like to add that just one quarter dip does not mean anything. So I think you have to read it in the perspective of saying that this was a one-off temporary blip. But we are very confident that the business is recovering, and this is a very strong business and this is a business that is on a growth trajectory. So I do not think you have to panic at one dip in one quarter.
- Neha Manpuria:** ***No, ma'am, fair enough I was just wondering from CAPEX and R&D funding in case the subsequent rounds of fundraising is delayed.***
- Kiran Mazumdar-Shaw:** As Siddharth just explained, we are well covered and well leveraged in that sense. I do not think we are really in a situation where we are desperate for raising the next level, but it is something that we are looking at because it is important for us to create the value that we are talking about.
- Siddharth Mittal:** Yesterday also there was an article in one of the newspapers that there has been a slowdown in the overall private equity transactions because the investors are taking a wait-and-watch approach. So naturally, there could be some impact as a result of COVID on the timing.
- Nithya Balasubramanian:** ***I had couple of questions on Insulin Glargine. So you did mention interchangeability. So one question is, do you have any visibility into what the FDA is expecting and any visibility on timelines as to when that may materialize? And the second one is basal insulins obviously rebates are very, very high; 70%, 75% rebate is what we see in this space and given that your intent has been to improve affordability in this space, I would expect a meaningful discount in this product? And interchangeability obviously, determines how much of a discount can Mylan actually give in this market? So question about how you are thinking about when this interchangeability might happen and how your discounting and pricing strategy might actually change depending on that?***

- Sundar Ramanan:** This is Sundar Ramanan. I will take the question with regards to the FDA and interchangeability. As you know that the agency issued a guidance for insulins that specifically talked about a pathway that will lead us to 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.
- Dr. Christiane Hamacher:** Regarding the pricing and discounts, the strategy is specific and we are not commenting on the details. But Mylan is very well versed and test all the capabilities to position our molecule in the US market in a successful way.
- Nithya Balasubramanian:** *If I might just follow it up, I understand that you do not want to comment on Mylan's commercial strategy, but the point I am making here is there is a huge swing between the kind of revenues that Mylan and subsequently, Biocon can make depending on whether there is interchangeable status or not. So is the plan then to go ahead and commercialize the product irrespective of whether you have interchangeability or not in June or whenever you have the approval and then tweak the strategy if and when you get interchangeability, and does that mean we might see significant changes in the market status as well?*
- Paul Thomas:** So I think a couple of things. I think it is a sizable market, right; we talk about \$2.2 billion market with discounts factored in. The existing rebate structure is factored in there already and we know that there is still a need on insulin affordability for patients. So that is waiting for Mylan to address. So we think there is an opportunity there. In terms of the criticality of interchangeability, I think we have talked before that this is certainly something that we are pursuing and Mylan has talked about that as well. But we have also seen that this market is very centrally driven by payers, by PBMs, and they are able to move market share. They have shown ability to switch between products without the requirement for interchangeability. So it can be a factor, but I would not characterize it as a critical must have for moving share in this market.
- Nithya Balasubramanian:** *Can I read that as interchangeability is not really critical for your billion dollar aspiration?*
- Paul Thomas:** Yes, I think that's fair.
- Shyam Srinivasan:** *Just the first one on the Small Molecules. Can you just talk us about the pricing environment right now in the US? Secondary data seems to show that it is kind of easing now. But are you seeing it in your portfolio as well? And do you think it is sustainable? Maybe there is some March effect with stocking up and stuff. But do you think you are now moving to a trajectory where inflation or deflation is kind of easing for US generics?*
- Siddharth Mittal:** Shyam, the pricing pressure has normalized which means there is still a price erosion which is an annualized price erosion in the range of 5-10%. The good

part is that with the strong dollar, we partially make it up. Otherwise, we end up giving us a discount. Now we do not see the situation changing where serious disruption in terms of competition or significant number of new approvals coming in from FDA which will increase the pricing pressure to the levels what we have seen in 2019.

Shyam Srinivasan: *Just carrying forward because of the COVID impact, we have seen a lot of noise around API and API shifting out of China and to potentially India and other countries. Even your conversations with your customers in the US and Europe, are you getting a sense of that you could actually play a larger role in API supply to these countries?*

Siddharth Mittal: I think there are definitely discussions happening, but I do not think that there has been anything concrete on this. I feel there is a lot of panic created because once the COVID started in China, everybody's eyes were towards China. And when the COVID spread to other parts of the world and China resumed normal operations, I think the focus has shifted to India because India is still dependent on China. So, I think the risk on China has been lesser of a focus. The fact that the regulatory time lines to qualify an alternative source ends up being few years, right now, in the absolute short term, the customers do not have a choice to switch over. But once the dust settles down and if things get to some levels of normalcy, that is when we will know really if there is a structural change of move from China to other parts of the world in terms of the API sourcing.

Sameer Baisiwala: *Christiane, when you mentioned that you expect eight approvals for developed markets by fiscal 2022, are you including Aspart and human insulin in this?*

Dr. Christiane Hamacher: Yes, both molecules are included -- Aspart and recombinant human insulin.

Sameer Baisiwala: *If you can update us on the progress of the clinical trials and if the current COVID situation is impacting these two drugs? And what are the filing timelines for the US market?*

Sundar Ramanan: The COVID will not affect our clinical development. We will keep you posted in the future calls with regards to our filing.

Sameer Baisiwala: *Just on the biosim sales this quarter, if I were to read your expectation going forward, when do you expect the Q3 fiscal '20 sales to return back -- is it in Q1 current year, Q2, any color would be very helpful?*

Dr. Christiane Hamacher: What we have clearly said is that we will recover from Q1 onwards and we will normalize back to growth from Q2 onwards.

Sameer Baisiwala: *When you say normalize, you are referring to Q3 level where we left, I guess?*

Dr. Christiane Hamacher: Yes, back to growth trajectory.

Sameer Baisiwala: *And as things stand today, what is the status on the manufacturing and outbound logistics, I mean is it more or less normalized, it is business as usual?*

Shreehas Tambe: Hi, Sameer. This is Shreehas here. So things are not perfectly normal here, but we are seeing that things are returning to a better position than it was a couple of months ago.

Sameer Baisiwala: *The employee cost has been going up every quarter for the last several quarters. So, is there any specific areas where we are hiring, are these high value talent that you're hiring, any color would be very useful.*

Dr. Christiane Hamacher: So with the high-value talents we are hiring, we are very-very specific and very-very strategic on hiring for a few key positions in our organization to deliver on the strategy and also the commercial execution in particular.

Sameer Baisiwala: *Christiane, is it for developed markets, is it for emerging markets, if you can help with that?*

Dr. Christiane Hamacher: It is actually for global functions where we cover all the markets.

Surya Patra: *Just one clarification I have before asking any question. Ma'am, in the opening remarks, you talked about having backward integrated activities like doing some of the manufacturing in-house instead of procuring the raw materials from outside. Is it about the Small Molecules business that you are referring or it is for the Biologics business?*

Kiran Mazumdar-Shaw: No, this is about Small Molecules. As you know, there was a lot of dependence on certain imports from China and I think that is what we were referring to saying. We actually had stocked up; we have a large inventory. And because of that we do not see any disruption.

Surya Patra: *In fact, this Malaysia venture since we have completed the year, can you just give some sense about the kind of breakeven situation there, what is the cost impact that we are still seeing for the consolidated business from that? You also mentioned about the higher operational cost right now for that set up. Along with that, what is the time line for the next phase of expansion there in Malaysia?*

M.B. Chinappa: Surya, Malaysia facility is still operating at a loss, in FY'20 the loss increased, but we will see in FY'21, Malaysia moving back to profitability with the launch of the Glargine in the US.

Surya Patra: *So, in fact, we are having a kind of impression that the losses at the Malaysia level should be decreasing compared to FY'19 with the supply starting from the current base whether we have not seen that kind of trend?*

Shreehas Tambe: Surya, this is Shreehas here. You are right, actually. We have said before, once we have approvals in the US and other markets start to come in, we will see Malaysia return to profitability in the coming year. Additionally, I think you had asked a question which is related to a subsequent phase of investment. I think in the opening remarks, Kiran and then Christiane also talked about the pre-approval that we are looking at for Glargine and a subsequent approval to get that into the US. At this point, we have adequate capacity to meet our current market projections, we are confident about that and we are geared up to take up the subsequent phase of investment shortly which we will keep you posted in due time.

Surya Patra: ***Just on the Branded Formulations business which is transitioning to moving towards to be part of the Biocon Biologics business and we have also winding of the JV there in the UAE, how should we be looking at? What about the licensing pact that the JV is currently having, whether it will be there with them or we will have that license impact, some color on that business possibly will be helpful?***

Siddharth Mittal: So let me talk about the JV business first. The JV revenues in the last whole fiscal was roughly Rs.80 odd crores with Biocon's share of JV loss at Rs.29 crores, which is a significant amount. So that is the reason why we are shutting down the operations. Now there were two parts of the business in UAE - One was the JV business which was purely the Small Molecules branded generics business which is what we are shutting down. And there is a second part which would continue – there are two biosimilars in the market - one is Glargine and second is Trastuzumab. These were included as part of Branded Formulation, but going forward they will be included in the Biosimilars segment.

Surya Patra: ***So what portion of the revenue line would really be moving out because of this restructuring sir?***

Siddharth Mittal: As I said, out of Rs.536 crores of Branded Formulation sales, roughly Rs.80 crores is the JV revenues.

Surya Patra: ***On the margin profile and the business progression that we have been talking, by 2022 we are expecting about a billion dollar kind of a biologic sale which is more than 3x of the current biologic revenue that we are generating. So given that ramp up or the jump that we are expecting to achieve and we are not also seeing that the R&D spend, which is the biggest cost component there, it is not likely to move in the similar tandem, so then should we not be seeing a kind of significant improvement in the overall profitability of biologics as well as the overall Biocon business by FY'2022?***

M.B. Chinappa: Surya, a couple of points. I will just answer the Biologics business. So when I meant steady margins, I said for FY'21 at the EBITDA level really with the benefits flowing below that. It is too early to guide for FY'22. It is dependent on R&D spends of course and the sales mix which is product mix and region

mix. We have not yet given guidance around FY'22 numbers. We will do that at appropriate time.

Siddharth Mittal: But what we have also said is that biosimilars business is the highest margin business and that business is the biggest growth driver over the next two years. The consol margins would go up and obviously from a R&D expenses perspective, absolute number would go up. But the 12% number is more for next year. As we go forward and we reach the billion dollar number, the percentage would start coming down even if the absolute number was up. The margin accretion would happen.

Kiran Mazumdar-Shaw: And as you said, since you are going to triple the top line of Biologics and it is a high margin business, so you can proportionately see that the R&D spend would obviously come down.

Aimee Truesdale: *First question is actually on China. Given the Mylan-Upjohn merger, when do you start expecting to see Biologic sales in China and is any of that included in the \$1 billion target?*

Kiran Mazumdar-Shaw: The China number is not included in the \$1 billion target.

Dr. Christiane Hamacher: There is absolutely no doubt that the merger of Mylan and Upjohn will absolutely strengthen the position and the opportunity we see for our biosimilars in China. It is very-very encouraging to see in the last two years that biosimilars have entered the national drug reimbursement listing which in one go allows that the whole nation has access to biosimilars. And we believe that Mylan and Upjohn together as they address, will play a strong role in China.

Aimee Truesdale: *Any sense of timeline on -- is it a matter of months or is it kind of years?*

Dr. Christiane Hamacher: No, we are currently not commenting on the timelines.

Aimee Truesdale: *Second question is you speak about expecting a recovery in the next few quarters. Just wondering what your base case is for COVID, when are you sort of building in for a vaccine or treatment to be available and you are building in a second phase?*

Kiran Mazumdar-Shaw: This is being speculated across the world, but as far as we are concerned, we are really focusing on safety in the workplace. And I think we will try and aim to keep our operations going and we will look at seeing how we can keep the logistics and the supply chain efficiently running. So I think that is where we will focus. It is very difficult for us to predict whether there is going to be a second wave or not. But we will be in a state of preparedness because we should plan for a second wave and that is the way we look at the future.

Nitin Agarwal: *Ma'am, will it be possible for you to give us a flavor of the geographical split between US and the non-US market for our Biologics business as it is now? And as it could be under the \$1 billion by FY'22, we are talking*

about \$1 billion of revenues, any sense on what kind of geographical mix we are looking at in the business there?

Dr. Christiane Hamacher: So what I can tell you there are three components that are important and I mentioned them in the order of magnitude to reach the \$1 billion component. Number one is the United States; component number two is Most of the world markets; and component number three is Europe and other developed markets.

Nitin Agarwal: ***Siddharth, what could be our consolidated net debt?***

Siddharth Mittal: So the consolidated net debt as of March'20 is Rs.760 crores - give or take, \$100 million.

Nitin Agarwal: ***You mentioned about the Biologics business partly being shifted from Branded Formulations to Biologics from next year. On an aggregate annual level, what would be the amount of the business that we are shifting into Biologics now?***

Siddharth Mittal: I just mentioned sometime back, Rs.536 crores was the full year revenue for Branded Formulations. Rs.80 crores was UAE, so remaining Rs.460 crores is branded India.

Nitin Agarwal: ***But that would not be all Biologics, right?***

Siddharth Mittal: Well, the Branded Formulations India business has been completely transferred under Biocon Biologics. So the 70%-plus of that revenue is biosimilars, but the remaining is pertaining to Small Molecules drugs, but the operations is being managed by Biosimilars business.

Nitin Agarwal: ***Hereon will be reported under Biologics revenues going forward?***

Siddharth Mittal: Biosimilars revenue. So, as I had mentioned earlier also that we will split Biologics into two -- Biosimilars and Novel Biologics.

Raj Mohan: ***On the Biologics front, you indicated to the post-COVID scenario where structurally one should expect a much stronger environment for biosimilars what with the global economies coming under severe financial strain. How about the structural impact on the regulatory environment like FDA due to COVID-19, do you anticipate engagements and approvals to be swifter? How do you see the movement towards approval of, say, Semglee in this context?***

Sundar Ramanan: At this point, we do not see any impact of COVID on the regulatory interactions with the agency and we remain confident about the Semglee approval along with our partner, Mylan as we have previously indicated.

Raj Mohan: *In fact, on the contrary, I was wondering whether things could be moving a bit more faster post-COVID than the global economic scenario when approvals come in faster?*

Sundar Ramanan: In the US, these are statutory timelines and FDA has to go through under PDUFA and BSUFA acts, they have certain mandate and standard timelines, and that is what they are going to go through.

Raj Mohan: *Next, coming to market share gains in Fulphila post your capacity expansion, where are we now currently in terms of market share and what is the internal estimate on reaching closer to 20% as the leader Coherus seems to have gained a couple of more points in market share this quarter from 20 to 22%?*

Paul Thomas: I think we have been consistent; we are around 6% market share level and we see this growing over time. I think as Mylan has talked about, the foundation is built, the capabilities are there from physician, payer and hospital standpoint. And there are green sprouts as they have talked about that they are seeing. So we expect steady progress upward on our share here.

Raj Mohan: *Mylan has in their call indicated to garnering about 3% market share in Ogivri. Has Biocon been impacted by lower profit share this quarter? And the larger recognition will flow in through the next quarter?*

Kiran Mazumdar-Shaw: Yes, we have been impacted by lower profit share this quarter. And as we said, there has been a lot of impact on account of COVID because we have seen a huge drop in hospital treatments which of course, have also impacted the uptake of many of these products. So, we do expect to see a good recovery this quarter. And as Paul just mentioned, there are green fronds that we are seeing and we expect this to now pick up and we will recover during this quarter.

Raj Mohan: *One final question on Etanercept which is I believe launched by Mylan in Europe. What is the market size? And when could the US launch be planned?*

Peter Meeus: Thank you for the question. So the current estimated value in Europe based on 2019 sales of the originators is about \$2 billion. As you know the CHMP has just given a positive recommendation end of March. The US launch is anticipated more towards the end of this decade. So, I hope that that addresses your question.

Charulata Gaidhani: *Can you quantify the loss from Malaysia in FY'20?*

M.B. Chinappa: Excluding R&D cost, it is Rs.160 crores.

Charulata Gaidhani: *What is the kind of growth we expect in Small Molecules going forward?*

Siddharth Mittal: The growth on a full year basis should be a high single-digit to low teens for Small Molecules business for the next one or two years.

Bharat Sheth: *Siddharth, you said that we are spending \$200 million on the Small Molecules. So when do we see the impact of that in translating in the top line and how much out of that will be for this backward integration if you can give some sense and color. So over the next couple or three years, how do we see the Small Molecules business?*

Siddharth Mittal: The gestation timelines from ground zero to going commercial are anywhere between four to five years. This \$200 million investment will be going into new manufacturing capacity. We have already started the Vizag immunosuppressant greenfield plant, and we will be adding more drug substance and drug product facilities which are part of this \$200 million outlay. We expect the revenues to start in three to four years timeline. But the full impact of the \$200 million investment would be definitely beyond that three, four years timeframe.

Bharat Sheth: *What kind of asset turnover do we really expect at the peak level?*

Siddharth Mittal: In Biocon Small Molecules, we do not talk asset turnover because it is a combination of API and Generic Formulations. API being a large component when you compare it with the other industry players. Their asset turnover tends to be high because they capture the generic formulations sales. So you have an apple to orange kind of comparison. But you look at the ROCE, last few years, it has been stable at 22%, 23%, and that number should be able to realize once we complete the investment phase.

Bharat Sheth: *Would you like to give some kind of guidance on the tax rate from FY'21 onwards?*

Siddharth Mittal: I think at a group level it should be somewhere around 25%. If I have to pick a range, it can fluctuate between 23% and 27%.

Bharat Sheth: *Once the Biologics which has been moving to this UK side, so we have the losses sitting in the Malaysia and UK also, there is no taxation, correct?*

M.B. Chinappa: Tax rates are lower and there are some more concessions under patent box. Malaysia has a tax break, but is currently operating at a loss and additional profits will not have a tax impact.

Bharat Sheth: *That is why I just want to understand from the whole consolidated basis. So, would it be a little lower than what you are looking, Siddharth?*

Siddharth Mittal: No, I would rather give a guidance which is more midway. There are a lot of moving parts on tax with so many subsidiaries. We have R&D expenses sitting in subsidiaries where there is no profit and the profitable commercial business sitting in entities where there are also moving parts in terms of the

tax, SEZ benefits. I would definitely expect that 25% is something you should factor in, in your model.

Prakash Agarwal: *Just a couple of clarifications. So one of the participants did ask about recovery from Q1 and normalization from Q2 which is a statement by Christiane. So just making it clear what you mean by normalization, is growth on a Q3 fiscal '20 number or do you expect to reach that level by Q2? My understanding was in Q1 itself; you will be at the Q3 number level. If you can clarify that, that will be helpful.*

Dr. Christiane Hamacher: So what we mean is recovery in Q1 and normalization is meaning going back to growth what we have seen in Q3.

M.B. Chinappa: Recovery is going back closer to where we were in Q3. Normalization is back on the growth trajectory that we have been showing over the last several quarters.

Prakash Agarwal: *We are heading towards the Q3 number in Q1 and in all likelihood we are all set to exceed the number, what we have already achieved in Q3, is that the way to understand?*

Dr. Christiane Hamacher: We are looking forward to a strong revenue growth in fiscal year '21 on the back of the molecules in the United States and also on the back of increased market penetration of our molecules in EU and rest of the world. We clearly expect that we will go back to the growth trajectory that we have seen before.

Prakash Agarwal: *Just to tie that up with your 2022 guidance of a billion dollars, so as one of the participants also said that you need to double every year. So what I understand is it would be more '22 heavy. So we would unlikely double this year, would that be correct understanding or closer to double?*

Dr. Christiane Hamacher: So we actually expect that for both fiscal year '21 as well as fiscal year '22, will see a strong growth trajectory. We have several molecules already on the market. We expect largely to be in the United States. Additional molecules to be launched include Bevacizumab and Aspart. All this gives us a strong revenue growth potential for both fiscal year '21 as well as fiscal year '22.

Prakash Agarwal: *So you mentioned from '23 to '25, you have visibility of three launches and '25 onwards, you have visibility of one or two, I missed that point, if you could just help repeat that, please?*

Dr. Christiane Hamacher: So what I have said is that our pipeline is expected to deliver at least three additional molecules between fiscal year '23 and fiscal year '25 and also then for the coming years, we expect to launch two molecules per year.

Prakash Agarwal: *Is there any update on the Sandoz deal like anything we can share, how are we progressed since we have crossed fiscal '20 as a year as a milestone. So anything you want to share?*

Dr. Christiane Hamacher: When it comes to Sandoz, the development of our molecules are in very early stages and what we have is according to plan.

Atishray Rahlan: *Firstly, I like to commend you on the \$0.10 mission initiative. I have two questions. The first one pertaining to the biosimilar insulin. Would you be able to provide a rough estimate of total insulin sales in FY'20 and a sort of approximation of the geographic distribution?*

Dr. Christiane Hamacher: For recombinant human insulin, our insulin franchise, I am not sharing the details on a product basis or across regions.

Atishray Rahlan: *What about insulin analogs?*

Dr. Christiane Hamacher: It is the same for the insulin analogs that we are not providing specific data on a product basis.

Atishray Rahlan: *Could you provide some sort of comment on the uptake you are seeing in Trastuzumab and Pegfilgrastim when it comes to the outpatient formularies in the US?*

Paul Thomas: So when you talk about formularies, oncology is a little bit different than a retail pharmacy product where the PBMs drive it. It is much more the insurance company coverage levels rather than PBM formularies and they are less of a factor. But coverage levels are quite high, really, the vast majority of payers are covering the product, so coverage is good.

Yatin Mohane: *My question is on the Biosimilar business. I think over the last couple of years, the market in US and Europe has evolved into a more competitive landscape with the innovators and other biosimilars adopting quite aggressive strategies including exclusivity contracts. So just wanted to get your view on what gives us confidence to sort of achieve the \$1 billion revenue target?*

Dr. Christiane Hamacher: We are actually very confident to achieve the \$1 billion revenue target. It has three important components. Our molecules in the United States, most-of-the-world's markets, where our biosimilar business also continue to do really, really well. We have also got many more registrations in the last year, for example, when it comes to Trastuzumab and we are now starting to commercialize this more and more. And also, Europe is the third component. What is not factored in this \$1 billion guideline is China. Also, with our increased portfolio, as I have mentioned Bevacizumab and Aspart, the fact that Trastuzumab was just recently launched and that Glargine is an upcoming launch in the United States, we remain very, very confident to cross the US\$1 billion line by end of fiscal year 2022.

Vishal Manchanda: *I have a question on the interchangeability status of Lantus. Can you guide whether this interchangeability status would only be for the vial or it would also be for the pen version?*

Sundar Ramanan: So like I mentioned before, we are pursuing and discussing with the agency on the interchangeability actively and we will come back to you once we have clarity.

Vishal Manchanda: ***Would any clinical trials be required or you have done some basic trials and on the basis of the same we are pursuing this interchangeability status?***

Sundar Ramanan: So late last year, the agency issued a guidance that talked about if the analytical package, similarity package is strong enough, there may be provisions to entertain the discussions with agency on interchangeability and biosimilarity. So that is exactly what we are doing.

Vishal Manchanda: ***And is there any chance that interchangeability status can come along with the Lantus approval that you are expecting anytime now or it is going to be a separate dialogue and it will take some time?***

Sundar Ramanan: When we get clarity on that, we will provide you the same as well.

Nithya Balasubramanian: ***I just wanted to check on your Copaxone filing in the US. Have you responded to the queries from the FDA? What is the current status? And do you have any visibility on the launch time?***

Siddharth Mittal: Yes, we have responded to the CRL on Copaxone to the FDA. The file is under review. We are going back and forth in terms of the information that the FDA is asking as they review our response. We have been assigned a new target action date, but at this stage, it is pretty early to comment when we will launch the product or if the approval is on track because the FDA still has to review certain critical sections. And given the complexity of this drug, we rather cross that bridge or cross the milestone where we know that the approval is imminent. And at that point of time, we will let you know.

- Ends -

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