Biocon Limited's Q4 & FY15 Earnings Conference Call
April 30, 2015

Key Participants from Biocon Group's Senior Management Team

- Kiran Mazumdar Shaw: Chairperson and Managing Director
- John Shaw: Vice Chairman
- Siddharth Mittal: President, Finance - Biocon
- Abhijit Barve: President, R&D
- Ravi Limaye: President, Marketing
- Peter Bains: CEO, Syngene International
- M.B. Chinappa: President, Finance - Syngene International
- Manoj Nerurkar: Chief Operating Officer, Syngene International
- Saurabh Paliwal: Head, Investor Relations

Presentation Session

Moderator: Ladies and Gentlemen, Good Day and Welcome to the Q4 & FY15 Earnings Conference Call of Biocon Limited. 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 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. Thank you and over to you sir.

Saurabh Paliwal: Thank you, Shyma and Good Afternoon everybody. Welcome to Biocon's Earnings Call for the 4th Quarter and Fiscal '15. Last night, we had released our results and hope you have received them, the same have also been posted on the stock exchanges and our company website. This afternoon to discuss the business performance and outlook we have with us Ms. Kiran Mazumdar-Shaw – Biocon's Chairperson and Managing Director along with the senior leadership team at Biocon.

Before we proceed with this call I would like to remind you that this call is being recorded and a replay will be available for the next few days immediately after the conclusion of this call. The transcript of the call shall be available soon on the company website. I would also like to add that today's discussion may be forward-looking in nature and must be viewed in conjunction with the risks that our business faces. The Safe Harbor language contained in our press release also pertains to the conference call. I would like to emphasize here the disclaimer regarding Syngene International Limited in relation to its proposed IPO applies to this conference call. After the end of this call, in case you have any additional questions, please feel free to get in touch with the IR team. 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 quarter and fiscal ended 31st March 2015. Let me present the Key Financial Highlights for Q4 and the Full Year 2014-15.

- Group sales for Q4 were Rs.830 crore which is a 15% year-on-year growth while for the full fiscal, the sales were Rs.3,059 crore, representing a growth of 7%.
- The Biopharmaceuticals segment sales for Q4 were at Rs.592 crore and Rs.2,236 crore for FY15 respectively. Now within this segment, Biopharma sales were Rs.494 crore for Q4 which represents a growth of 12% and for FY15 the sales were Rs.1,806 crores which represents a modest growth of 3% year-on-year.
- Branded Formulations sales grew 6% in Q4 to attain Rs.98 crore while for the full year the business grew 10% to achieve sales of Rs.430 crore.
- The Research Services segment (Syngene) delivered sales of Rs.238 crore in Q4 and Rs.823 crores for the full year FY15 which translates to 27% growth year-on-year for Q4 and 15% growth on an annualized basis. These numbers are adjusted for inter-company sales and other income numbers. Now standalone revenues for Syngene International were Rs.252 crore in Q4 and Rs.872 crores in FY15, which depicts a 27% growth for the quarter and 17% growth year-on-year respectively. As shared earlier, Syngene has filed a Draft Red Herring Prospectus with SEBI on the 22nd of April 2015 and this takes us one step closer towards the proposed IPO for Syngene. The timing of the IPO will be dependent upon market conditions and receipt of various approvals including approvals from SEBI, FIPB and other statutory bodies. Given that we are in the silent period post filing the Draft Red Herring Prospectus, we cannot make any forward-looking statements regarding this business or the proposed IPO.
- R&D spends: At a gross level we have spent Rs.329 crore on R&D, of this amount Rs.169 crore is reported in the P&L, which represents 8% of Biopharmaceuticals segment sales or the Biopharma sales as we call it. We have capitalized an amount of Rs.59 crore, while the balance has been offset against deferred revenue.
- Group EBITDA was Rs.202 crore for Q4 and Rs.749 crore for FY15 with EBITDA margins at 24% both for Q4 as well as for the full year FY15. The lack in EBITDA growth for the full year is largely due to increased R&D spends. Core margins, that is EBITDA margins excluding effects of other income, licensing, and R&D spends continue to be strong, they stood at 28% for Q4 and 26% for the full year, reflecting strong operations.
- FY15 also saw us book a FOREX loss of Rs.20 crore on account of amortization of FOREX premium and hedging losses, these losses appear under the head 'other expenses'.
- Group net profit for the quarter was at a Rs.202 crore, but this of course includes exceptional income, notably sale of shares of Syngene by Biocon Research Limited to Silver Leaf Oak. Q4 net profit excluding this was at Rs.106 crore and for the full year adjusted net profit was Rs.402 crore with net profit margin at 13%. Adding exceptional income to this, the net profit stands at Rs.497 crore.
- Long-term borrowings for the group at the end of Q4 stood at Rs.770 crore on account of loan taken for construction of our Malaysia Insulin facility.

Now, discussing our segmental businesses.

I would like to start with **Biopharma**. We have seen an improved performance from our Biopharma business in Q4. Increased sales of both small molecule APIs as well as Biosimilars, coupled with better a customer mix resulted in a better performance. It includes revenues received from Cubist this quarter. From a full year perspective, however, the Biopharma business continues to face a few headwinds. The legacy Statins basket continues to face pricing pressures, though volumes have been maintained. While we continue working towards redeploying sales from the Middle East to other geographies, there is continued uncertainty around Fidaxomicin and we have faced capacity constraints around our Insulin business which we are rectifying presently.

Our **Branded Formulations** business has grown slower as compared to previous years, but I would like to make a few important statements pertaining to this business. We have clearly focused on a strategic shift for this particular business where we have chosen to profile this as a specialty segment where we have deliberately rationalized our product portfolio, we have focused on making sure that we get away from our top line focus to a profitability-based focus. We have actually focused on product rationalization, field force rationalization, and this has actually delivered much better profitability for us this fiscal. So, although at a top line level we have seen modest growth, we are pleased that our strategic shift has actually started to get better realization from this particular growth vertical.

The domestic Insulin business continues to grow. We plan to launch Disposable Devices in FY16 from which we expect to have a positive impact to our Insulin business, especially that related to Glargine.

In Oncology, our flagship product CANMAb™ which is biosimilar Trastuzumab had a very encouraging start, completing its first full year of sales. This bodes well for the rest of our Biosimilar pipeline which we plan to introduce in the Indian market in the future.

Our **generic Insulins and Biosimilars programs** are advancing aggressively in the clinic. Global Trastuzumab and global Insulin Glargine trials which are Phase-III trials continue to advance significantly. As communicated in Q3, two additional global biosimilar programs are advancing in the clinic and by the end of the financial year we expect total of five programs including the India trial of Biosimilar Bevacizumab to be in Phase III.

In terms of **Novel Molecules**, our Oral Insulin *IN 105* program continues to progress well with the first set of US clinical trials completed this month. The US studies which we have undertaken can be classified as Phase-Ib/2a trials conducted on 100 subjects under US IND. To date a total exposure to *IN 105* has been 400 subjects including Type-I diabetics, Type-II diabetics and healthy volunteers. We continue to remain very excited about this molecule. Work on *Itolizumab* continues. As communicated last quarter, requirement of US regulatory approval for the licensee has delayed the process. In the meanwhile, in parallel, we are working towards getting proof-of-concept data in the rare neurological indications, where there is a significant unmet medical need.

I am also pleased to share that we have commissioned our Malaysia Insulins plant. In FY16, the plant will undergo a series of operational processes - scale up, validation, and stability, which is basically a qualification process required for regulatory inspections before we seek approvals from various regulators around the world.

I will end here and open this up for question-and-answers. Thank you.

Q&A Session

Moderator: Thank you, ma'am. Ladies and Gentlemen, we will now begin the question-and-answer session. The first question is from the line of Surya Patra from PhillipCapital. Please go ahead.

Surya Patra: My first question is on the Malaysia unit. Ma'am, in fact, just wanted to understand the structure of the Malaysia plant, whether it is multiple units or how is it like, we know that this would be a kind of integrated unit - both bulk as well as fill finish kind of structure, what would be the size compared to the existing unit what we are currently having in Bengaluru and how you would be capitalizing this entire unit – whether it would be in staggered manner or how is it, can you give some sense on it?

Kiran Mazumdar-Shaw: So I will answer the first part of your question to say that yes, this is an integrated facility which will have both drug substance and drug product. Yes, it is certainly a multi-drug product in terms of its design. I cannot give you exact scale differences between the India facility and the Malaysia facility, but suffice to say it is much larger than the India capacity that we have put in place. In terms of capitalization, I will leave it to Siddharth to give you some optics on this.

Siddharth Mittal: Surya, the capitalization of this plant would be done once we get a few major market approvals. So all the costs that are incurred to get the qualification from various regulators would be capitalized, and once we get approvals from the regulators like FDA or EMA at that point of time we will start depreciating the plant.

Surya Patra: So that means it would be led by the number of countries approval that we are getting?

Siddharth Mittal: It would be the major market approval. Since the plant capacity as we mentioned is significantly above the India capacity and the intended use for this plant is for the developed markets, so as per the accounting standards the plant capitalization starts when it has been put to the intended use, which would happen once we get either a FDA or EMA approval.

Surya Patra: Is it fair to believe that most of the developmental activities about Insulin would be taken care from the new unit henceforth?

Siddharth Mittal: Yes, and we have mentioned earlier that to harmonize our Malaysia plant along with our US plans, we would undertake developmental activities in Malaysia.

Surya Patra: So that indicates possibly some of the capacity will be released from the Indian facility which is currently occupied by the developmental activities?

Kiran Mazumdar-Shaw: We will use both facilities optimally, let us put it that way.

Surya Patra: Second question would be get an update on the Fidaxomicin because that used to be a key contributor both on the top line as well as bottom line. There have been a couple of positive large developments also relating to that. Merck is now the owner of Fidaxomicin product in US. So, should we considering a big bang kind of revival in the Fidaxomicin supply starting first quarter FY16?

Siddharth Mittal: Surya, that looks unlikely at this stage. Being a partnered molecule, we would not like to comment on their strategy. However, this quarter we did have our revenues from Cubist and that did lead to the growth that we have seen in Biopharma segment.

Surya Patra: If not big bang kind of revival, but a normalized kind of business structure which we would be seeing for Fidaxomicin even going ahead?

Siddharth Mittal: We cannot comment on that till we really understand the details from Merck.

Surya Patra: Regarding Insulin Glargine, last quarter there was around 10 countries kind of registration that we are having and this quarter we are indicating something like 20 countries approvals.

Kiran Mazumdar-Shaw: Surya, you should take the most significant approval as being Mexico. Even if we get registration from multiple countries, you have to look at where is it from that you are going to generate sizeable revenues. We believe that Mexico is really one of such markets because of the kind of tenders that they come out with. We realize that this is one significant approval which will actually allow us to pursue some good growth in Glargine.

Surya Patra: Since Mexico is kind of a semi-regulated market, do you think that it would lead to a kind of multiple such semi-regulated market entry easier for us?

Kiran Mazumdar-Shaw: We are seeing a lot of good visibility in terms of regulatory approvals in many of Mexico-like markets. Having said that we are also very keenly focused on our global Phase-III clinical trials for Glargine, which is really advancing very well and I think that is the space to watch.

Surya Patra: Considering the Malaysia commissioning now and progress happening in the Insulin Glargine front, what would be the change in revenue mix in the Biopharma business from the Insulin side one should look at compared to FY15 and possibly two year down the line?

Kiran Mazumdar-Shaw: I think it is going to be significant because as you know we have already given you some optics on Biocon's billion dollar revenue composition. We expect $200 million contributed from Biosimilars which will obviously include largely Insulin Glargine, recombinant Human Insulin and Trastuzumab.

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

Prakash Agarwal: Just a couple of questions here: First one, on the commissioning of the facility, if you could give us broad timelines of the completion of validation batches and when we can commercialize first the emerging market and to follow on with the developed markets?

Kiran Mazumdar-Shaw: We expect that we should start having regulatory inspections over the next 9 to 12-months and thereafter we will be able to enter many of the emerging markets, and shortly after that we hope that we can also enter developed markets.

Prakash Agarwal: So in a year or two emerging markets and thereafter developed markets?

Kiran Mazumdar-Shaw: May be even less than 2-years you might be able to if you are lucky get into a developed market, but, yes, your timelines are very fair.

Prakash Agarwal: Second question on India Formulations: We are doing the strategy of rationalization. So is it fair to assume that this would go on for a couple of quarters because of the high base last year and our new products getting introduced, so the next year bump up will be much superior both in terms of revenue growth and margins?

Kiran Mazumdar-Shaw: Yes, you have read that correctly. I think this year has been a real year of rationalization, we have deliberately shrunk our product offerings. We are focused on making us into a very specialty-driven company and our whole Branded Formulations portfolio and thrust has been about developing the specialty profile. So we are focused on our strengths which are really diabetology, oncology, nephrology, immunology, and immunotherapy. So these are the areas that we want to focus on and I think this has paid off very well for us this year. So although we have taken a hit on the top line where we have had many brands where we have been the 30th/40th brand in the market, those are the kinds of brands we have shed. We are now focused on market share and brand creation. So we want to definitely play a very strong leadership role and get recognized as a specialty company in the area.

Prakash Agarwal: With new products you would definitely see at least a double-digit growth going forward?

Kiran Mazumdar-Shaw: Yeah, you can see that we have had a very stellar success with CANMAb™. CANMAb™ is one of the most successful product launches recognized by the market this year, and so we believe that we are going to be introducing many more such products, and hope that our specialty profile will get more visibility.

Prakash Agarwal: On the gross margin front if I look at, though we have improved on a quarter-on-quarter perspective, but if I look at year-on-year perspective, the gross margins actually came off, I understand from EBITDA margin perspective because of higher R&D. But if you could clarify why gross margin is lower versus 4Q'14 and what is the way forward, how should we look at since we are expecting revenue mix to improve?

Siddharth Mittal: So last year we had Fidaxomicin sales in Q4, and we have mentioned in the past that this molecule was a very profitable molecule for us. This quarter Fidaxomicin sales have been significantly lower. So that had a negative impact on the gross margins.

Prakash Agarwal: How should we take it going forward since we are expecting revenue mix to improve substantially?

Siddharth Mittal: We do not expect the gross margin to move significantly from the levels we have seen in FY15 till we enter developed markets.

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

Ranjit Kapadia: My first question relates to Formulations business. If you can quantify the number of MRs and what is the strategy going forward for this business because we have seen a lot of shake out in this business? My second question relates to the Malaysian facility. What is the cost differential between Malaysia and Indian facility if you can clarify?

Ravi Limaye: The first question on number of MRs, my answer to that would be, as Kiran said, we are focused on creating a specialty organization and MR numbers are aligned to that kind of strategy, we are at about 1000 plus. So we think that is the kind of number we ideally need.

Siddharth Mittal: On the second question we do not give indication of our cost, but needless to say Malaysian facility is a bigger facility and newer facility compared to our Bengaluru facility. So we definitely expect that the COGS would be competitive.

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

Sameer Baisiwala: On Fidaxomicin, you mentioned that you had some lumpy payment coming from Cubist in 4Q. So, is this fresh sales that the company has done and is this something that is going to continue as we go forward?

Siddharth Mittal: Sameer, we had fresh sales as well as some contractual capacity reservation fees that Cubist is obligated to pay on an annualized basis.

Sameer Baisiwala: Do you think now this business is going to be more recurring in nature or this was one-off offtake by Cubist?

Siddharth Mittal: As I mentioned earlier it is difficult to comment on whether this will be recurring or not, we definitely hope it is recurring. However, as I mentioned that there are some contractual capacity reservation fees which tend to be lumpy because there are certain dates on which it accrues. So we definitely expect that in case the supplies are low we can get some capacity reservation fees.

Sameer Baisiwala: The second question is what percentage of the current market in India for Insulin is presently on Disposable Device?

Ravi Limaye: On disposable device the market is approximately Rs.330 crore as per IMS, this is all Insulin and Insulin Analogs put together.

Sameer Baisiwala: Which would make it about 30-35% of the overall market

Ravi Limaye: Overall market is ~Rs.1600 crore, so this is about 20%.

Sameer Baisiwala: And you see the market transitioning towards this Disposable Device?

Ravi Limaye: If you see the growth of the Disposable Device, it is certainly ahead of the overall market. More and more people now prefer that, but we have to also take it to consideration the economics which is important in the Indian context. So it will be a balance between the two. But, yes, people who are affluent will certainly prefer a disposable device.

Sameer Baisiwala: My third question is there any update on the harmonized filings for Human Insulin both in US and Europe?

Abhijit Barve: So Sameer, this is Abhijit. As the Malaysia plant is coming on board, we are looking forward to this harmonized filing that we have been talking about. So it will be partly integrated with this entire exercise that we are going through in terms of qualification, etc.

Sameer Baisiwala: Is there some sort of a color that you want to give for the core business, growth, margin, etc., for next year or so?

Siddharth Mittal: In terms of numbers or percentage, we cannot give guidance but what we have said for the next couple of years Branded Formulations, Research Services business and Biosimilar businesses are going to grow, in small molecules the growth will be in single-digits and we continue to maintain that guidance.

Moderator: Thank you. The next question is from the line of Hitesh Mahida from Antique Stock Broking. Please go ahead.

Hitesh Mahida: If I see your quarter-on-quarter Biopharma sales excluding Branded has gone up by almost 15%, so, it is almost $10 million. So, is it fair to say that majority of that is because of the capacity contract reservation fees which you have received from our partner for Fidaxomicin?

Siddharth Mittal: So that is a smaller chunk of that growth but we have had growth across our portfolios including Immunosuppressants and Insulin.

Hitesh Mahida: Second, our Biopharma contribution has gone up from 56 to 59% quarter-on-quarter which would have a lower gross margin compared to some of our other Branded and Syngene. Despite that we have seen a good jump in our gross margins. So, is it again due to that one-time fee?

Siddharth Mittal: No, in fact, Branded Formulations gross margin is better than Biopharma and so is Syngene. Definitely, the one-time fees that we have received from Cubist has added to the bottom line because there is no associated direct cost, but there are also some inventories that we carry for Cubist that we have to amortize. If you look at the net margin it has been at the company average. So there has been no uptick on gross margin or net margin because of Cubist capacity reservation fees.

Hitesh Mahida: So then what has led to this improvement?

Siddharth Mittal: I said that Insulin also grew and we had sales of some Biosimilars and gross margins on those are high.

Hitesh Mahida: Research Services business first half they delivered only 6% growth and in the second half they have delivered almost 23% growth. So, like to understand what has led to this huge jump in growth in the second half compared to the first half – is there any contract which we commence from 3Q?

Peter Bains: At the beginning of FY15, we had guided that the year would likely evolve in two distinct halves: a first half in which sales were somewhat muted, and the second half would pick up and that is indeed what we have delivered.

Hitesh Mahida: Yeah, but can you help us understand what has been the reason behind this?

Kiran Mazumdar-Shaw:I think what we can share with you is that Syngene has seen a good sustained kind of growth in its core businesses and its clients have committed to that business. Apart from that, they have had good business realization in the second half and also they have started offering much differentiated services which started paying off and delivering growth in the second half.

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

Abhishek Sharma: I had a question on Biopharma business. Just wanted to understand what territories are you cutting your exposure to? And what new territories are you trying to explore? In terms of new territories, what is the product portfolio that you intend to take there – is it Immunosuppressants, APIs or is it solely Insulin?

Kiran Mazumdar-Shaw: To answer your question, as you know, the only challenging geographical region for us has been the Middle East. It has really been the very volatile markets where there is a lot of conflict, so those are the high credit risk kind of markets which include Egypt, Syria and Iran. These are the main countries where really we have the challenges. So obviously we have made great efforts to lower our dependence on these markets, and, in fact, focus on other rest of the world markets which are really in the LATAM region, Southeast Asia and in some of the Eastern European markets. We have realized that in this last quarter some of these efforts have paid off for us and going forward we feel more confident that our dependence on Middle East markets which were very volatile is now no longer going to challenge us or be a threat to our growth.

Abhishek Sharma: In terms of what products are you taking to these markets?

Kiran Mazumdar-Shaw: All the products. These markets were not just about Insulin or just about one product, these have been markets for all our product offering, and so we are basically looking at the new markets for all these products.

Abhishek Sharma: If you can give us some color on what Egypt, Syria and Iran would constitute out of your total Biopharma sales?

Siddharth Mittal: It is in single digit.

Moderator: Thank you. The next question is from the line of Girish Bakhru from HSBC. Please go ahead.

Girish Bakhru: Just a question on Insulin. Just wanted your thoughts on how the market will progress specifically now Sanofi is trying to switch Lantus prescriptions to the new product that they have got approval for Toujeo, they were commenting on the ADA last month only that they might even try to do a hard switch. What are your thoughts there – would the market really move quickly to the new product?

Ravi LImaye: The new product as you know has just been launched in the US. So we need to see how the switch happens because we need to see basically how the payers' and the clinicians look at the new product in terms of its differentiation. So I think it is too early to comment.

Girish Bakhru: Would you have any idea if Lilly has launched the Biosimilar Insulin Glargine in European markets where they got approval?

Ravi Limaye: No.

Girish Bakhru: On the Oral Insulin, I know you are still calibrating the data. If you could comment on the safety profile, have you observed any adverse events or anything on that front?

Dr. Abhijit Barve: So Girish, as Kiran mentioned, we have completed the first set of studies this month, and these studies were designed to answer a number of questions that we had discussed with Bristol-Myers Squibb and the data as it stands, we have not seen something unusual in terms of any new safety signals or any of the safety signals that we would be concerned about. So as Kiran mentioned we continue to be very excited about the prospect of this particular asset.

Girish Bakhru: Itolizumab, the discussions are still ongoing I would assume. Or have there been any progress on out-licensing?

Kiran Mazumdar-Shaw: No, I told you that we have to overcome this regulatory hurdle in the US, but we are not stopping development. We decided to proceed with the development so that it will generate some valuable data which will only add to the value of the asset.

Girish Bakhru: Ma'am, you had already commented last time also that the Cuban relations are improving. So when do we see the regulatory hurdle going away?

Kiran Mazumdar-Shaw: Hopefully, it will go away, but right now we do have to still overcome that regulatory requirement. We are already addressing that, but at the same time we believe this asset is so important that we do not want to stop the development of this asset.

Moderator: Thank you. The next question is from the line of Nitin Agarwal from IDFC Securities. Please go ahead.

Nitin Agarwal: Siddharth, on this Malaysia plant capitalization you mentioned you will capitalize the plant only when the developed market approvals are received. So what happens if once we start to get the emerging market approval, we would not supply to those markets before then, how will accounting really work there?

Siddharth Mittal: We would supply to those markets. The emerging markets will not fill the plant to its full capacity. What we think is since this plant has been built primarily for the developed markets, the sales from emerging markets would be incidental to that and in terms of percentage it will not be a significant portion of the entire capacity.

Nitin Agarwal: We are looking at a couple of years for the developed market approvals to come through?

Siddharth Mittal: Yes.

Nitin Agarwal: I guess our capitalization start somewhere around FY18 is where most likely?

Siddharth Mittal: Around that time.

Nitin Agarwal: Secondly, while we do not discuss individual numbers and all, but can you give us some sense on over the last couple of years how the Biosimilar portfolio per se has progressed, we did give a number for FY13 or '14 if I remember on the overall portfolio, how has that sort of moved from there?

Siddharth Mittal: It has been growing. Last year, in FY14, we did have challenge when we were struggling with capacity for Insulin drug substance which we overcame. But this year we had, as Kiran mentioned, capacity constraints in drug product and again we are addressing those challenges. We launched our Trastuzumab last year that has been ramping up in India, sale to Mylan is ramping up, and us along with Mylan are registering in ROW countries. So this division has done well this year for us and would continue to do well.

Nitin Agarwal: What do you sell to Mylan in Biosimilars?

Siddharth Mittal: Trastuzumab as you know that it is co-developed with Mylan, so they have also launched their Trastuzumab in India, plus they have registered as per their public release in 15 countries, so we will supply to them and then they will sell it in those countries.

Moderator: Thank you. The next question is from the line of Ranveer Singh from Sharekhan Limited. Please go ahead.

Ranveer Singh: Just on the Disposable business, I wanted to understand that what kind of investment we have done so far in Disposable and whether this will be able to supplement our growth there in domestic market?

Siddharth Mittal: So the investment has been in a disposable assembly line and for development of the disposable pens. We have paid some milestone payments to the partner for the design and as I mentioned there is investment in the assembly line. I cannot disclose specifically the amount invested, but needless to say that developed markets are more of device oriented markets, and when we start the sales in these developed markets, ROI on this investment would be quite accretive.

Ranveer Singh: So the way we will be seeing expansion of market or the market will be replaced by this new line of products?

Ravi Limaye: It depends on market-to-market, in some markets the market has actually moved to disposable pens while in some markets it is a mix of disposable and reusable. So it depends on the market that we are talking about.

Ranveer Singh: In India perspective, wanted to understand?

Ravi Limaye: I already gave the numbers; in India it is about Rs.330 crore market in the Rs.1600 crore Insulins market, will give you an idea, you have about 20-25% share from the Disposable Pens.

Ranveer Singh: Secondly, excluding CANMAb™, what would have been growth there in India?

Ravi Limaye: I do not think we can give these numbers. CANMAb™ as you know has been very successful.

Ranveer Singh: What I understand, CANMAb™ maybe growing fast, but contribution of CANMAb™ is significant right now or it is just a small contribution there in total sales?

Kiran Mazumdar-Shaw: I will answer that by saying that all our key brands are growing 25% to 50%, CANMAb™ of course has grown much higher than that because we had a very small base the previous year, but CANMAb™ is beginning to contribute significantly.

Ranveer Singh: Would you like to give any guidance for next year?

Kiran Mazumdar-Shaw: We have given you a kind of guidance for the $1 billion target that we have. So we have indicated that our Branded Formulations business should attain a size of $200 million or in excess of Rs.1,000 crore over the next 3 to 4 years. So I think you can extrapolate from that.

Moderator: Thank you. The next question is from the line of Purvi Shah from Dalal & Broacha Stock Broking. Please go ahead.

Purvi Shah: Ma'am, just wanted to understand the tax rate. Since this fiscal we have paid around 17%. So, going forward what is the tax rate that we are looking at?

Siddharth Mittal: 20 to 22%.

Purvi Shah: If you could also tell us the CAPEX figure?

Siddharth Mittal: I think Syngene had already indicated that they are going to invest approximately $200 million in the next 4-5 years and Biocon is going to invest in a couple of Greenfield projects. Apart from that our maintenance CAPEX would be around Rs.200 to 250 crore per year.

Moderator: Thank you. The next question is from the line of Vrijesh Kasera from Edelweiss. Please go ahead.

Vrijesh Kasera: Teva acquiring Mylan… I know it is too early in the game but still if it happens, how do we see this deal affecting our deal with Mylan?

Kiran Mazumdar-Shaw: It does not have any material impact on our arrangement with Mylan because the obligations would continue on to Teva if such a transaction were to materialize. If you look at Teva's presentation that is in public domain, they have clearly recognized that Biocon's Biosimilar pipeline which is partnered with Mylan is of high value and high interest to them. So, I think that should give you some indication of the importance of our portfolio of Biosimilars.

Vrijesh Kasera: Why have been the tax rate last fiscal low?

Siddharth Mittal: We have received some R&D benefits. As Kiran mentioned, our R&D expenses have almost doubled. As you are aware that we get 35(2) (AB) benefit on R&D. We have received some of those benefits plus we had benefit of deferred tax on sale of Syngene shares.

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

Shraddha Patil: My first question was a follow up in relation to the depreciation question. Can we go for with the same logic with regards to the borrowing cost for the Malaysia plant – will we be capitalizing the borrowing cost till the time the major approvals do not come in for the plant?

Siddharth Mittal: What I mentioned is that we will start depreciating after FDA/EMA approval comes but we would stop capitalizing the cost once we have received the regulatory approvals and get the

manufacturing licenses. So, like we have DCGI in India, there is a local authority in Malaysia which gives the manufacturing license, it is called MPCB and once we receive those approvals, we would stop for capitalizing any further cost. After that the cost would be expensed.

Shraddha Patil: So same goes with the interest cost as well?

Siddharth Mittal: Yes.

Shraddha Patil: Could you please give the figure of the interest cost which is capitalized pertaining to Malaysia for the FY15?

Siddharth Mittal: I do not have it readily available with me, it would be there in our annual report once we release it, and it is not a very significant number though, as we have we have interest subsidies from the government.

Shraddha Patil: Would this be what would continue for the next year as well?

Siddharth Mittal: Yes.

Shraddha Patil: We had a funding of around 60% from debt coming in for the Malaysia plant. So, out of that how much is already in the books as on 31st March?

Siddharth Mittal: We have taken debt of $130 million and the entire amount is in the books.

Shraddha Patil: So no further debt coming in for the Phase-I?

Siddharth Mittal: We are going to take additional debt to fund our pre-operative expenses till revenues start.

Moderator: Thank you. The next question is from the line of Krishnendu Saha from Quantum Mutual Fund. Please go ahead.

Krishnendu Saha: A simple question on Syngene. How many employees are there right now?

Peter Bains: 2,664 as on 31st March 2015.

Krishnendu Saha: How much of them are dedicated to BMS?

Peter Bains: 425.

Krishnendu Saha: Is it possible to get a break up as to how much would be our Research and how much would be Manufacturing?

Siddharth Mittal: I would encourage you to read DRHP which has all the details.

Moderator: Thank you. The next question is from the line of Bharat Sheth from Quest Investments. Please go ahead.

Bharat Sheth: This Malaysia plant when regulatory approval timeline will start once the plant is in place? Normally what is the process, can you explain a bit in detail?

Abhijit Barve: Typically what happens is that we have just commissioned the plant. Scale up batches will make sure that the product quality is consistent with what we are saying it is a new plant. So once that happens, we really will file with the regulator and then they come there for inspection. So that is typically how things progress. And as Kiran mentioned at the beginning, different regulators have a different schedule in terms of when they come and visit these facilities for inspection. So that to some extent will be driven by what their calendar looks like. But I think we will start getting hopefully regulatory approvals between 9 and 12 months.

Bharat Sheth: From the date of commencement?

Management: Correct.

Bharat Sheth: As you said developed market, one is Europe and another which are the developed markets that we are looking for this?

Management: US

Moderator: Thank you. The next question is a follow up from the line of Nitin Agarwal from IDFC Securities. Please go ahead.

Nitin Agarwal: I just wanted to understand on the Biosimilar you mentioned five Biosimilars are in clinical development right now, is that right?

Kiran Mazumdar-Shaw: We said five Biosimilars will be in Phase-III clinical trials by the end of this year.

Nitin Agarwal: Our strategy is we do not necessarily launch in India before we go ahead with the global launch or?

Kiran Mazumdar-Shaw: No, that is not what we are trying to say, we are trying to say that we have two programs in advanced Phase-III clinical trials which is Glargine and Trastuzumab, both those products are in India. Then we have Bevacizumab Phase-III trials which are going to take place in India, but because the patent of this molecule is much further down the line, we will only commence the global Phase-III trials a little later. Then there are two more programs which are entering Phase-III trials and we will disclose it as soon as they enter the Phase-III trials.

Nitin Agarwal: I guess they will follow the normal trajectory of India launch followed by other markets?

Kiran Mazumdar-Shaw: Not necessary, but you can almost take it that should be the pattern.

Abhijit Barve: It depends on two things – one is the regulatory requirements and secondly is the market size.

Nitin Agarwal: So, when you initiate Phase-III global trials for these two molecules they would be like global trials on the lines of where you are doing for Glargine and Trastuzumab?

Kiran Mazumdar-Shaw: Yes.

Nitin Agarwal: This would be partnered with Mylan?

Kiran Mazumdar-Shaw: Yes.

Moderator: Thank you. The next question is from the line of Mehul Seth from PhillipCapital. Please go ahead.

Mehul Seth: This question is related to Tacrolimus shortage in US market. So, does the company have any incremental sales due to this?

Ravi Limaye: Tacrolimus in US as you know broadly the market is divided into the innovator product and the generics. Amongst the generics, we supply to some of the major companies. So if there is a shortage, then certainly it will be an upside for us. But we need to first examine what is the level of shortage, how long and so on and so forth. So it is early to answer that. But we are qualified by at least two or three major players in the US.

Mehul Seth: Means I want to know about this current quarter. Do you have any incremental sales due to this?

Management: We have not analyzed that.

Moderator: Thank you. The next follow up question is from the line of Ranveer Singh from Sharekhan Limited. Please go ahead.

Ranveer Singh: Wanted to understand your initial remarks relating to Syngene that we have certain regulatory approvals pending and the market if conducive then we will go with it. So just wanted to understand, whether we have already filed for FIPB approvals and for other regulatory approvals or we will wait for market to be conducive or more favorable, then we will go for it or how…?

Kiran Mazumdar-Shaw: No, as things stand, we are all geared up to list this year. We have already applied for these regulatory approvals.

Moderator: Thank you. The next follow up question is from the line of Abhishek Sharma from IIFL. Please go ahead.

Abhishek Sharma: Has your partner PiSA launched the Glargine product in Mexico?

Kiran Mazumdar-Shaw: No, I think they are expecting to do it very soon.

Moderator: Thank you. The next follow up question is from the line of Purvi Shah from Dalal & Broacha Stock Broking. Please go ahead.

Purvi Shah: Ma'am, would like to understand on the Itolizumab proof trials. Could the out-licensing be before the proof-of-concept establishment or post that, how do we go about this thing?

Abhijit Barve: Just to ensure that I understood your question correctly, we will continue with the development and depending on when the out-licensing happens, it would. As Kiran mentioned, the reason for continuing the development activity is that it has only got to add value to the program as we move ahead. However, the licensing things are not something which are you can plan in a particular way. So, we would like to keep them separate. So the development will continue and the partnering will happen based on what we have already discussed.

Purvi Shah: Can we quantify how much has been invested on both the molecules of IN 105 and Itolizumab till date?

Siddharth Mittal: We cannot share that number. For IN 105, when we stuck the partnership with BMS, they had paid us advance money for some of the trials, so our cost was not significant. On Itolizumab there has not been a significant cost since most of the trials so far have been done in India, unlike expensive global trials.

Purvi Shah: Just one more clarification; for the R&D activities that we carry out, the deduction that we get is generally for the trials that are done in India, right?

Siddharth Mittal: Correct.

Purvi Shah: So, since we are having a couple of molecules in pipeline, why is the tax …?

Siddharth Mittal: As you know, we have started our filing this year and we are developing more ANDAs and these are all developed in India and that is where we get the benefit.

Purvi Shah: So then in FY15 we paid around 17% of tax and we are saying that going forward it will be 20-22% where do we see that increase coming?

Siddharth Mittal: That is the normalized level. This year we saw reduction because of the incremental benefit we got. Most of our trials are outside India as you will be aware, where you do not get the tax benefit. Only on the expenses incurred in India you get tax benefits. There are two stages – once that enters the clinical, all the preclinical activities are done in India. So you can get tax benefit in those.

Purvi Shah: In FY17, the Malaysian plant is coming on stream. So is that taken into consideration in this tax and the tax rate again would be different because you will be having some benefits from that?

Siddharth Mittal: The guidance given is for the current business. For Malaysia we have a tax holiday for 10-years from the year we generate profits. So Malaysia revenues or Malaysia taxes have not been considered in this guidance of 20-22%.

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

Shraddha Patil: I just had a little doubt regarding the 9 to 12 month' timeline that was given for the regulatory inspection. So is it that the inspections will go on till the next 9 to 12 months and then probably in FY17 we will expect the EM production starting?

Abhijit Barve: What we said is that depending on when these regulatory authorities come for inspection, these can happen anywhere between the 9 to 12 months' timeline and then after that it is not that immediately they are going to give an approval, so they will take another couple of months before it happens.

Shraddha Patil: But generally, how is the timeline for an emerging market approval to come in like can it be more than 6-months to 1-year?

Siddharth Mittal: I think it would be fair to say that FY17 is when we expect some emerging market sales to begin. It might not be higher volume or value but we do expect that we can start commercialization in FY17.

Shraddha Patil: Regarding Biocon, what would be the kind of regular CAPEX that we would see?

Siddharth Mittal: Around Rs.150-200 crore every year.

Shraddha Patil: In the previous calls you had mentioned that you look forward to see some oral solid dosage facility coming in for the ANDAs. So, what would be the rough timeline?

Siddharth Mittal: We expect the facility to be commissioned in early 2017.

Shraddha Patil: What could be the CAPEX?

Siddharth Mittal: We have not given exact number, but these kind of facilities are anywhere between Rs.150-200 crore.

Moderator: Thank you. Ladies and Gentlemen, with that we conclude this conference call. Thank you for joining us. You may now disconnect your lines

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Note: This document has been edited to improve readability