Biocon Limited's Q4 & FY16 Earnings Conference Call
April 27, 2016

Key Participants from Biocon Group's Senior Management Team

- Kiran Mazumdar Shaw: Chairperson and Managing Director
- John Shaw: Vice Chairman
- Siddharth Mittal: President, Finance
- Ravi Limaye: President, Marketing
- Narendra Chirmule: Sr. Vice President, R&D
- Paul Thomas, Vice President, Biosimilars
- Bhavesh Patel, Vice President, Generic Formulations
- Saurabh Paliwal: Head, Investor Relations

Presentation Session

Moderator: Ladies and Gentlemen, Good Day and Welcome the Biocon Limited Q4 FY'16 Earnings Conference Call. As a reminder, all participant lines will be in the listen-only mode and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing '*' then '0' on your touchtone phone. Please note that this conference is being recorded. I now hand the conference over to Mr. Saurabh Paliwal from Biocon Investor Relations. Thank you and over to you Mr. Paliwal.

Saurabh Paliwal: Thank you, Margaret, and Good Afternoon, Ladies and Gentlemen, and Welcome to Biocon's Investor Call for the Fourth Quarter and the Full Year-ended 31st March 2016.

Before I 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 immediately following the conclusion of this call. The call transcript shall be made available on the website in the coming days.

Today to discuss the company's business performance and outlook, we have Ms. Kiran Mazumdar-Shaw – Biocon's Chairperson and Managing Director, and other colleagues from the senior management team.

I would like to take this opportunity to remind everyone about the Safe Harbor pertaining to this conference call. Today's discussion may be forward-looking in nature based on management's current beliefs and expectations. It must be viewed in conjunction with the risks that our business faces that could cause our future results, performance or achievements to differ significantly from what is expressed or implied by such forward-looking statements. After the end of this call, if you need any further information or clarifications, please feel free to get in touch with me.

Now, I would like to turn the call over to Ms. Kiran Mazumdar. Over to you, ma'am.

Kiran Mazumdar-Shaw: Thanks, Saurabh. Good Afternoon, Everyone and Welcome to Biocon's Earnings Call for the Fourth Quarter and the Fiscal Year-ended 31st March 2016.

I will start by saying that this was a landmark year for the group as we finished FY'16 on a strong note with many firsts during the year to our credit. We received our first Biosimilar approval in a developed market with Japan approving our Insulin Glargine. Our partner Fujifilm Pharma expects to commercialize the product in the first half of FY'17. Biocon unlocked tremendous value in Syngene by listing it on the stock exchanges post a very successful IPO, making it the first Research Services Company of its kind in the country.

Biocon's consolidated revenues crossed Rs.1000 crores in a quarter for the first time in Q4. Syngene on the other hand crossed the Rs.1000 crores in revenues for the full year for the first time. Apart from this, we announced cost and profit share partnership with Lab PiSA of Mexico for the development and commercialization for Recombinant Human Insulin, wherein we will be fronting the regulatory and commercial efforts in the US. Some other highlights include our first generic formulation approval for Rosuvastatin in the EU, plus the acquisition and integration of assets from Acacia Lifesciences for manufacturing advanced intermediate of potent APIs in Vizag.

Now moving on, let me now present key Financial Highlights. I will first discuss the Highlights for the Quarter and then for the Full Year.

For the Fourth Quarter FY'16,

- Group sales grew 17% to Rs.971 crores.
- Biocon sales was Rs.655 crores for Q4, representing a growth of 11%. Within this, Biopharma sales were Rs.554 crores for Q4, a growth of 12% and this growth was on account largely from Biosimilars in emerging markets. Branded Formulations sales were Rs.101 crores in Q4, though the performance was rather flat with an effective growth of a modest 3%.
- Syngene, our Research Services subsidiary contributed record sales of Rs.316 crores in the quarter, a growth of 32% year-on-year. These numbers are on a consolidated basis and therefore adjusted for intercompany sales. On a standalone basis, Syngene recorded sales of Rs.326 crores and an EBITDA of Rs.106 crores with net profit of Rs.66 crores this quarter.
- We incurred total spend of Rs.152 crores on R&D this quarter. Of this amount, Rs.100 crores is reported in the P&L corresponding to 15% of Biopharmaceutical segment sales. We capitalized an amount of Rs.47 crores while the balance amount was offset against deferred revenue. Group EBITDA was at Rs.238 crores for Q4, reflecting a growth of 18% with EBITDA

margins of 24%. Clearly, revenue growth aided by a good product mix helped improve gross margins this quarter, but that improvement was offset by the impact of higher R&D expenses. In that context, we have been able to maintain our EBITDA margins year-on-year. In fact, core margins, i.e., EBITDA margins net of licensing, impact of forex and R&D continue to be strong, and they stood at 35% for the quarter, as against 31% last fiscal for the same period, reflecting growing strength in our operations.

- We also booked FOREX loss this quarter of Rs.17 crores on account of amortization of FOREX premium and hedging losses, the losses appear under other expenses.

- Pursuant to execution of our agreement with Lab PiSA of Mexico, which changes the nature of Biocon's future obligations on the rh-insulin program, the balance of deferred revenues of Rs.268 crores relating to this program has been recognized as income in the consolidated statement of Profit & Loss for Q4 and FY'16 and is disclosed under exceptional items. This accounting is consistent with treatment of deferred revenue upon partnering with Mylan in 2013 for the co-development of Insulin Analogs.

- Consequently, the group net profit for the quarter was Rs.361 crores. Adjusting for the exceptional item, the net profit for Q4 stood at Rs.105 crores, this will include tax on the exceptional income and this translates into a net profit margin of 10%.

- Long-term borrowings for the group at the end of FY'16 stood at Rs.2072 crores. The borrowings are to fund the group's CAPEX requirements in India and Malaysia.

Coming to the Financial Highlights for the Full Year-ended 31st March, 2016,

- Sales grew 13% to Rs.3451 crores at a consolidated level.
- Biocon's sales were Rs.2391 crores, representing a growth of 7%. Of this, Biopharma sales were Rs.1954 crores, a growth of 8% while Branded Formulations clocked sales of Rs.437 crores in FY'16, which is a flat performance with a modest 2% increase.
- Syngene crossed a major milestone of Rs.1000 crores in the fiscal year-ended 31st March 2016 with a contribution of Rs.1060 crores at the year-end. On a standalone basis, Syngene recorded Rs.1086 crores in sales, EBITDA of Rs.364 crores and net profit of an all-time Rs.221 crores.
- Gross R&D expense for the year were Rs.427 crores, of which Rs.275 crores is reported in the P&L, representing 12% of Biopharmaceuticals sales. Total amount capitalized during the year was Rs.104 crores while we offset Rs.49 crores from deferred revenue. The R&D spends for the year are in line with our comments in prior periods; we expect R&D spends to remain at this elevated level between 12-15% of Biopharmaceuticals sales in FY'17 as well.
- Group EBITDA was Rs.903 crores with EBITDA margins at 25%.

- Net profit for the year was Rs.896 crores, but adjusting for exceptional items in Q2 & Q4, the net profit for FY'16 stood at Rs.437 crores with a net profit margin of 12%.

Now moving on to discuss individual business verticals:

The **Biopharma business** did well in Q4, growing 12% year-on-year, while it grew 8% in the full year. Better small molecule product mix, increase sales of Insulins and launch of Trastuzumab in emerging markets resulted in the improved performance during the year; however, I would like to highlight that we continue to see pricing headwinds in the legacy API business, especially in Statins.

The performance of our **Branded Formulations** vertical in Q4 and FY'16 as a whole has been flat. As we communicated in Q3, this business has been rationalized and is in a rebooting phase after we have shelved a large number of products in order to shape this particular division into a specialty franchise. However, we delivered strong growth in our key focus areas of Insulins and Biosimilars. The negative impact was felt mainly in our outsourced oral products and disruption in supply of key in-licensed products.

Our Middle East Branded Formulations business through NeoBiocon did well, but delays in registrations impacted Sri Lanka. We remain committed to strengthening this Branded Formulations business with a focus on chronic therapies. Key brands that contribute to majority of sales in this vertical continued to perform well with our top brands growing in double-digits. We expect Branded Formulations in India to grow at or above the industry average in FY'17.

Now touching upon **Syngene**, this continues to perform well and robustly with broad-based growth seen across all three verticals, namely, the Discovery Services segment, the Development & Manufacturing Services and Dedicated Centers. Syngene is investing in its future growth drivers, which includes the Mangalore facility for production of various molecules, Syngene Research Center, Formulation Development Center, as well as the Biologics manufacturing plant.

R&D Highlights: FY'16 was a significant year in terms of the clinical advances made in many of our various R&D programs. Progress made by our various Biosimilar programs puts us on track for regulatory filings in US and EU for many of them in FY'17. As mentioned earlier, key success was the Japanese approval of our Insulin Glargine. This enables us to open many new markets, especially in large emerging markets like South Africa, Turkey, Russia, Brazil and others, which were up until now difficult to access.

Coming to our **Novel Molecules Portfolio**: We have announced positive results from our Insulin Tregopil Phase-I studies in the US and we are now set for the next phase of development, which we look to validate the product positioning as Prandial Insulin that could potentially mimic endogenous Insulin in a larger patient cohort. Clinical development of our novel Anti-CD6 Monoclonal Antibody

Itolizumab continues in Australia with dosing ongoing in healthy volunteers. These trials will evaluate pharmacokinetics and establish comparability of the subcutaneous route of administration of Itolizumab in comparison to the intravenous route currently approved in India.

Finally, **recap on our CAPEX initiatives for future growth**. In FY'15 we commissioned our Malaysian Insulin facility which is currently in the final stages of validation. We expect to receive regulatory approvals for the plant imminently which will enable commercial sales of Insulin in Malaysia and to other emerging markets sometime in the second half of FY'17. We have made substantial progress in the construction of the potent Oral Solid Dosage facility for our Generics Formulations business and an additional Sterile Formulations facility for our Biologics business, which is also increasing in its size. These plants are being built in our SEZ in Bangalore and are expected to be commissioned in early 2017. We would subsequently seek regulatory qualification for them.

Syngene recently commissioned the Syngene Research Center and also began construction of the Greenfield manufacturing facility in Mangalore. Investments were also made towards expansion of the API plant, Biologics manufacturing capacity, a new formulations facility and adding other services and new capabilities. We have chosen to part fund these CAPEX initiatives by debt. As a result of drawing down our loan facilities, we have seen long-term borrowings increase significantly this quarter with a corresponding increase in the cash balance.

I would now like to touch upon some **Corporate Restructuring**: As a part of our continuous focus to delineate our key business growth drivers, we have restructured our legal entities this year to enable us to unlock value for our respective businesses at an opportune time. As part of this exercise, we will now consolidate our Biosimilar assets under Biocon Biologics Limited, a new entity incorporated in the United Kingdom, and a subsidiary of Biocon Limited India. UK was chosen as the preferred location for this entity, due to its strategic geographic location in terms of its proximity to key global markets in the US and EU.

In conclusion, FY'16 has been a very significant year for us at Biocon. We unlocked tremendous value with the successful capital market listing of Syngene, we received our first developed market approval for Biosimilar Insulin Glargine in Japan and the approval of our first Generic Formulation Rosuvastatin in EU. We made significant clinical progress with all our lead Biosimilar programs and in the qualification of the Malaysian facility.

The focus in FY'17 therefore is to build upon the successes in FY'16. We want to also focus on key developed market filings of our Biosimilar portfolio, which will set the stage for Biocon into becoming a leading global Biosimilar player. Regulatory approvals of our new manufacturing facilities coupled with increased penetration of our Biosimilar products in emerging markets should provide the impetus to the Biopharma business in FY'17.

Focus on growing key brands will also enable us to build the Branded Formulations business and get it back on a high growth trajectory while Syngene will continue to grow on the back of capacity additions, new services and its key customers' expectations. Clearly, the thrust will firmly be on execution.

I would now like to open the session to Questions-and-Answers. Thank you.

Q&A Session

Moderator: Thank you very much. We will now begin with the Question-and-Answer Session. The first question is from the line of Manoj Garg from HealthCo. Please go ahead.

Manoj Garg: A few questions on your recently submitted ANDA for Glatiramer 40 mg with your partner Apotex. One, we have seen other ANDAs on Glatiramer languish at the FDA for multiple years, as FDA has repeatedly asked for incremental analytical and gene testing. So just wanted to get a better understanding of your level of interaction with and guidance from the FDA prior to submitting the ANDA? Two, your ANDA would have been submitted prior to the FDA draft guidance that was issued earlier this month on the product. So just wanted to see if there were any surprises in that document versus what was submitted. Lastly, perhaps you can just talk in general about some of your capabilities that you believe will give you a differentiated edge relative to some of the competitive files?

Bhavesh Patel: Yes, we are in discussion with FDA with our partners and our GA-40 mg ANDA is under review. Beyond that, we cannot provide you any other information related to this filing. But in terms of FDA guidance, we believe that we have a solid dossier**.**

Manoj Garg: Then I guess maybe you could provide some color as to the decision to go, to file straight on the 40 mg and not start with 20 mg?

Kiran Mazumdar-Shaw: We have filed a 20 mg and then we have also filed a 40 mg and we believe that we are in a good position because we have leveraged a lot of our biologic characterization capabilities in developing this formulation.

Moderator: Thank you. The next question is from the line of Abhishek Sharma from India Infoline. Please go ahead.

Abhishek Sharma: Two questions on the ongoing clinical trials of your Biosimilars. I just wanted to understand what were the interim milestones that were achieved for Glargine? On the Pegfilgrastim trial, apart from the fact that you met the primary endpoint, did you encounter any red flags in terms of safety or not meeting the secondary endpoint?

Paul Thomas: This is Paul Thomas. I will start with the Pegfilgrastim. As you said, it has met the primary endpoint as was pre-specified and we do not have any concerns with that and that is moving ahead well towards filing. I will turn it over to Narendra Chirmule, our Head of R&D for Glargine.

Dr. Narendra Chirmule: I would echo the same response that Paul gave, which is we met the primary endpoints for Glargine and we await the final results where we would be submitting the file very shortly.

Abhishek Sharma: So basically the data has been unlocked and you have some preliminary information in terms of your primary endpoints having been met. Is it?

Dr. Narendra Chirmule: That is correct. During the process of evaluation of the unblinding process, there is a process that is prescribed in the clinical protocols, which allows us to look at this interim data and that data allows us to ensure that we are committed to submit and that is where we are with both Pegfilgrastim as well as with the Glargine.

Abhishek Sharma: In terms of timeframe, how does this move forward from here given the fact that the data is with you now?

Kiran Mazumdar-Shaw: We have already indicated that we will be submitting these dossiers in FY'17 and we remain committed to that.

Moderator: Thank you. The next question is from the line of Sameer Baisiwala from Morgan Stanley. Please go ahead.

Sameer Baisiwala: A couple of questions here; one is, what I could get hold of your clinical trial design, it looks like other than Glargine, the three other lead compounds are probably not being conducting clinical trials in the US, it is all non-US geographies where you are doing these trials that is for Pegfilgrastim, Trastu and Adalimumab. So just curious would that be acceptable to FDA and this is based on your discussion with it?

Paul Thomas: Yes, that is correct, I think the countries that are included in the trials are listed in the registries and we have had many discussions with FDA on all of our programs and we are confident that the approach is acceptable with FDA.

Sameer Baisiwala: I presume I have some other parallel examples with other companies doing the same?

Paul Thomas: Yes, I think the footprint that we have for our trials is actually quite a common approach for Biosimilar trials, basically being conducted in the areas where there is the highest unmet need and the highest scope for Biosimilar recruitment in these trials.

Sameer Baisiwala: Second question is on your clinical trial Phase-III for Trastuzumab. There I think what you are doing it for is metastatic breast cancer. Just curious based on Celltrion's experience that it is now going back to the drawing board and now doing it for EBC, it is early stage breast cancer. So is there a risk that you too would be required to do that?

Paul Thomas: I think we have to look at each company's programs as an independent entity, each one has its own set of data and own set of circumstances and approach to the trials, given the nature of the drug and the disease state and the mechanism of action which is common across the indications, we are confident that our metastatic breast cancer approach will lead towards extrapolation.

Sameer Baisiwala: I presume this is in consultation with the FDA?

Paul Thomas: Yes.

Sameer Baisiwala: Just one final question is on Glargine; you indicated that Japanese market is about $144 million, just a couple of questions on that. So is this a very under penetrated market and so therefore there is scope for expanding the market? Second, what would be the market dynamics -- would this be through retail push or would there be tender, and how are you thinking about the pricing on this?

Kiran Mazumdar-Shaw: So let me try and answer that, Sameer. Basically, I think the way we look at the Japanese market is it is definitely a retail push as far we know. Secondly I think we view the Japanese regulatory approval as really a validation of the product quality and the dossier that we have basically got approved by PMDA in Japan. What we are looking at is to really use this as an opportunity to open many-many other markets, especially large emerging markets where we were not able to access because of various regulatory concerns. This obviously now has enabled us to fast track many of these markets. Secondly, I think this also positions us very strongly as we submit our dossiers for EU and US. Again, given the Japanese approval, I think the approvability of our dossiers in US and EU are also extremely high. So, I think this is what the optics are about our Glargine dossier.

Sameer Baisiwala: Kiran, just curious because based on clinicaltrials.gov, it looks like your Glargine US trials are probably not over yet or just about getting over. You must have filed a Japanese dossier quite some time back. So what clinical data did you use it over there? Second, for the other large emerging markets, from now when do you enter Brazil, Russia, South Africa in a year, in two years?

Kiran Mazumdar-Shaw: The emerging markets will be sooner than later, let us put it that way. But I think what you are talking about in terms of US, I think most of the trial is over and it is really a sort of a final phase of the trial and basically the approach taken both in Japan and elsewhere is very similar.

Sameer Baisiwala: So, which clinical trial data did you use for Japanese filing? I presume you must have done it a year or two back.

Kiran Mazumdar-Shaw: There was a trial conducted in Japan.

Moderator: Thank you. The next question is from the line of Prakash Agarwal from Axis Capital. Please go ahead.

Prakash Agarwal: Ma'am, first question on the R&D side, you have seen a good spike in the R&D and just wanted to get some color on which areas of which molecules and any new categories which have been included or is it primarily the big four that we have is going into advanced stages and that is needing all the cash if you can help us understand.

Dr. Narendra Chirmule: This is Naren Chirmule. So, you are correct. I think what we are seeing now in the increasing R&D spend is a reflection of the successes we have had in the last couple of years. In the last couple of years, we have really done well selecting molecules which we want to advance in our pipeline, and as they go into later stage clinical trials, the higher investment is expected. So it is not a surprise for us, this was anticipated.

Prakash Agarwal: I am aware, but what I am trying to ask is, would you say that these are more so for the big four molecules which are into the last stage as ma'am just mentioned or is it…?

Siddharth Mittal: The increase is across Biosimilars, Novels and ANDAs. As you would have seen in the press release, we have made significant progress in Biosimilars, we are also advancing our Novels in global clinic, as well as the filings we have done for ANDA. So this is a broad based increase not in a particular vertical.

Prakash Agarwal: Would you be able to share the breakup if any?

Siddharth Mittal: I can only say one thing; the difference between the P&L and the gross expense of Rs.52 crores that definitely pertains to Trastuzumab and Glargine. So you can see that the one-third is definitely for those two programs. The increase compared to last quarter has been primarily on account of Novels and ANDAs.

Prakash Agarwal: If you could also give some color on what is the deferred R&D still in the books?

Siddharth Mittal: There is no significant deferred R&D in the books. Significant portion of deferred R&D that was in the books was towards the rh-Insulin which has been written back as exceptional income this quarter.

Prakash Agarwal: So going forward everything is going to be expensed?

Siddharth Mittal: Yes or capitalized as the case maybe.

Prakash Agarwal: So capitalize because of yourself doing the trials for the developed markets?

Siddharth Mittal: Yes, for Glargine and Trastuzumab. For all other molecules at this stage it will be all expensed.

Prakash Agarwal: Just trying to understand the big milestone on the Japan approval. Is it fair to understand that the licensing income that we have mentioned is from Japan?

Siddharth Mittal: We do not give a breakup of licensing income, again the licensing income of Rs.23 crores this quarter is broad based, in our Small Molecule division as well as our Biosimilars division. There would be a milestone payment from Japan, which would be up on the launch, which can be expected in the first half corresponding to the launch in Japan.

Prakash Agarwal: So it has not booked yet?

Siddharth Mittal: Not yet.

Prakash Agarwal: On the base business, we have seen some improvement as the Insulin and the MAbs have picked up in EM. Just trying and understand that with Malaysia which is expected in second half fiscal 2017 or more so fiscal 2018?

Siddharth Mittal: Second half fiscal '17 is what we have mentioned in the past and we maintain the same for revenues to commence.

Prakash Agarwal: So you are already touching teens now in the Biopharma business. So would that be fair that with this facility coming on track, you would have more volume and value growth which could be upwards of 20%, since with Japan, you mentioned that there will be more markets like the Brazil, Russia of the world, so the other EM markets, the bigger markets would join in, and by that time you will have the easing of capacity, so just trying to see that, the first step is you touched double-digit growth in Biopharma business with the help of Insulin and MAbs, would we see much higher growth, is that fair to assume?

Siddharth Mittal: We will continue to see higher growth from our Biosimilars in emerging markets. Our Small Molecule business would continue to grow in the mid-single digits and we definitely hope to have a much better growth next year compared to what we have had this year in Branded Formulations.

Prakash Agarwal: Lastly, one comment on Biosimilars on track for regulatory submissions for some of in Europe and US. So when you say Insulin and Trastuzumab, so the filings for EU and US happen at the same time or…?

Siddharth Mittal: The requirements for both the authorities are different and the timing will also be different, some might require additional data, thought it would not be significantly apart from each other, but it will not be at the same time.

Moderator: Thank you. The next question is from the line of Shraddha Patil from Wealth Managers. Please go ahead.

Shraddha Patil: My first question pertains to Branded Formulations. As we have sort of completed the rationalization of the division, what kind of margins do we see at the end of Q4 in the Branded Formulations?

Siddharth Mittal: Margins were in low-teens.

Shraddha Patil: Secondly, as far guidance for the financial year 2019 where we had guided 20% of the total sales, so do we still maintain that guidance for the Branded Formulations given the flat growth that we have seen in FY'15?

Siddharth Mittal: Yes, we are confident of achieving Rs.1000 crores in FY'19.

Shraddha Patil: If you could highlight what would be the strategy for that?

Siddharth Mittal: We have said four things that the growth is going to come from the growth of the existing key brands and even in the last year, while we have seen a muted growth on an overall basis and part of it was because of the rationalization, our key brands continued to grow in the high double digits. The second is geographical expansion. We do have a franchise as you know in Middle East, which traditionally has been classified under Biopharma business and will be reclassified under the Branded Formulations business plus we are looking at expanding into additional geographies. Third, we are looking at licensing certain specialized molecules within our three or four core therapeutic indications that we operate in and these will be novel drugs. Lastly, launch of additional Biosimilars that we are developing for our global markets.

Shraddha Patil: So, any of the Biosimilars portfolio will come under the Branded Formulations is what you are trying to say?

Siddharth Mittal: The Biosimilars that we currently sell in India which includes Insulin, Glargine, Trastuzumab are already included and reported under Branded Formulations. As we have said in the past, we are also doing an India Phase-III trial for Bevacizumab, which at some point of time once launched in India would also be included under Branded Formulations.

Shraddha Patil: But nothing more than these two Trastuzumab and Glargine currently, so out of the…?

Siddharth Mittal: rh-Insulin is there.

Shraddha Patil: If you could please provide the break up or the figure on the tax on the exceptional item in the quarter gone and for the full year?

Siddharth Mittal: Rs.268 crores was the exceptional income, this was essentially the write-back of deferred revenue from Pfizer. This income was in our Swiss subsidiary Biocon SA, and the tax on that transaction was Rs.12 crores and for the full year taxes are Rs.117 crores, the main component is Rs.100 crores, which was on account of Syngene IPO. At a standalone level in Biocon, we had net income of approx Rs.500 crores on which we had MAT tax of 21%.

Shraddha Patil: So Rs.100 crores from the IPO and Rs.12 crores on this particular…?

Siddharth Mittal: On Pfizer deferred revenue.

Shraddha Patil: If you could help us understand more about the rationale behind Biocon Biologics Limited?

Siddharth Mittal: As Kiran mentioned earlier that we are reorganizing our legal entities to reflect each of our growth verticals. We have five growth verticals being Small Molecules and Generic Formulations; Branded Formulations; Biologics, which essentially comprises of Biosimilars and Novels; and the Research Services. We had very few legal entities and most of our legal entities had a mix of each of the vertical. So we wanted to clearly demark our legal entities to reflect each of the vertical so that we can unlock value for each of the vertical in an appropriate way at an opportune time. In the past, we have monetized our Enzymes business by divesting that business to Novozymes, we took Syngene to the capital markets, and as I have mentioned that for rest of our business, we might look at monetizing the same at an opportune time.

Shraddha Patil: So monetizing in any of the previous way that you have done that you just mentioned the Enzymes business or Syngene way?

Kiran Mazumdar-Shaw: It would be looking at various options.

Shraddha Patil: If you could provide an update on the ANDA filings that we have done?

Siddharth Mittal: In total of 7-8 filings so far, we will continue to have 5-6 each year.

Shraddha Patil: So 7-8 filings in this current year?

Siddharth Mittal: Cumulative and some of those are already public now, we have already got the approval for our Generic Rosuvastatin in Europe, you would have read recently on Simvastatin dossier

that we acquired. Bhavesh, our ANDA Business Division Head had mentioned about generic Copaxone, there was another lawsuit on one of the other products, which is a Para-IV filing in December. So, that would give an indication of the kind of filings we are doing.

Moderator: Thank you. The next question is from the line of Vishal Manchanda from Sunidhi Securities. Please go ahead.

Vishal Manchanda: I have one on Lantus Biosimilar. As I understand, there are few device and formulation patents that still protect Lantus in the US. So could you guide us once Biocon gets an approval, is there a potential threat that Sanofi might litigate Biocon on infringement on their unexpired patents? They actually did so in case of Eli Lilly. So I was just wondering if this could happen with Biocon.

Kiran Mazumdar-Shaw: We do not want to comment on this.

Moderator: Thank you. The next question is from the line of Sudhakar P from Span Capital Services. Please go ahead.

Sudhakar P: I had a couple of questions. My first question would be on your CAPEX for the current year FY'17 and FY'18 ex-Syngene. I understand that Syngene is going to spend around $200 million over next two years. So what would be Biocon's standalone CAPEX?

Siddharth Mittal: Traditionally, we have had maintenance CAPEX of anywhere between Rs.75 crores to Rs.100 crores a year. In addition to that, we had started commissioning of our Oral Solid Dosage facility and second Formulations line in Bangalore, which were around Rs.160 crores each, part of the cash outflow was there in FY'16 and we would have a component of that in FY'17. I would say the overall CAPEX for Biocon when you combine maintenance CAPEX and the carryover of the two new facilities should be in the range of Rs.300-325 crores.

Sudhakar P: I understand that debt level has also gone up. So will the debt level go up from the current level also or the existing debt would more or less take care of CAPEX?

Siddharth Mittal: It will take care of the CAPEX. The debt level has gone up, but I should also draw your attention to the cash balance, the cash balance has also gone up corresponding to the debt increase.

Sudhakar P: My point was, is this the peak debt?

Siddharth Mittal: The only additional debt that we are going to take from this point on is to fund our working capital in Malaysia. We took some additional debt this year to fund the pre-operating expenses for FY'16 as we continue to incur these expenses till commercialization begins.

Sudhakar P: My second question is on your R&D expenses. You mentioned that R&D would be roughly around 12% to 15% of your Biopharma revenue. So just wanted to understand what you would be charging to P&L and what would be capitalized, is there some way we can estimate it?

Siddharth Mittal: What we have mentioned 12% to 15% is what is in the P&L and not the gross amount. At a gross level if you see this year, we have Rs.427 crores on total Biopharma revenue of Rs.2390 crores, so that is almost 20% at gross and the P&L is 12-15%.

Sudhakar P: So on a gross level what would be your R&D spend for next year?

Siddharth Mittal: It will be in the same range; 18% to 20%.

Sudhakar P: Another question is on your FY'19 target of $1 billion revenue. Are you still on track for that?

Siddharth Mittal: Yes.

Sudhakar P: You mentioned that your core EBITDA margin is around 35% for the quarter. So how do you see the margins improve from the current level, any sense on margin you see next two to three years down the line?

Siddharth Mittal: Biosimilar business is definitely more accretive in terms of margin compared to our traditional Small Molecule and the Branded Formulations business. As the Biosimilar business as a percentage of overall business goes up, we definitely expect that the margins that we have seen in Q4 can be sustained in long-term. However, we have discussed in the past that once we stop capitalizing the expenses on our Malaysian facility, there would be some part of expenses that will flow through our P&L.

Sudhakar P: That would happen end of FY'17?

Siddharth Mittal: It would happen sometime in the second half of FY'17.

Moderator: Thank you. The next question is from the line of Ujwal Shah from Quest Investment. Please go ahead.

Ujwal Shah: My question pertains to Rosuvastatin. When can we expect launch of the product and what kind of competition has been seen in the market for this product?

Ravi Limaye: As was announced in our press release, there are about 10 or 12 markets where the market is already open in EU and there will be some other markets where the market will open in early 2018, which is put together $1.2 billion number that was given. In terms of competition, well, there are

about 30 generic players already in the market; however, you must appreciate that 4 out of these 30 generic players account for about 50% market share. So that is the nature of the market in the EU markets where the product is already off patent.

Ujwal Shah: In terms of the Biosimilars in the emerging markets, we have seen good growth in 4Q FY'16. So can you help us know which all markets have we already launched Trastuzumab and Glargine?

Ravi Limaye: I would not give you exact details for competitive reasons; however, we have made entry with our Trastuzumab in certain important markets in the Middle East and North Africa, we have also entered into certain markets in South East Asia, you already have heard about our approval in Japan for Glargine and we will launch that product in the market soon and as we speak, more and more markets are opening up, so over the next six months, you will see entry in a few more emerging markets. So it looks very encouraging at this stage.

Ujwal Shah: If you all can give some idea about rh-Insulin program in US, what kind of progress can we see from here on, and when can we possibly see more actions from the same?

Kiran Mazumdar-Shaw: As you know, we just signed the deal, so we have just about started the program and I think we will be able to give you more optics on the development over the next few quarters.

Moderator: Thank you. The next question is from the line of Shariq Merchant from Ambit Capital. Please go ahead.

Shariq Merchant: I just wanted to understand the exceptional item a little better; the Rs.268 crores was on account of changes of future obligations. So does that mean that this is only a book entry or is this an actual inflow of cash and can this also be recurring?

Siddharth Mittal: This is an accounting entry, cash was received in 2012 when Pfizer had terminated the agreement, that time, for rh-Insulin, there was $51 million that was received, of that $51 million in the last couple of years, we had spent close to $14-15 million, and the remaining amount which was lying in the deferred is what was written back and obviously this is one-time. So we do not have any more balance in deferred as I mentioned some time back. The cash has already been received and has been invested as a part of our equity in the Malaysian facility.

Shariq Merchant: So why write it back right now and not earlier?

Siddharth Mittal: When the agreement had terminated with Pfizer, that time we had certain continuing obligations to conduct clinical trials. Since, we had a change in partner from Pfizer to PiSA existing

continuing obligation has been exhausted and now we have a new obligation with PiSA. As a part of PiSA agreement we havereceived small upfront, which is what will be used to partially offset the development expenses. As Kiran had mentioned in her opening remarks, this accounting was consistent with the treatment that we had followed when we had partnered for development of Insulin Analogs with Mylan. $51 million was only for rh-Insulin and there was a large sum which was there for analogs received from Pfizer, which was also treated as exceptional income when we had partnered analogs with Mylan.

Moderator: Thank you. The next question is from the line of Purvi Shah from Sharekhan. Please go ahead.

Purvi Shah: Sir, my question is regarding on the other expenses as mentioned in the opening remarks there was some FX item. So excluding that also I guess the figure was around Rs.86 crores, which is much higher compared to the other quarters. So is there anything else that is there sitting on the other expenses?

Siddharth Mittal: No, these are all normal operating expenses, it is also linked to the level of business activities.

Purvi Shah: So is this the rate that we can assume going forward would be…?

Siddharth Mittal: Every year we have seen our operating expenses go up. While we try to keep our expenses in control, but due to inflation, we have our utilities and other expenses go up every year. Though the increase in expenses may not be at the same pace as our revenues grow, but definitely we do not expect that the expenses would start going down.

Purvi Shah: If you could tell us what are the hedges in the book currently?

Siddharth Mittal: W**e** hedge 100% of our net foreign currency exposure for the first 12-months and 50% to 70% for the second 12-months and these hedges are by way of plain vanilla options or range forwards.

Purvi Shah: If you could say what is the option that we have taken currently in it?

Siddharth Mittal: As I mentioned most of hedges in Biopharma businesses is in form of range forwards, with range in between 66 to 73, 74 and upwards. We continue to benefit from the depreciation of rupee with an overall ceiling and we are protected for any downside in case rupee appreciates.

Purvi Shah: If you could give guidance what would be the tax rate going forward for the next two years?

Siddharth Mittal: We have guided for 22-24% and we hope to be within that. This year the tax rate has been higher on account of MAT, in 2015 fiscal we were under current tax and we had certain R&D benefits that were eligible for deduction under 35 (2) (AB). However, in FY'16 because of the Syngene IPO, we had to get out of current tax and move into MAT, which is at 21% and hence we were not able to get the R&D benefits. Next year we do expect tax rate of 22-24% because a lot of the R&D benefits are being sunset as per the last budget.

Moderator: Thank you. The next question is from the line of Deep Master from Enam Holdings. Please go ahead.

Deep Master: I just wanted to know if you have any CAPEX obligations to the Lab PiSA agreement for FY'17 and FY'18?

Siddharth Mittal: No, we have no CAPEX. As we have mentioned that the drug substance for rh-Insulin for US markets would be manufactured by Biocon either in our Indian facility or our Malaysian facility and the drug product would be manufactured by PiSA and the facility would be set up by PiSA.

Deep Master: But, do you have any further trials related costs?

Siddharth Mittal: Yes, it will be there.

Deep Master: Would that come to R&D?

Siddharth Mittal: It will come to R&D and as Kiran mentioned that we still have to work out the details with PiSA and in the coming quarters we will have more clarity in terms of what are the activities and the costs associated with those trials.

Deep Master: I had one question on your filing process. The first phase of filings in the US, will that be under the 505(b) (2) route or the NDA route?

Siddharth Mittal: We have announced in the past that Glargine, we plan to file under 505(b)(2). However, our other Biosimilars would be under 351(k) path.

Deep Master: I am asking because of the recent circular by the FDA which said that any approvals that do not come by March 23rd 2020 would not be considered under 505. So…?

Kiran Mazumdar-Shaw: All our filings are expected to be before that.

Dr. Narendra Chirmule: Of the programs that are advanced today.

Moderator: Thank you. The next question is from the line of Ranjit Kapadia from Centrum Broking. Please go ahead.

Ranjit Kapadia: Sir, my question relates to statin APIs. If you can elaborate what is the global pricing scenario now in the Statin business?

Ravi Limaye: So the Statin business continues to be extremely competitive in terms of pricing. Most of them as you know are old statins as the patents have expired quite a while back. So yes, the answer is extremely competitive in terms of pricing.

Ranjit Kapadia: So, what are the advantages we are enjoying over the competitors?

Ravi Limaye: The biggest advantage is the quality. The biggest advantage is the recognition by the USFDA not having any observations yet. So these are all things which certainly add up. You must understand that once you are a qualified source, you are a qualified source. So there is no point in changing a qualified source. So, it is important to get more and more customers with us.

Moderator: Thank you. The next question is from the line of Sameer Baisiwala from Morgan Stanley. Please go ahead.

Sameer Baisiwala: On the partnership with PiSA, what are the timelines when you can launch rh-Insulin in the US market?

Kiran Mazumdar-Shaw: Obviously, we still have to develop the program and you just heard that you need to submit the file before 2020. So we will be aiming for that and I think the only optics we can give you is that there is a review process, so you would not be in the market before 2021 or 2022.

Sameer Baisiwala: The second is I am just wondering you mentioned that why you have chosen to incorporate the Biosimilar assets in the UK geography. Whether it offers any tax benefits and would it not have helped to go to places like Switzerland from that perspective?

Siddharth Mittal: There are no additional tax benefits in UK, the headline tax rate itself is 20%, though UK has certain tax advantages under patent box regime for certain qualifying R&D programs. Switzerland is not part of the European Union and as Kiran had mentioned in her opening remarks that the reason we chose UK was because we wanted to be close to the US and the European markets. So when we do filing in Europe, we can file through UK, but not through Swiss.

Sameer Baisiwala: It is a very general comment that would you make a distinction between your Biosimilar filings in the US and in the Europe in terms of IP-related court cases to say that US this would be a burden to be overcome, but in Europe this could be actually a lot softer?

Kiran Mazumdar-Shaw: I think this is something that we really cannot answer with too much certainty or specificity, it depends. It would be on a case-by-case basis.

Sameer Baisiwala: I thought this is true based on the experience so far by other companies.

Kiran Mazumdar-Shaw: Yes, generally okay, that is the kind of perception, so I think you can go by that general perception I guess it is, but I do not want to generalize and find that for a specific dossier you might find some other aspects.

Sameer Baisiwala: On your ANDA strategy, are you working on some long-acting injectables, microspheres and those kind of products?

Kiran Mazumdar-Shaw: I cannot really share that with you at this point.

Moderator: Thank you. The next question is from the line of Abhishek Sharma from India Infoline. Please go ahead.

Abhishek Sharma: I had this question around Insulin Glargine again. So Lilly has been in the German market for about six months now, and they have only been able to gain 2% market share with the Basaglar. So do you think there are some commercial challenges which could sort of delay gaining of market share by Generics in this category?

Kiran Mazumdar-Shaw: I do not think we can really comment on Lilly's strategy, because our strategy would be far more aggressive I think, I think Mylan would be very, very aggressive in terms of getting market share. Lilly has a very different approach and a different way of marketing their Insulin Glargine, where they want to really take the portfolio approach, so I really cannot comment too much.

Abhishek Sharma: If I could just follow-up on that comment, the aggression would be led by pricing or an enhanced presence in the market detailing to the doctors, etc.?

Kiran Mazumdar-Shaw: I think you have to ask that question to Mylan.

Moderator: Thank you. The next question is from the line of Harith Ahmed from Spark Capital. Please go ahead.

Harith Ahamed: On Biosimilar filings expected, since there are litigations likely following your filings, so who will be bearing the legal costs -- will it be shared by Biocon and Mylan or is Mylan entirely…?

Siddharth Mittal: All regulatory costs and legal costs are shared between Biocon and Mylan.

Harith Ahamed: On the Malaysian facility, can you share the CWIP on the balance sheet related to the facility now as of March?

Siddharth Mittal: Harith, I will take it offline as I do not have the numbers readily available with me, but I will have Saurabh or I will send you an e-mail with the number.

Moderator: Thank you. The next question is from the line of Surjit Pal from Prabhudas Lilladher. Please go ahead.

Surjit Pal: Kiran, could you please share the rh-Insulin market because what we heard or what we have seen is that the major market in Insulin is mainly long acting. So could you please throw some light on rh-Insulin market in US?

Kiran Mazumdar-Shaw: The deal with Lab PiSA is only for the US market because that we believe is the largest market. If you look at the entire Insulin opportunity in the US, the rh-Insulin itself is a $2 billion opportunity and that is what the addressable market for us is and we believe that we can actually get a good sizable chunk of this market because the innovators are basically vacating the space and focusing a lot on the analogs. So we think there is going to be a nice business to go after.

Surjit Pal: Your previous talks about Oral Insulin program, is it currently on or you were putting on hold?

Dr. Narendra Chirmule: We are very excited, we are going to be starting our next phase of our clinical trials and I think this is an area that we have talked about last time and as we generate new data and we have new plans we will talk to you more about the plans for this program. To say that we presented the data that we submitted in the last quarter, we have got some very good data from the Phase-I and all our international advisors have advised us that this program has a lot of promise.

Surjit Pal: Are you also actively looking for partner for this program?

Dr. Narendra Chirmule: Yes, like in every other Novel program, we are always looking for licensing partners who can develop these molecules with us.

Surjit Pal: Your domestic Insulin has come under price restriction. I do not know about what is the current status of the Glargine in that area. Could you throw some light on that, your previous plan for growth and after how much it has changed post that entering into this price restriction list of the government?

Ravi Limaye: So the price restriction that you are talking about is the rh-Insulin for India and we do not think that would have any significant impact on our growth strategy, I do not think that really matters to that extent, it is insignificant.

Kiran Mazumdar-Shaw: Because we have been selling it under price control for a long time.

Surjit Pal: That is true, but the bigger guys who were selling at a higher price if they come down, that might affect your growth in volume?

Kiran Mazumdar-Shaw: No, I do not think so, if you look at the market share today, the big guys have always had a big market share, and we would like to get more market share, which is our approach.

Ravi Limaye: If there is a price control, it is applicable to everybody, right.

Kiran Mazumdar-Shaw: The difference in pricing is not significant, so, I think this is not about price, this is really about how do you capture market share and get more prescribers really.

Moderator: Thank you. The next question is from the line of Sree Srihari from PCS Securities. Please go ahead.

Sree Srihari: Firstly, I would like to know what is the FOREX loss Q-o-Q or Y-o-Y and for the full year. Secondly, if you could please give the share of Biosimilars in the Biopharma pie?

Siddharth Mittal: The Biosimilars in the Biopharma pie is not being broken up. We do expect that as we rationalize some of these entities, we will be reporting by verticals probably starting first quarter. So from first quarter onwards probably you can get much more granular clarity in terms of revenues. In terms of your first question, we had FOREX loss of Rs.17 crores this quarter, we had FOREX loss of Rs.17 crores also in the fourth quarter of last year. So in total there has been no change when you compare the two; however, let me also give you a break-up of Rs.17 crores; Biocon Biopharma had Rs.1 crore gain, while Research Services or Syngene had Rs.18 crores of loss. On a full year basis, FY'16 at a group level, the total loss was Rs.13 crores compared to Rs.17 crores in the last fiscal. For Q3 FY'16, there was a loss of Rs.4 crores compared to Rs.5 crores in last Q3 of FY'15.

Sree Srihari: Regarding the share of Biosimilars, can you give some indicative number -- is it in single digits or…?

Siddharth Mittal: You can consider at 15% of the total Biopharmaceuticals revenue.

Moderator: Thank you. As there are no further questions, I would now like to hand the floor over to Mr. Saurabh Paliwal for closing comments.

Saurabh Paliwal: Thank you for joining us today. But before we conclude, I have a small clarificatory statement with regard to earlier questions about Biosimilars that are or will be part of our Branded Formulations business. Our response mentioned products that are in our internal divisions, which we

refer to as Biosimilars. These comments do not imply any regulatory designation of the product as Biosimilar in India.

With that, thank you very much for joining us and we look forward to seeing you again next quarter. Have a Good Evening.

Moderator: Thank you. On behalf of Biocon Limited, that concludes this conference. Thank you for joining us and you may now disconnect your lines.

Note: The transcript has been edited to improve readability and includes corrections to statements or numbers.