Transcript

Biocon Limited Q4 FY19 Earnings Conference Call
April 26, 2019

Participants from Biocon's Senior Management Team

- Kiran Mazumdar-Shaw: Chairperson & Managing Director
- Arun Chandavarkar, Chief Executive Officer & Jt. Managing Director - Biocon
- Siddharth Mittal: Chief Financial Officer - Biocon
- Shreehas Tambe: Chief Operating Officer - Biocon Biologics
- Paul Thomas, Chief Commercial - Biocon Biologics
- Saurabh Paliwal: Head, Investor Relations - Biocon

Prepared Remarks Session:

Saurabh Paliwal: Thank you, Lizz Ann, and good morning, ladies and gentlemen. I am Saurabh Paliwal from Biocon Investor Relations team, and I welcome you to today's earnings call for the Fourth Quarter and Full Year of Fiscal 2018-19.

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 shall be made available on our website in the coming days.

Moving along, to discuss the company's business performance for this quarter and the year and also the outlook, we have today with us the leadership team at Biocon, comprising of Dr. Kiran Mazumdar-Shaw -- our Chairperson and Managing Director, and other senior colleagues from the management team.

I would like to take this opportunity to remind everyone about the Safe Harbor related to this call. Today's discussion may be forward-looking in nature based on management's current beliefs and expectation. 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. Post the conclusion of the call, if you have any further questions or need any clarifications, please get in touch with me.

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

Kiran Mazumdar-Shaw: Thanks, Saurabh, and good morning, everyone. I welcome you to Biocon's earnings call for the fourth quarter and the fiscal year-end 2018-19.

I would like to start with some key announcements for the quarter.

- Dr. Christiane Hamacher has been appointed the CEO of Biocon Biologics and has been entrusted with the responsibility to lead the Biosimilars business and transform it into a major global player in Biologics. Dr. Hamacher comes with more than 20 years of leadership experience in both strategic and operational

roles across the value chain in the global pharma sector, spanning Asia, Europe and the US with leading multinational pharma companies.

- Our partner, Mylan, commenced commercialization of Biosimilar Trastuzumab under the brand name Ogivri in Europe.

- Syngene, our Research Services subsidiary, announced the opening of its Centre for Advanced Protein Studies, set up in collaboration with the Biotechnology Industry Research

- Assistance Council or BIRAC, at Syngene's campus in Bengaluru. The 2,000 sq.ft. centre hosts a state-of-the-art GLP-accredited analytical lab which will be available to BIRAC-funded start-ups, SMEs, MMEs and academia in India at an affordable cost. The center will run under the "Innovate in India" program of the National Biopharma Mission, Department of Biotechnology announced by the Government of India.

- To commemorate the 40th Anniversary of Biocon, the Board of Directors of the Company at the meeting held yesterday, recommended the issue of 1 bonus share for every 1 share held in Biocon. The board also recommended a final dividend of Re.1 per share pre-bonus for FY'19.

- Furthermore, I am extremely happy to say that as a part of our $1 billion aspirational revenue guidance for FY'19, three of our strategic business segments, namely Small Molecules, Biologics and Research Services, either met or exceeded their targets. We could not meet our consolidated $1 billion revenue guidance as our Branded Formulations fell short given the external and internal challenges faced by the business.

Moving on, I will now present the key financial highlights. I will first discuss the highlights for the quarter followed by the highlights for the year:

- Total revenues for the quarter was up 26% at Rs.1,557 crores.

- Revenue from operations stood at Rs.1,529 crores in Q4 which grew 31%.

From a segment perspective,

- Small Molecules segment revenue was Rs.472 crores for Q4, up 11%;

- The Biologics segment revenue grew 87% to Rs.451 crores;

- Branded Formulations revenues were Rs.133 crores, down 11%; while

- Research Services grew 30% and registered Rs.534 crores.

- Gross R&D spend was Rs. 166 crores for this quarter, which corresponds to 17% of revenue ex-Syngene. Of this amount, Rs. 92 crores is reported in the P&L, while the balance amount has been capitalized. The R&D expenses this quarter are higher on account of higher spends in ANDA programs, the impact of which is reflected in Q4 segment margins for Small Molecules.

- We booked a FOREX loss of Rs. 7 crores as compared to a gain of Rs. 42 crores last year. This loss is reflected in other expenses line in the profit & loss statement.

- EBITDA for Q4 stood at Rs. 431 crores with EBITDA margins at 28% compared to 24% last year. EBITDA margins have increased despite a much higher R&D spend and a net negative FOREX impact, thus reflecting a very strong operating performance.

- Core margins, that is EBITDA margins net of licensing, impact of FOREX and R&D, stood at 34%, which is up from last year's 26%. Net profit for the quarter was Rs. 214 crores, growth of 64% over Q4 last year on account of improved operational performance.

- The effective tax rate of 14% for the quarter is lower than last year's 21% on account of tax benefit on R&D, including additional CAPEX and offsets of profits in the UK entity against carry-forward losses from prior years.

Now coming to Financial Highlights for FY'19:

- Consolidated revenues for the year were Rs.5,659 crores, up 31%.

- Revenue from operations were Rs.5,514 crores, which grew 34% compared to last fiscal. This includes licensing income of Rs. 25 crores as compared to Rs. 23 crores last year.

From a segment perspective,

- Small Molecules segment revenues were at Rs.1,773 crores, up 18%.

- Biologics revenue doubled to Rs. 1,517 crores;

- Branded Formulations revenue grew 7% to Rs.656 crores; while

- Syngene revenues were at Rs.1,826 crores, up 28%.

- We incurred gross spend of Rs. 480 crores on R&D this year, corresponding to 13% of revenues excluding Syngene. Of this amount, Rs. 290 crores is reported in the P&L while the balance amount of Rs. 190 crores has been capitalized. This amount relates to biosimilars and insulin development expenses. R&D expenses increased in FY'19 on account of higher spends on biosimilars as well as the ANDA programs.

- For the full year, we booked a FOREX gain of Rs. 28 crores as compared to Rs. 83 crores that was recognized the previous year.

- EBITDA was at Rs. 1,538 crores for the year, up 49% with EBITDA margins at 27% benefiting from better operational performance.

- Core margins, that is EBITDA margins net of licensing, impact of FOREX and R&D, stood at 32%, up from 27% the previous year.

- Reported net profit for the year stood at Rs. 905 crores, which includes certain exceptional items. Adjusted for exceptional items and associated tax, net profit for the year was Rs.729 crores, a growth of 96% YoY with net profit margins at 13%.

- The effective tax rate for the full year, when excluding exceptional items, stood at 19%, which is lower than the previous year's 26% due to availment of R&D incentives and benefit of carry-forward losses we had in our UK entity as previously commented upon.

Now coming to reviewing business segment performance for the full year -

Small Molecules recorded 18% growth and on account of APIs as well as a ramp-up in our Generic Formulations business which completed its first full year of commercial operations. Higher volumes and pricing stability for statins and immunosuppressants led the growth in API sales, while Generic Formulations business recorded

robust growth albeit from a small base due to new product introductions in the US market. We successfully commercialized Atorvastatin and Simvastatin formulations in the US and recorded market share gains in the previously launched Rosuvastatin formulations. More launches are expected in the next 2-3 years which cumulatively are expected to provide revenue growth visibility in this segment.

Coming to **Biologics,** FY'19 has been a landmark year as it crossed the $200 million revenue milestone this year. Our Biosimilars strategy has begun to deliver with the start of monetization of our Biosimilars pipeline in the developed markets of US and EU. The launch of biosimilar Pegfilgrastim in the US and the ramp-up of sales of our biosimilar Trastuzumab in emerging markets were the main contributors to this growth.

Other notable highlights include the launch of biosimilar Insulin Glargine, biosimilar Trastuzumab and in-licensed biosimilar Adalimumab by our partner Mylan in Europe. Higher revenues including impact of profit sharing in both developing and emerging markets offset higher R&D and fixed costs, leading to significant improvement in our quality of earnings, not only in the Biologics segment but also at the consolidated level. The segment PBIT for Biologics improved from a negative 2% last year to 26% in FY'19, reflecting a very strong performance over last year.

Now coming to **Branded Formulations**, performance was muted largely on account of decline in our UAE business. Metabolics, Nephrology, Critical Care and Market Access divisions were the key growth drivers for the India business. Key brands like Insugen, Basalog, Erypro, Tacrograf and Psorid reported strong double-digit growth. The UAE performance for the year was impacted by uncertainty in the local market, including delays in drug registration with the local health authorities and repricing of branded generic products mandated by the Ministry of Health.

On a more positive note though, we launched our first Biosimilar Trastuzumab under the brand name Canhera, which is aimed at providing an affordable treatment option and increasing access to this medicine for patients suffering from breast cancer. The launch of Canhera represents our second biosimilar launch in the UAE market, initially having launched Biosimilar Insulin Glargine under the brand name Glaricon.

Research Services or Syngene delivered a very strong performance during the year, driven by robust performances in both Discovery Services and dedicated R&D centers. During the year, Syngene further expanded its customer base as well as its existing client relationships. The expansion of ongoing strategic collaboration with Baxter also led to the commissioning of additional infrastructure for them.

Coming to some **product development updates**.

When it comes to biosimilars, the global development programs for both Biosimilar Bevacizumab and Insulin Aspart are progressing well in Phase-III clinical trials.

In terms of Novels, our Phase 1b/2 trial in acute graft versus host disease with our novel asset Itolizumab was initiated by our partner Equillium, who has licensed our novel anti-CD6 monoclonal antibody for US and Canada markets. Equillium has been awarded Fast Track and Orphan Drug designations for the molecule in both prevention and treatment of acute graft versus host disease by the US FDA.

Now coming to **Outlook** -

In the coming fiscal, we expect the growth momentum across our business segments to continue, led by higher biosimilars revenues. While we expect core margins percentage to sustain, R&D expenses across our business segments as well as depreciation are expected to significantly increase. Furthermore, in FY'20, our investment in human capital will also significantly increase on account of setting up an organizational structure to support

independent functioning of our Biosimilars business under Biocon Biologics, and we have also set up a Boston-based subsidiary, Bicara Therapeutics, to support our immune-oncology programs which have been pursued under our novel programs. We expect these investments to augur well in pursuing our ambition of enabling access to affordable biologic therapies to patients worldwide whilst establishing Biocon as a leading global player in biologics.

With that, I would like to open the floor to questions and answers. Thank you.

Q&A Session:

Prakash Agarwal, Axis Capital, Axis Capital: *A question ma'am on the R&D outlook, we have seen a constant jump and that is the lifeline for any pharma company. But how do we look forward on the R&D side both at gross level and at P&L level?*

Kiran Mazumdar-Shaw: I would give you a sort of a broad guideline to basically look at R&D expense as being roughly 15% of our revenues ex-Syngene.

Prakash Agarwal, Axis Capital: *This is more so for fiscal '20 guidance?*

Kiran Mazumdar-Shaw: Yes, and this will, as I said, it is going to cover both Biosimilars and our ANDA as well as our novel programs.

Prakash Agarwal, Axis Capital: *This is passing through the P&L, 15%?*

Kiran Mazumdar-Shaw: This is gross, but there will be a certain amount capitalized, depending on which part of the program expenditure pertains to our Biosimilars.

Prakash Agarwal, Axis Capital: *Secondly, a clarity on the comment you made that we expect to sustain core EBITDA margins, and you defined core EBITDA margins ex of R&D. So, with the growth momentum across business segments and even in Biosimilars, would it not be fair to assume that the core EBITDA margin would actually improve to sustain, what are the things we should keep in mind?*

Kiran Mazumdar-Shaw: So, I just mentioned that we are going to see of course increased R&D spends. But remember, we are also investing in CAPEX which is also likely to see...

Siddharth Mittal: Prakash, I think you have to look at the core EBITDA margins already increased 800 basis points compared to last year in FY'19, and a large part of that was driven by increased contribution from Biosimilars. What we are saying is in spite of increased expenses like was mentioned in the call previously in the staffing costs and other expenses, we expect our core EBITDA margins to be sustained at the FY'19 levels.

Prakash Agarwal, Axis Capital: *One comment on the transfer of equity in Biocon Biologics to Biocon Biologics India Limited. So what is the rationale there? Is the money raising plan going to happen from India level or what is the broad thought there?*

Siddharth Mittal: We are kind of looking at consolidating our Biosimilars business under Biocon Biologics India Limited. And one of the potential options for money-raising is the IPO, and we can consider raising money at this entity level.

Tushar Manudhane, Motilal Oswal Securities: *Just on the Biosimilars biologics revenue. So year-on-year, the traction has been great, but sequentially if I see despite launches in Europe and even a few more emerging*

markets, the revenue traction has been more or less steady. So is this the kind of pace which we should go ahead unless there are new approvals?

Paul Thomas: I think what we will see is that on a broad basis, year-on-year, we expect continued growth momentum as we have talked about, and I think that is the theme. I think as you go more granularly, you will see some lumpiness here and there when we have launches, we have tenders, we still have a significant amount of emerging markets business that is part of this where there is QoQ variation. But overall, the trend is for definitely continued growth momentum.

Tushar Manudhane, Motilal Oswal Securities: *So how much of this business would be from the tender base?*

Paul Thomas: We have a good mix right now across products and across regions, right, from developed markets and emerging markets, and a portion of emerging markets will be this. It is not a majority of our business, but these kinds of factors and supplying timelines will drive some variation across quarters. But I think I would not put a specific number on it. It is not a majority of the business but enough to impact some of these trends.

Tushar Manudhane, Motilal Oswal Securities: *Just on Small Molecules, if you can just help growth in terms of price, volume and the impact of currency?*

Siddharth Mittal: Currency, if you look at last year, was roughly Rs. 65 to a dollar, this year has been little over Rs. 68. So the impact of currency is 5% on a dollar-linked business. And Small Molecules, a large part of our businesses are rupee-linked given we supply to a lot of the Indian generic companies. So of the 18% full year growth that we reported, I would say a large part of that would be linked to increased volumes. We have seen pricing stabilize, but we are not seeing pricing necessarily go up. So, a very small component, as I said, on the segment revenue coming from FOREX. But majority of the growth is from the volume uptick.

Tushar Manudhane, Motilal Oswal Securities: *If you can help me on the effective tax rate which way should go for FY '20?*

Siddharth Mittal: What we have said is that it will fluctuate between 22-25% at a group level. This year has been slightly lower because as was explained in the opening remarks that we benefited from R&D incentives and CAPEX as well as the operating expenses in India, and this benefit is going to be available for another one year, after which, the benefit goes away completely. We also have few facilities which are currently under SEZ which will come out of the tax holiday period. Our UK entity turned profitable this year because of increased sales in our Biosimilars business which led to utilization of some of the carry-forward losses. So with next year, obviously, we will be paying full taxes without the benefit of carryforward losses. So we would see the tax rate increase on account of some of these benefits going away next year. So you should factor in somewhere between 22-25% on a steady-state basis. Again, it could fluctuate between the quarters because sometimes if the R&D expenses go up and then you get the tax incentives in R&D, the tax rate might come down. But again, on a full year basis, you can consider 22-25%.

Shyam Srinivasan, Goldman Sachs Research: *My first one is on the Neulasta market. If you look at secondary data, I think both you and Coherus seem to be doing pretty well in a kind of a duopoly. So just want to understand how we should think about this market -- do you think more of that entire syringes will over time, what is the thought process, over time, will it move all towards the Biosimilars or not? And the second question in that is do you think at some point of time given the economics, Onpro is something that one can target as well?*

Paul Thomas: I think on all of these innovator strategies to have multiple different presentations in the mix as part of their biosimilar responses, these are things some of the companies have said themselves explicitly, I think these may be challenges that need to be addressed but are not expected to be permanent challenges. Finally, the value provided by Biosimilars is going to drive things. So in the long-term, we see great opportunities despite

the various things that come up on the different products. And so I think that we see a good growth ahead of us on this product, and I think as you have noted, the traction and the momentum that is in the market right now on this product is good.

Shyam Srinivasan, Goldman Sachs Research: *So you think there is still upside from a share perspective on the...*

Paul Thomas: Yes, over the next quarters, we expect continued growth.

Shyam Srinivasan, Goldman Sachs Research: *My second question on the Biologics segment is we had insulin, we had Trastuzumab launch in Europe. So just any traction, any commentary from Europe, specifically on the biologics side -- is it like very early days or is it like are we still waiting for tenders and stuff, Can you just give us some color?*

Paul Thomas: I think you have hit it on the head. I think it is early days. We are very happy that we have these approvals, these launches in place. We have our start there, but I think it is early days to make comments on that.

Shyam Srinivasan, Goldman Sachs Research: *My last question is on the R&D guidance that was given. Are you also sharing how it is going to be split across because this quarter, we saw small molecules R&D shoot up. But can you give us a broad brush in FY'20 of how this R&D is going to be broadly split into over the different segments?*

Siddharth Mittal: No, Shyam, we do not break it up. I think you will get that number at the end of the year once we report the actuals and the entity financials are uploaded, so there you can see the actual numbers by our business segments, but not on an outlook basis.

Neha Manpuria, JP Morgan Research: *As we were seeing market share traction in Neulasta and with launches coming through in Europe and possibly in the US in the next year, how should we look at our CAPEX tracking the requirement of capacity as market share ramps up across US, Europe and emerging markets?*

Dr. Arun Chandavarkar: In the past, I think we have always guided that there would be requirements for CAPEX, and some of it we have already alluded to in our previous conversations where we already initiated investments in a large antibody facility in Bangalore. Clearly, there are other small modular investments in some of our other facilities whether it is the drug product facility in Bangalore or in Malaysia and elsewhere. So this prudent way of capital allocation in a modular way will continue going forward on top of the large antibody facility that we have already initiated.

Neha Manpuria, JP Morgan Research: *So if you could give us a number possibly of what the CAPEX spend was in FY'19, and how we should see it tracking in FY20/21 probably given the Biologics business ramp up.*

Dr. Arun Chandavarkar: I think the large antibody facility in the previous I believe we had hinted that it might be of the order of $200-odd million. And on top of that, not at the Biologics segment, but at a group level, we always say that we have another Rs.150-odd crores CAPEX, which is like an annual recurring CAPEX. It was not just maintenance CAPEX but also some of the balancing capacities that we keep incrementally adding. This is across our businesses, biosimilars as well as small molecules.

Neha Manpuria, JP Morgan Research: *The second question is on the Biologics business. I understand the EM business has lumpiness. Given the Europe launches and the traction we have seen in US, if you could give us any color on how should we look at the market share increase that the secondary data is showing versus the flat revenues QoQ, it would be great?*

Dr. Arun Chandavarkar: I think if you look at the IQVIA data for Fulphila, I think it tracks at around 15-16% market share in the syringe presentation. And my sense is that, as Paul alluded to earlier, we expect to see steady growth over the next fiscal as far as the developed markets are concerned. I think the lumpiness that you talked about was in a few emerging markets tenders. So we continue to anticipate significant growth in our Biologics business next year. And on a top line basis, we hope that the uptick that you have seen this year over the previous year will continue next year as well.

Nitin Agarwal, IDFC Securities: *On the R&D capitalization in the quarter, what kind of programs have we begun to capitalize now because understanding was a lot of the capitalization of R&D was done with the Mylan programs with the human insulin programs?*

Siddharth Mittal: That is right. So the capitalized programs are Trastuzumab, Bevacizumab, Glargine and human insulin.

Nitin Agarwal, IDFC Securities: *But we should not be incurring incrementally a lot of costs on these programs, right, because all these trials largely should have been done by now?*

Siddharth Mittal: Well, Bevacizumab is in global Phase-III. So large part of capitalization is from Bevacizumab. Also, human insulin is entering the Phase-I, so there are expenses for that. You are right for Trastuzumab, the costs are tapering down, and there are some costs that we incurred for Glargine as we had to complete some work as everybody might be aware for the US.

Nitin Agarwal, IDFC Securities: *So on a trend basis, the proportion of capitalization should come off, right, as we go next couple of years?*

Siddharth Mittal: Yes, it should come down.

Nitin Agarwal, IDFC Securities: *Secondly, on the Branded Formulations business, the slow growth that we have had in the Middle East market in this year, how should we look at this market now going forward?*

Siddharth Mittal: I think we expect some challenges to continue in the first half of next fiscal year. The reason is that there has been price revision by the Ministry of Health, and that has led to destocking, and we will also have to take some shelf stock adjustment on the inventory held by our customers because of the revised pricing and we do expect H1 to be impacted for this segment because of UAE.

Nitin Agarwal, IDFC Securities: *The gross margin in these three quarters have some fair proportion of Biologics. Is that the sort of gross margin level we should assume to sustain or are we looking for a possibility meaningful increases in gross margins with the increase in Biologics revenues?*

Siddharth Mittal: I would say for next year we will expect it to sustain. The launches in the US are going to be in this fiscal year, but the effect of those launches in increased market share and full year impact will be seen in FY'21. That is why we had mentioned that the core margins would remain stable in FY'20 compared to FY'19, and you will see an incremental growth in FY'21 over FY'20 coming from the impact of US launches.

Surya Patra, Phillip Capital: *Sir, just wanted to have a sense on the R&D again. So like in the earliest comments that you have indicated, about 15% kind of the Biopharma sales, excluding Research Services revenue, so 15% of that would be the R&D. So in fact, we have already achieved that number in the current quarter, and hopefully we should be seeing a kind of meaningful ramp-up in the Biologics revenues led by obviously the progress that we are witnessing on the Pegfilgrastim front, as per some third-party data, it says that, okay, already 20% market share that we have gained, and the other two product launches are also likely to happen at some part of the*

current financial year. So then despite that, do you see, okay, there will be a kind of incremental pressure from the R&D budget front on the overall margin?

Siddharth Mittal: You should not look at Q4, but full year FY'19, where we were ~13% of revenues ex-Syngene, and that number would go up to 15% in FY20, as will the revenues. So I think what we mentioned is that the core margin percentage would remain the same, but the absolute R&D value will go up. One is the 2% incremental spend. Second is the revenues going up in all business segments and the third is the reduced capitalization. I think Nitin had asked that question, and I have explained that the capitalization would start coming down over a period of time as we would have some of these programs which are capitalized, complete.

Surya Patra, Phillip Capital: *But do you not think there should be some benefit flowing from the cost, reducing it to the Malaysia plant level with the launch of Glargine or even some ramp up that we would be seeing in the emerging market, coming to the margin front, so sustaining margin from that, if I am discussing then?*

Siddharth Mittal: At this stage, we do not expect any benefit. So while you are talking about Malaysia, which is getting to a breakeven stage and will start generating profit as we go along, we will also have new plants which will get capitalized. In FY'19, we capitalized our second injectable plant in Bangalore. Next year, we will be capitalizing the oral solid dosage plant in Bangalore, and few other plants will come on.

Surya Patra, Phillip Capital: *Now any clarity about the launch of Trastuzumab in US and Glargine in US, why because there is already indication by Roche anyway that, okay, when they expect the generic competition and hopefully, Biocon being the first mover on that front at least having things before hand compared to competition. So what is your sense there?*

Dr. Arun Chandavarkar: I think on Trastuzumab, we have to maintain our position that we have previously maintained. Since there is a global settlement between Mylan and Roche, we would not be able to comment on the exact timing. And you are free to draw your own inferences from other commentary. But from our side, we continue to maintain that.

Siddharth Mittal: Only difference is Mylan, Roche, and we have said in the past, the launch is in calendar 2019.

Surya Patra, Phillip Capital: *Can you give share your -thought process towards the Bicara Therapeutics initiative what we have taken? Considering the Sandoz allied portfolio, what we are working on the Biosimilar front, this Bicara, how is that different, whether this is a novel biologic, and in toto, so the R&D budget, whether we can be surprised on the real spend front also considering all the things that is going on currently?*

Kiran Mazumdar-Shaw: So to answer your question, we are very excited with our immune-oncology pipeline which has been in the form of fusion antibodies. Now as you know, fusion antibodies, bi-specific antibodies, T-cell engaging antibodies, this is a very hot area. And we are actually right up front with a lot of these leading-edge kind of therapeutics. And whilst it was being done at Biocon, we felt that we needed to accelerate these programs, and we felt it was best done in the US, and Boston is one of the biotech hubs in the world which has been doing a lot of this kind of work where you can get the best of people, best of scientific advice to really accelerate these kind of programs. So we felt that it was best to create a Boston-based subsidiary and now start developing these programs with that kind of base. We are very excited with our first lead program which is basically EGFR TGF-beta molecule, which basically brings T cells to the tumor to kill it. So, there are many types of tumor that express EGFR. So we are very happy and excited with this kind of a development.

Now coming to of course the other parts of our business that will require R&D investment, yes, it is a fact that R&D is a very integral part of our business, and it is an investment in the future. If you do not invest in R&D, we will not be able to generate a pipeline that will sustain future growth and profitability. So whether it is our Biologics business, whether it is novels or whether it is our ANDA generics business, I think we will need to invest in creating

these new opportunities for us if we are to sustain and actually augment and accelerate our growth prospects. So that is why I think we need to basically invest in R&D in the way we are. However, given the fact that our earnings quality is improving because of investments in the Biologics business in the past, we believe that we can sustain the kind of increased expenditure through these increased opportunities that they we are creating by way of these new molecules. So I think it is a very exciting inflection point for Biocon. You can see that all our investments that we have made in Biosimilars have finally begun to payback for us. And we think that every one of these investments is going to pay back for Biocon big time.

Surya Patra, Phillip Capital: *Ma'am, in fact, after achieving successfully the $200 million kind of a revenue mark for the Biologics in FY'19, which has been set out a couple of years back, so do you have any such guidance that you would like to have or provide about biologic opportunities?*

Kiran Mazumdar-Shaw: No, at this time, it is very early to make those kinds of predictions. We keep looking at the way this business is growing and maybe at some stage, we will again probably give you some aspirational target.

Damayanti Kerai, HSBC Research: *So my question is regarding Biosimilar market in Europe. So you mentioned that it is early days in Europe for the launches, which we have done, and we definitely need to wait before we see traction coming in. But at the same time, we understand that Europe is more competitive market compared to US and maybe less attractive in terms of pricing. So how do you see yourselves here like what kind of particular edge would you believe Biocon, Mylan has in this particular competitive market, and any comments regarding that?*

Paul Thomas: I think you have laid out the background well. It is early days. It is a different market landscape from the US. I think the other piece of it is that Biosimilar traction overall has been very good. Acceptance of Biosimilars is quite good in Europe and they have been leading the way. It is a very diverse market and I think it would not be a topic we can get into details out here and it could be a good discussion point with Mylan who is leading the commercialization there as well, but I think there is a lot of differences across markets there as well, and I think in all of these it is about picking the right place that we want to compete in each market.

Damayanti Kerai, HSBC Research: *So you remain optimistic on European opportunities also or going ahead, it will be more focused on the US for Biosimilars, because we understand that, yes, Europe is a very diverse market but at the same time, it is very competitive and in terms of pricing there are lots of variations. So going ahead you will be preferring focusing on US over Europe or how are you planning?*

Paul Thomas: Europe will definitely be a very important component of our product mix. I think Pegfilgrastim in the US, we are the first to market there has a certain flavor to it. But Europe will definitely overall be an important part of our mix going forward.

Siddharth Mittal: I would just add one thing here that US will always be more attractive than Europe for the reasons you mentioned. The business competition, the pricing scenario is much better. It is not fragmented market like Europe where each country will require a different strategy. So overall for any pharma company, whether it is in generic pharma or biosimilars, US will continue to be more attractive than Europe.

Damayanti Kerai, HSBC Research: *Second, can you provide update on the Malaysia plant like how we are ramping up and what are our expectations and the next one or two years from that plant?*

Siddharth Mittal: So we continue to ramp up insulin sales in emerging markets. Over the next one to two years, the big growth driver there is Glargine. Mylan has already launched Glargine in Europe, though it is early days. We definitely expect to ramp up over the one to two year period. We will also look at launching Glargine in the US once we get the approval and that will be the big growth driver both in terms of the value and the volume for Malaysia.

Sameer Baisiwala, Morgan Stanley Research: *A quick question on Beva. I can see that at least seven players in the regulatory pipeline in Phase III or onwards, so do you think this is an asset worth pursuing?*

Siddharth Mittal: Sameer, even for Trastuzumab, there were more than seven. But how many finally cross the finish line, I think that is more important. And as far as the US is concerned, there is a limited competition and so far there has been only one approval there. We are on track to completing our Phase-III and will not the first to get approved, but we will not be far from the competition. There is a big opportunity for this molecule, both in the US and Europe, and we think that it can be a big growth driver for us in the next four to five years' time period.

Sameer Baisiwala, Morgan Stanley Research: *Second is on the US Neulasta launch. Given that if I am not wrong, Part-B and clinical setting product, generally, the adoption is expected to be slower, but what you guys have achieved in six months to hit almost 20% market share, and Coherus is also chipping in. So any color you can add as to why the adoption has been stronger or what is it that you are seeing in this market?*

Paul Thomas: I think Arun commented on this in the last quarter as well. The nature of Pegfilgrastim has advantages in terms of a shorter-term therapy. That does make it a little bit easier than certain products. Part-B has maybe certain complications, it has certain advantages also in the way that those products are purchased. But overall I think it just shows that there is a need for Biosimilars in the market and there are complications in the US market, and there has been a lot of talk about that, but there is an underlying demand there, and there is an underlying value for Biosimilars that is going to be realized.

Sameer Baisiwala, Morgan Stanley Research: *Any update on the Glargine filed for the US in terms of site switch that you are planning to do earlier?*

Shreehas Tambe: So we have responded to the agency, and we are working with them to take this through into the approval process. So we remain on track as we have guided before, Sameer and we expect that switch to be in market as guided earlier.

Sameer Baisiwala, Morgan Stanley Research: *When we talk of European launch, I think you need to go country-by-country to take pricing approval and so on and so forth which is a fair bit I would say different from the US where a launch means launch and you are in the market. So when you announced in European market, when do you really get all the price approvals, and you are on the ground in all the countries, what is the time lag between the two?*

Siddharth Mittal: We mentioned launch even if it has been launched in one country. As you rightly said that we have to get registrations, in certain cases, the pricing approvals in each country, and each country will have a different timelines. But when Mylan launches, they might have launched in one country or a few countries. So those details we do not comment on.

Sameer Baisiwala, Morgan Stanley Research: *And that is the reason why in Q4 we are not seeing any meaningful contribution from three launches in Europe. Would that be correct?*

Siddharth Mittal: That is partially the reason, and the other reason is that it is also the early days because if it is a tender market, then your growth will come in alignment with the tender supply. If it is a payer reimbursed market then the contract period will decide when the growth comes in. If it is a retail market obviously there will be a time to ramp up.

Charulata Gaidhani, Dalal & Broacha: *I wanted to know the status on the Bevacizumab trial.*

Shreehas Tambe: So the global trial is on track, and we should be in a place to submit somewhere towards the end of this calendar year into the US and probably early Q1 in the EU.

Charulata Gaidhani, Dalal & Broacha: *So when do you expect the data to come in?*

Dr. Arun Chandavarkar: So we should probably have that data earlier towards Q2 of this year.

Charulata Gaidhani, Dalal & Broacha: *My second question pertains to your opinion on the Medicare for All Scheme in the US?*

Paul Thomas: I think that is one of many discussions that are going on in terms of how access can be increased per patient. Increased access will be a good thing for patients and Biosimilars will have an important role to play in that. I think commenting on that specific proposal I think is probably premature.

Charulata Gaidhani, Dalal & Broacha: *But do you think it will bring it down the prices?*

Paul Thomas: There are various flavors of all of these proposals and various ways, I mean, Biosimilars, of course, we expect there to be savings to the health care systems because of lower pricing. And so reforms in these systems should favor and work with the objectives of Biosimilars overall. There are already a wide variety of procurement mechanisms in the US that have different pricing dynamics. We will have to see more on how the specifics play out.

Ranjit Kapadia, Centrum Broking: *My first question refers to pricing pressure in the US for API and generic formulations. The second question is we have achieved margin improvement mainly coming from sharp reduction in material costs. So how this has been achieved if you can throw some light on this?*

Siddharth Mittal: So on your first question, we have seen stability in the pricing in the US this year. Though there is a continued annual pricing decrease that happened, but the pricing has stabilized compared to a year back and we do not expect that to change unless the dynamics in the US change for some reasons which is beyond our control. Material cost is not the right cost to look at, you should be looking at the gross margins. Our gross margins have improved. Material cost does not come down drastically. On QoQ basis, if you are looking at the 7% reduction, also see that the revenues have gone down but the gross margin has gone up from 62% in Q3 to 64%, and that is because of a better product mix.

Ranjit Kapadia, Centrum Broking: *Sir, regarding other income, it is a sharp fall. So, is there any one-off item?*

Siddharth Mittal: Last year in Q4, we had FOREX gain, which was recorded in other income. This year we had FOREX loss, which was recorded in other expenses.

Aditya Khemka, DSP Investment Managers: *Sir, two questions. So you made a comment on EMs not being a majority of your Biosimilar revenues. Is it fair to assess that out of whatever your Biologic revenue you are reporting, less than 50% is coming from the emerging markets?*

Paul Thomas: That comment was that tenders are not the majority of our business.

Aditya Khemka, DSP Investment Managers: *And tenders are only in emerging markets. Is that correct?*

Paul Thomas: No, there are tenders in Europe as well.

Aditya Khemka, DSP Investment Managers: *I know you are not giving out the number but if you could just qualitatively, directionally tell us, from the third quarter to the fourth quarter of this fiscal, have your emerging market revenue in Biosimilars grown, declined, and what has that trend been in developed markets, grown or declined?*

Siddharth Mittal: The numbers from Q3 to Q4 in Biologics has remained same, and I would say the mix also broadly same, there is not a significant change in the ratio of emerging markets to developed markets.

Aditya Khemka, DSP Investment Managers: *Yes, so therein lies my confusion, sir. So your market share in Pegfilgrastim in the US has gone up significantly from your previous quarter average to this quarter average whereas your comment sort of says that your revenue might have been stable in both the quarters. So what am I missing here -- Was there a channel fill in the last quarter which was not recorded this quarter in the US?*

Siddharth Mittal: That could happen. We also booked revenues in two stages -- One is when we supply to Mylan; and second, we booked the profit when Mylan supplies to their customers. And I think what the IQVIA data and some of the other data has reported when finally the drug is liquidated at the point of administration. So we have three different points. It would be very difficult to reconcile the numbers in that three different point in time.

Aditya Khemka, DSP Investment Managers: *So do you feel there is a meaningful change in inventory at Mylan's level because that is where your sales would be correlated to?*

Siddharth Mittal: Yes.

Aditya Khemka, DSP Investment Managers: *There is a sharp reduction in inventory at Mylan's level?*

Siddharth Mittal: There is a reduction.

Harith Ahamed: *Could you please provide net debt number as of March 2019? And also the CAPEX incurred during the year?*

Siddharth Mittal: So the net debt at group level is Rs. 600 crores give or take. CAPEX again at the group level excluding the R&D capitalized, the tangible CAPEX is Rs.1,200 crores again at the group level for FY '19.

Harith Ahamed: *Could you also provide some timelines around the completion of trials and filings for Insulin Aspart?*

Shreehas Tambe: For Insulin Aspart, we expect to be filing in the EU somewhere end of Q3 or early Q4, and in the US probably towards mid-2020.

- Ends -

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