Biocon Limited's Q3 FY16 Earnings Conference Call
January 22, 2016

Key Participants from Biocon Group's Senior Management Team

- Kiran Mazumdar Shaw: Chairperson and Managing Director
- John Shaw: Vice Chairman
- Arun Chandavarkar, CEO & Jt. Managing Director
- Siddharth Mittal: President, Finance
- Ravi Limaye: President, Marketing
- Shreehas Tambe, Sr. Vice President, Insulin
- Paul Thomas, Vice President, Biosimilars
- Narendra Chirmule: Sr. Vice President, R&D
- MB Chinappa: President, Finance, Syngene International
- Saurabh Paliwal: Head, Investor Relations

Presentation Session

Moderator: Good day, Ladies and Gentlemen and welcome to the Biocon Limited Q3 FY16 Earnings Conference Call. As a reminder, all participant lines will be in the listen-only mode. There will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during this 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, sir.

Saurabh Paliwal: Thank you, Malika and Good Morning everybody. Thank you for joining us today for Biocon's Q3 & 9M FY'16 Earnings Conference call. I am Saurabh Paliwal from the IR team.

We declared our results last night, hope they have been received by you. We have also posted them on our company website. Today, in this call to discuss the Business Performance and Outlook, we have Ms. Kiran Mazumdar-Shaw – Biocon's Chairperson and Managing Director and people from the senior management team at Biocon.

Before we proceed with this call, I would like to remind everybody that this call is being recorded and a replay will be available for the next few days. The call transcript shall be made available on a website in due course. I would further like to add that this discussion today maybe 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 this conference call.

After the end of this call, in case you have any additional questions, please feel free to get in touch with us.

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

Kiran Mazumdar-Shaw: Thanks, Saurabh and Good Morning, everyone. Let me start by wishing everyone a Very Happy, Rewarding and a Prosperous 2016.

I would like to start by saying that at a Group level Biocon has reported a very good set of numbers with a very improved quality of earnings. But before I get into analyzing the quality of earnings, I would like to start with some headline numbers:

- Consolidated revenues for Q3 were Rs.857 crore, a growth of 10% year-on-year;
  - Biopharma business sales were at Rs.454 crore;
  - Branded Formulations sales were at Rs.104 crore this quarter;
  - Syngene continued its strong performance growing 23% at Biocon consolidated level with sales of Rs.270 crore. Syngene will have separate investor call which will give much more optics on the Syngene standalone numbers.
- We have booked FOREX loss of Rs.4 crore in Q3 at a group level and this is reported under 'other expenses'.
- Group EBITDA was at Rs.209 crore for Q3 which is a growth of 23%. EBITDA margin improved by 260 basis points to 24%. The improvement in margins is on the back of a 45% increase in R&D spends booked in the P&L. A better biopharma product mix and increased contribution from Syngene resulted in this improvement.
- Group net profit for the quarter grew 13% to Rs.103 crore, net profit margin stood at 12%. Furthermore, when you look at Biocon excluding Syngene, the net profit grew 28%. This is despite an increased R&D cost by Rs.21 crore and higher tax outgo of Rs.14 crore this quarter compared to the corresponding period last year, and this as I mentioned earlier is the reason why you are seeing a much stronger quality of earnings of the Biocon Biopharma business.
- Gross R&D spends were Rs.91 crore representing 7% increase year-on-year, net R&D spends as reported in the P&L were at Rs.68 crore which actually is 45% increase over last year. We capitalized an amount of approximately Rs.19 crore where the balance amount of approximately Rs.5 crore was offset against deferred revenue. Clearly, the increase in spends is a reflection of the advancement made by our Biosimilar programs in the clinic.

The **Biopharma** business as I mentioned earlier shows a top line growth of 4%, but we have seen marked improvement in the quality of earnings on account of a better sales mix and progress in partnering our Biosimilar assets in key emerging markets. This has been supported by increased contributions from Immunosuppressants and Insulins and licensing income derived from licensing Trastuzumab and Glargine in key emerging markets.

As part of our Generic Formulations foray, we have filed 2 more ANDAs this quarter. Our cumulative filings remain in single digits but we are on track to file 20 to 25 ANDAs over the next few years. This we believe is an important part of our vertical integration plans for the business and we have in this context started the construction of our potent Oral Solid Dosage facility in Bengaluru.

Now coming to **Branded Formulations**: The flat numbers this quarter have been below our own expectations. The business has undergone a rationalization of the product portfolio to restore a strong focus on Specialty Molecules, each having a potential to be a big brand. The positive aspect of our Branded Formulations business is that within the overall flat numbers, growth of key brands has been healthy and will improve further as we strengthen our leadership team in the Branded Formulations business. We were also impacted by supply issues for one of our key in-licensed product but this should be resolved this quarter.

The business is in a rebooting stage, I would like to emphasize this point and we remain committed to strengthening this business and creating a sizable and profitable specialty domestic franchise.

Now coming to **Insulins and Biosimilar Programs**, I think this is very exciting year for Biocon as we are set for several regulatory filings with US FDA and EMEA this year. Our partnered Biosimilar program continues to make good clinical progress and of the nine programs that are partnered with Mylan we have four programs in global Phase-III trials while the fifth program is advancing as per plan in the global Phase-I trial. Based on the clinical advancement thus far, the Biocon-Mylan Biosimilars partnership is progressing well towards four regulatory filings in US and EU in this calendar year, representing an opportunity of over US$30 billion. These filings should provide us with an early mover advantage for these products in these key developed markets.

Now coming to **Novel Programs**: I am very pleased to share with you that when it comes to our Oral Insulin Program which henceforth shall be referred to as Insulin Tregopil, we have reported some very positive clinical data outcome from a wave of Phase-I studies which was concluded last year. This provide as the basis to move forward for the next phase of clinical development of this very important molecule. The Phase-I studies were conducted in the US under US IND and were initiated in partnership with Bristol-Myers Squibb prior to the divestment of the diabetes franchise to AstraZeneca. Subsequent development of Insulin Tregopil, i.e. the next phase of clinical studies will be undertaken by Biocon. This is a very exciting movement for Biocon and hopefully for patients around the world.

When it comes to Itolizumab… another very important and interesting molecule, we have initiated key clinical studies using a subcutaneous version of Itolizumab, which we believe is an imperative feature to have for an autoimmune drug. Right now the drug is in an infusion form and we would like to convert this into a subcutaneous version. The Phase-I study in healthy volunteers aims to evaluate pharmacokinetics and establish comparability of the subcutaneous route of administration of Itolizumab with the already approved intravenous route in India. These trials are being done in Australia and once these are done we will be ready to file and continue with clinical development under a US IND.

Syngene performance in Q3 was very strong with a 23% top line growth year-on-year on a standalone basis delivering Rs.281 crore in revenues. EBITDA was at Rs.94 crore while net profit was at Rs.59 crore. Adjusting for minority shareholding Syngene contributed Rs.43 crore to Biocon's bottom line.

The business performance in Syngene was broad based across its three verticals -- Discovery Services, Dedicated Centers and Development and Manufacturing Services. Syngene full year outlook is consistent with the momentum in the business and is aligned with achieving its target revenue of US$250 million by FY18.

I would also like to welcome Syngene's new CEO-designate Jonathan Hunt. Jonathan joined Syngene's executive leadership team earlier this month and brings in over two decades of expertise in the Global Biopharma sector. He will lead the company post the retirement of the current CEO -- Peter Bains at the end of March 2016, which means he will assume charge as CEO from 1st April 2016.

To summarize, I would like to once again report a very good set of numbers this quarter: 23% increase in EBITDA, this is on the back of increased R&D spends as well as an increased tax this quarter; 13% increase in net profit which collectively points to a much improved quality of earnings. Biocon's Biosimilar journey is coming to an inflection point with molecules in Phase-III Clinical Trials making

excellent progress with US and EU regulatory filings planned during this calendar year. This we believe is going to set the stage for Biocon's sustainable and a very profitable journey in the coming years.

With this I would like to open the session for Question-and-Answers. Thank you.

Moderator: Thank you very much, ma'am. Ladies and Gentlemen, we will now begin the Question-and-Answer-Session. We have the first question from the line of Dheeresh Pathak from Goldman Sachs. Please go ahead.

Dheeresh Pathak: On the Domestic Formulations business, if you can give a sense of the core business or the brands which are not being rationalized, what is their underlying market growth?

Ravi Limaye: So our core brands are basically brands in therapeutic areas like Diabetes, Oncology, Immunology, Transplantation, and Virology. If you take out the products which Kiran mentioned, the in-licensed product, where we had some kind of supply issues, the core business is growing well. Diabetes is showing high double-digit growth, Oncology is showing double-digit growth, Virology is a new business, so I do not think we can comment on the growth, Immunology is again a new business, so I do not think we should comment on the core, Transplantation is growing ahead of the market. So the core business continues to do well.

Dheeresh Pathak: So, would it be fair to say that the core business ex of the issues in the in-licensed product and whatever you are rationalizing would be ahead of the market growth, which is in mid-teens?

Ravi Limaye: Yes, they are ahead of the market growth. Also we need to understand they are expected to grow even better in coming year. Our endeavor is to make sure that these brands grow faster than what they are growing so that they make up for the rationalized products.

Dheeresh Pathak: In terms of our expectation, we should expect FY17 to show that growth in your reported numbers or should it be FY18?

Ravi Limaye: Yes, FY17 should be showing good growth.

Dheeresh Pathak: The R&D which is mentioned in the P&L as Rs.67.9-odd crore, this is not including your partner's share, this is just your share of the R&D that you have expensed through the P&L?

Siddharth Mittal: That is correct.

Dheeresh Pathak: When you are going to file this year for the regulated markets, what is your expectation of the approvals and the launch timing?

Arun Chandavarkar: As we mentioned, we are planning to have four filings in this year. As far as the approval timelines are concerned we do not wish to comment on that at this stage, but safe to say it would take probably a year or longer.

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

Girish Bakhru: On the filing part again; so four filings this year, how do you see them panned out over the year like whether a few filings can happen in the first half or how do you look at it?

Arun Chandavarkar: Yes, the filings will be spread throughout the year including the possibility of a few filings in the first half.

Girish Bakhru: I am just trying to get a sense, all these three programs are at the equal stage or do you see some really at the end stage where this filing is the next?

Arun Chandavarkar: We made substantial progress on the clinicals and we are really at the end stage of the clinical assessment on many of these programs. So clearly some filings will be imminent in the first half, some will be in the second half.

Girish Bakhru: On Trastuzumab, you have put in the press release that of course some of the licensing income has come from these markets. Which markets are these? If you can also give us some potential guidance on how this opportunity will pan out in the emerging markets particularly?

Arun Chandavarkar: For the products that we are talking about which is the Diabetes portfolio and the Oncology Trastuzumab, I can tell you that emerging markets does represent a very significant opportunity. Whilst we cannot disclose the specific countries where we have done the partnering but these are all countries key to the emerging markets growth. Globally, we believe that emerging markets would represent anywhere from 12% to 15% of the global opportunity for many of these molecules. So they are a sizeable opportunity for Biocon.

Moderator: Thank you. The next question is from the line of Surya Patra from Phillip Capital. Please go ahead.

Surya Patra: As you indicated in the initial remarks that you would be continuing the next step of the clinical development for Insulin Tregopil. So for that can you just give us some sense whether we would be looking for some partner or if we are planning ourselves for the further level of a clinical development in US, then what is the cost or what is the budget that we have set or what is the licensing potential if we go with a partner, so basically what is the next step that we are looking for Tregopil, can you just say something on this?

Kiran Mazumdar-Shaw: What we are doing for the next phase is to basically take it up the validation chain so to speak is to really validate in a larger patient cohort the very exciting findings that we have had in the first wave of studies. We believe that once we establish and validate these findings in a larger patient cohort, this will actually prepare itself for a much more attractive partnership opportunity or licensing opportunity. So we are being advised as I mentioned in our press release by key opinion leaders and experts in the field of Diabetes and Endocrinology, this we believe is going to now position us in a very-very attractive way for this asset.

Surya Patra: Here again the Phase-II and all the types of a clinical development would be required, right?

Kiran Mazumdar-Shaw: We will be taking it to the next wave which means that we will be incurring some cost but obviously it would not be huge cost because as I mentioned this is about validating some exciting findings. If you read our press release for Tregopil, you will see some of the very exciting indicators and this has been done in a Phase-I setting and we now need is to basically expand the patient base and start looking at the target profile for this particular drug and how we want to develop the drug. So this is the way we are going to now design the next set of studies and validate all the findings that we have had in the Phase-I studies.

Surya Patra: In the trials the kind of indications what we have mentioned in the press release is that, we have done various kind of dosing and comparable studies also with the existing lines of products and that is also giving positive indications. So, normally those kind of study happens in the Phase-II if I am not wrong?

Kiran Mazumdar-Shaw: If you remember, we have done extensive studies with this particular drug, in fact, I think to date we have over 400 patients who have actually been on this drug. So, it is a very safe drug, we have actually established efficacy in various trials, but I think these wave of studies were particularly addressing some key aspects of the drug which you need to do before you start developing it in a bigger way. So this was an understanding that we were addressing because today whenever you develop such drugs, you need to understand mechanism of action, you need to understand the science behind the drug, and you need to understand how the drug works in the metabolic and physiological setting. So there are a lot of questions you need to answer. This is what we have done in these wave of studies. When you actually then take it into a much larger patient cohort, it validates everything that you have gleaned from these studies which then makes it very valuable as an asset.

Surya Patra: When do you see the commercial supply of Insulin from the Malaysia plant, ma'am?

Siddharth Mittal: Later part of FY17.

Surya Patra: That you mean to say to the advanced market or even to the emerging market?

Siddharth Mittal: Emerging markets. The developed markets would be dependent on when we file for the approval of Glargine and when we get the approval from FDA and EMEA.

Surya Patra: This quarter, we have seen something like a significant jump in the R&D spends sequentially as well as YoY so far as our number is concerned. So, considering the four molecules in the Phase-III global trials, should we see this is a kind of a peak number that we are currently seeing or further it should see a kind of up-move or it will gradually decline, how should one see the R&D spend so far as our share is concerned?

Siddharth Mittal: On an overall basis it will be around 10% to 12% of the P&L. This is lumpy quarter-on-quarter. So we should not look it at on a quarterly basis. As far as the question around peak, I do not think so it is still to peak. We are looking at significant R&D spends even though we are close to filing, that does not mean the costs go away, there are certain set of trials that continue even post filing

and you keep on generating the data which has to be ready by the time the regulators review the file. Our guidance around 12% of our revenues on the P&L will continue.

Surya Patra: 12% of our Biopharma revenue that way?

Siddharth Mittal: Yes.

Surya Patra: Since we are in the completion phase of a Phase-III clinical trial of four molecules, so by now we would have a fair sense, what is the kind of spend that is required for developing Biosimilar for the advanced market, so any comment on that, what is the kind of spend?

Kiran Mazumdar-Shaw: I think the general sort of acceptance is it depends on what the molecule will cost you anywhere between US$50 million to US$100 million plus.

Surya Patra: We have also indicated that the filing would happen both simultaneous in US and Europe for the four Biosimilars. But whether the progress in the US front is faster than Europe?

Arun Chandavarkar: The trials are designed as global trials. So clearly based on the outcome off the trials we will be approaching both jurisdictions. There may not be identical timelines in terms of the same month, but yes, both are expected this calendar year.

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

Prakash Agarwal: A question on Insulin Glargine. We recently saw Eli Lilly getting an approval and also settling for 2016 launch from the time of their filing 2013. To just to take it further, is there any sort of advancement or learnings that we have in terms of the pathway that we can get post filing a faster approval, any idea would have helped?

Arun Chandavarkar: So one approach as you can see that what Lilly has set the way forward for people to follow is that we always had a strategy as a collaboration between Biocon and Mylan to file in the US using the 505(b)(2) pathway. Seeing that Lilly has also followed that trend and has received approval, it sort of validates our strategy of adopting that pathway in the US, likewise the pathway in Europe. So it validates the pathway. In terms of your specific comment upon accelerating an approval, I guess each dossier has its own strategy so that would really depend on our dossier. We are confident that the dossier we would file would be of adequate quality to receive approvals. Launch of course depends on approvals as well as other considerations around IP. That I would not wish to comment on at this stage.

Prakash Agarwal: On the emerging markets, there was a comment on the licensing income and I understand this is for Trastuzumab. But when do we start seeing the revenues also kicking in from the sales of Trastuzumab in these emerging markets?

Ravi Limaye: So there are about three emerging markets, I would not name them for obvious reasons, where we expect revenue to start early next fiscal.

Arun Chandavarkar: One of the comments which I made earlier, I just want to again reiterate that if you see the Licensing income that we obtained this quarter, it essentially shows the progress we are making in terms of securing our commercial future in these key emerging markets and these key emerging markets are as I mentioned amongst the top-15 or top-20 markets in emerging markets, representing a very sizeable potential and these span markets in LATAM, Middle East, CIS as an example.

Ravi Limaye: Trastuzumab, for example, the top 15 emerging markets account for 96% of Trastuzumab sales in emerging markets. So our focus is on these 15 markets. Similarly, for Glargine 15 markets account for about 90% of Glargine total sales in emerging markets. So we focus on these markets.

Prakash Agarwal: So it is fair to assume that the three markets that you talk about are among the top-15?

Ravi Limaye: Yes.

Prakash Agarwal: By when do you expect this top-15 to be covered by us?

Ravi Limaye: In many of these top 15 markets we are either already partnered or we are at an advanced stage of discussion. So we are almost at a stage where we are covering 70% to 80% of markets already, the rest 20% will be covered in due course.

Prakash Agarwal: Is it fair to assume that it takes some time post the partnership to launch and commercialize and start booking revenue?

Arun Chandavarkar: That is country-by-country.

Siddharth Mittal: If you recall we started our partnering for Trastuzumab six quarters back. So, all those would start yielding revenue in the early next fiscal.

Prakash Agarwal: Some sharing thoughts on how the progress on the Insulins for the emerging market like we had a recent launch in one of the key emerging markets in Mexico and Malaysia. So, have we started seeing some market share ramp up, any thought would have helped?

Shreehas Tambe: I think we made significant progress there; in Mexico, Glargine has been approved under the newly published bio-comparability guidelines which were published in Mexico. So I think with the launch of the product there we are seeing a lot of interest there in Mexico. Also, in Mexico, it is a tender market. So we will see ups and downs on that, but I think we are seeing a good opportunity in Mexico at this point.

Prakash Agarwal: What is the CAPEX incurred so far and the plan for '16 and '17?

Siddharth Mittal: While CAPEX so far has been around Rs.520 crore that includes our portion of Phase-I of Malaysia and our India expansion. As far as next couple of years CAPEX is concerned as we have said that we have already started commissioning our second Formulations Facility in

Bengaluru for Biologics and also as Kiran mentioned in her opening comments that we have started construction of our Oral Solid Dosage facility in Bengaluru. Apart from that we would be looking at setting up a second Biologics Facility for Monoclonal Antibodies, also in Bengaluru. This does not include CAPEX of Syngene which they have communicated and they would talk about it more in their earnings call.

Prakash Agarwal: Any number for '17 sir?

Siddharth Mittal: I cannot give an exact number because the timing and some of the details are still being worked out. So if you look at historically our maintenance CAPEX has been in the range of Rs.100-150 crore and we expect over and above this the Monoclonal Antibodies plant CAPEX to come in, which again as I said that timing, how much we spend in next year is all dependent on timing and sharing with Mylan.

Prakash Agarwal: On the NLEM impact for the India business, is there any ballpark number you would share, what are the key products impacted and what is the impact?

Arun Chandavarkar: There has been no major impact for Biocon.

Moderator: Thank you. The next question is from the line of Niraj Somaiya from Rose Red Management. Please go ahead.

Niraj Somaiya: My first question would be on FY18 which you have a target of over billion dollars. Seeing the current results and now you started filing, do you think you are on track to achieve these numbers or would there be any variation, what would the management like to say on that?

Kiran Mazumdar-Shaw: We are on track, we are very committed to achieving this target, and we believe we are very confident that given the kind of traction we are seeing in all our business segments, we should be able to achieve this particular target by FY19.

Niraj Somaiya: My second question is on the Phase-III, the four products which you are going to file it in the next one year or one-and-a-half years. If 30 billion market what would be your addressable size maybe in 3-5-years from now or could you give us some more light in terms of the picture what could Biocon share be or what could Biocon be looking at?

Arun Chandavarkar: We cannot give specific guidance in terms of the number, but clearly we are partnered with Mylan and Mylan we view as a very strong commercial partner who I presume would be aggressive in garnering market share. So we clearly see ourselves as amongst the first wave of Biosimilar companies and our ambition is of course to be a dominant player in this sector.

Niraj Somaiya: If I ask slightly differently, would you have the capacity whenever you are ready, whenever to deliver the goods maybe two years or what sort of CAPEX would you need to build that sort of capacity?

Arun Chandavarkar: We have adequate capacity for the early phase of our introduction and as Siddharth mentioned in response to an earlier question on CAPEX, we of course have CAPEX plans to further expand capacity as we gain market share.

Niraj Somaiya: My third question is on the Malaysian facility. How much is more yet to be done in terms of CAPEX and when would it be ready and up and running, can you throw some more light on that?

Siddharth Mittal: The CAPEX is done. The only thing that we are capitalizing now are the pre-operating expenses which also would stop shortly because we would be getting the regulatory approvals and that is when we stop capitalizing further expenses.

Niraj Somaiya: So would it be next two quarters would it be ready up and running in terms of interest and depreciation coming in the P&L?

Siddharth Mittal: Interest and other operating expenses would come on the P&L. The depreciation would come once we get the regulatory approvals from US and Europe which would take probably one and a half-to two years.

Niraj Somaiya: This new Oral facility which you want to build amount of investment or CAPEX will you require?

Siddharth Mittal: It is roughly Rs.150 crore.

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

Sudhakar Prabhu: Just two questions; one is if I look at your balance sheet, you have a debt of around Rs.1200 crore, and cash is almost similar, also you do not have major CAPEX line up this year. So, why don't you not pay off your debt and reduce your interest cost?

Management: First of all, the majority of debt of Rs.1200 crore is for our Malaysian plant. As we have mentioned in the past that Malaysia we got funding at very attractive rates through subsidies from the government. So we do not want to pay off the debt which we have got at a very attractive rate. Second, the cash that is on our balance sheet, as I mentioned sometime back, we have huge CAPEX requirements in the coming years. One of the reasons we did IPO of Syngene apart from monetizing the value was also to raise cash to fund our CAPEX and R&D programs and we would be needing that cash for our future CAPEX and R&D needs.

Sudhakar Prabhu: So what is your average interest cost?

Siddharth Mittal: This is a dollar loan and not get into specifics but the market rate for five to six years tenure loan for a company like Biocon is between 2 to 3%.

Sudhakar Prabhu: This entire Rs.1200 crore is FOREX loan?

Siddharth Mittal: Yes, it is all dollar loan.

Sudhakar Prabhu: How much have you spent till now on your Malaysian facility?

Siddharth Mittal: The plant and machinery is around US$200 million and apart from that the expenses that are being capitalized are around US$30 million to US$40 million.

Sudhakar Prabhu: My third question is on your EBITDA margins. We have seen sequential improvement in EBITDA for last couple of quarters. Do you see progressively margins improve from here also?

Siddharth Mittal: That is the endeavor that we have to keep on improving the product mix and increasing the EBITDA margin. As we enter developed markets and more emerging markets with Biosimilars, we should definitely see improvement in our EBITDA margins.

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

Ujwal Shah: I wanted to understand more on the India Formulations Business. I personally thought we were done with the product rationalization process and now actually you would start gaining growth in that sense. So has the product rationalization phase gotten over? In terms of margins for this quarter, has they been better than the last quarter?

Arun Chandavarkar: So the product rationalization process is behind us. As Ravi mentioned in his comments to an earlier question, in the key anchor products which would be our future growth drivers, we have shown a very healthy double-digit growth. It is not getting reflected in the overall Branded Formulations number because last year we would have had a different basket of products, but, for example, in the Insulin segment which is of course a key business for us, in our Oncology segment, for example, in CANMAb or Trastuzumab which is the key segment for us and in some of the other key segments we are showing good double-digit growth in most cases above market trends and this should only improve in the next fiscal.

Ujwal Shah: Secondly on Insulin Tregopil, just to get an understanding does this mean that now the drug would be in Phase-II trial. What about our partnership with BMS? Now that they have transferred their portfolio to AstraZeneca?

Kiran Mazumdar-Shaw: I would like to answer that by saying, yes, the next wave of studies will be in the sort of the ambit of Phase-II studies. As far as BMS is concerned as I mentioned earlier on we had entered into this partnership prior to the divestment of their Diabetes franchise to AstraZeneca. So we believe that it is in the best interest of Biocon to really pursue this program on its own for the next wave of studies.

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

Ranjeet Kapadia: My question refers to NeoBiocon which has launched Jalra and Jalra-M in the UAE market, in collaboration with Novartis. Are we planning to introduce more products from Novartis? What is the game plan in UAE market? How are our products doing in that market?

Ravi Limaye: We are positioning ourselves as a partner of choice in GCC countries. The first product you saw came from Novartis. We already are talking to not only Novartis but also other companies to strengthen our product portfolio in our strategic areas of interest.

Ranjeet Kapadia: How is the market expanding in UAE and other Middle East countries?

Ravi Limaye: We are the fastest growing company in GCC. We are now amongst the top 25 companies in GCC, a market dominated basically by multinational companies. Some of our brands are amongst the top-2 or 3 brands in their respective therapeutic areas. We have a very strong business consolidating by the day in that market.

Ranjeet Kapadia: Do you feel that this will definitely strengthen the Domestic Formulations business?

Ravi Limaye: These are two different state of businesses but the strategy for Indian Domestic Formulations will be also on the similar line. We will strengthen our portfolio in India as well. We will position ourselves as a partner of choice in some of our core therapeutic areas. We will add new products in these areas. Of course there will be products coming from our own pipeline in Oncology, Diabetes, etc. Broadly, strategy will be same but these are two different businesses in two different geographies of the world.

Ranjeet Kapadia: Are we talking to Novartis for some other products?

Ravi Limaye: I have already mentioned but these are obviously confidential, we cannot disclose. I said not only Novartis but also other companies. When you have a business which is growing at 30-40% I am sure there will be interest from various companies to partner with us.

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

Surjeet Pal: Kiran, there are things are that Lilly has got approval but we have seen those approval are not an interchangeable approval and there is no specific policy concrete in US where they will allow any Biosimilars for interchangeable things which is still in draft stage. Now, the point is that if your product or if your partnership product in US market got approval including Insulin and those are not interchangeable, what kind of success you are expecting fighting with big guys with their wide range of expansion in the whole market in terms of sales and distribution, both Europe and US? Do you think that as a Biosimilar producer, you will have that kind of might to fight with in market share?

Arun Chandavarkar: I will answer that question in two ways - One is of course we have also clearly stated that we are also seeking interchangeability for products like Glargine where interchangeability helps early penetration in terms of market share. Having said that if you look at the recent experience of companies which have launched Biosimilars in Europe, not just Oncology molecules but also Autoimmune molecules, the market penetration despite absence of interchangeability has been fairly

good, largely because finally when it comes down to healthcare budgets, the payors make a significant impact and have a huge influence in terms of who gets the market share. I would not belittle the influence of payors in how we ramp up sales quickly. Lastly the point I would like to make is that Mylan as a global partner is very experienced in this. That is the main reason of us partnering Mylan and we are confident that Mylan has the adequate experience and commercial strategies to gain significant market share.

Surjeet Pal: Another trend has been seen in Europe at least in a couple of countries where Biosimilar was launched and the very first day the erosion has become 70%. Given the change of interchangeability currently hanging, where you will be maintaining very good sales and distribution team, do you think going forward when it would be more crowded it would be sustainable business?

Arun Chandavarkar: We are clearly positioning ourselves as being amongst the strong wave of Biosimilar players. We are not here to dabble in this business or just get very low market share. Clearly, both Mylan and Biocon wish to be amongst the dominant players. Whilst we cannot disclose specific strategies, clearly, our aim is to be a dominant player in this business. There is no two ways about it.

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

Harith Ahamed: I understand there has been a couple of inspections of your API facilities in Bengaluru in calendar 2015. Can you talk a bit about the outcomes of those inspections?

Arun Chandavarkar: We have had two inspections from the US FDA at our Bengaluru facility, but if you go back over the last two years between Syngene and Biocon, I believe we must have had about eight-odd inspections straddling three sites in Bengaluru as well as our Hyderabad site and so far I am pleased to report that we had a clean track record.

Harith Ahamed: So you have received the EIR Report from the FDA on these two inspections?

Arun Chandavarkar: We are awaiting EIR on the second one but that is just a procedural thing, we have got clearance because the approvals are in place which triggered this inspection.

Harith Ahamed: On the Biosimilars which are in Phase-III currently the global trials, I understand the products are being supplied from your Bengaluru facilities, right?

Arun Chandavarkar: Yes.

Harith Ahamed: Is this an FDA-approved facility and post-commercialization will you be able to supply from the same facility?

Arun Chandavarkar: Whilst the FDA has not inspected these facilities specifically for our Biosimilars because we are yet to file the applications. For example, our Injectable facility would manufacture the Biosimilars also manufactures other products and our recent FDA inspections for those other products basically give us comfort that we should be okay when they come for the Biosimilar inspections as well. Having said that we have also got a Biosimilar drug substance facility like our Insulin facilities, we have

been inspected by regulated markets and emerging markets like the Europeans and we have received approvals there as well.

Harith Ahamed: Last question, one on the balance sheet - your other non-current assets have gone up by roughly Rs.200 crore versus March 2015. So, I understand it is not coming from Syngene. So what is driving this?

Siddharth Mittal: This is fixed deposit for a period more than one year. We have to classify the deposits maturing beyond one year to other non-current assets. The funds from the Syngene IPO were invested in fixed deposits for long-term up to two years.

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

Abhishek Sharma: I just wanted to understand conceptually around the Biosimilar launches planned for emerging markets. Do you guys have to do country-specific trials for these, and if yes, then what is the status on some of your key products going into emerging markets?

Arun Chandavarkar: There are a few countries that require local trials and wherever it is required we are on track.

Abhishek Sharma: I just wanted some sort of correlate on where you are ready to launch and what did that market require and what else would be required for you to sort of take some of our key products ahead?

Arun Chandavarkar: There are two or three types of markets over here. As Ravi already mentioned the markets we are targeting are all amongst the top 15-20 markets in emerging markets which represent 90% to 95% of the value in these emerging markets. Some of these markets would approve the product based on the quality of the dossier we have already generated so far. Some markets require local clinical trials. We are clearly addressing both market opportunities and we expect approvals in both categories of markets this year.

Abhishek Sharma: In terms of your already ready dossier which you just mentioned, have you done some sort of trials for your lead products -- Trastu and…?

Arun Chandavarkar: Of course. Approval in India which we received in early 2014 was based on a trial that would satisfy not just Indian requirements but would satisfy many other requirements as well. As you know in Trastuzumab we have already completed a global Phase-I trial and our global Phase-III is progressing rapidly towards completion.

Abhishek Sharma: In terms of your existing dossier, that Indian trial forms the anchor trial so to say?

Arun Chandavarkar: In terms of having a CSR, yes.

Abhishek Sharma: In terms of manufacturing, within your own internal system where is the manufacturing located for the Biosimilars?

Arun Chandavarkar: If you look at Biosimilars as a monoclonal antibody we have a facility in Bengaluru for the drug substance as well as the drug product. For our Insulins facilities we of course have a facility in Bengaluru and you are aware of our facility in Malaysia.

Abhishek Sharma: On the API business, which is in your base Biopharma business, what kind of competitive intensity have you seen in Statins and Immunosuppressants in the last 12-months? What do you have in terms of your pipeline which could sort of offset the competitive pressures that you would be seeing in the base business?

Ravi Limaye: So the competitive intensity depends on the products, say, for example, for statins the competitive intensity is high, but if you take say for Immunosuppressants the competitive intensity is relatively low. So it depends on the nature of the product. That is why we have been saying this repeatedly that our endeavor is to move the product mix to a more profitable business which means in a way also where the competitive intensity is low.

Abhishek Sharma: What has been the trend in the last 12 months, I mean, have you seen some sort of a let up for?

Kiran Mazumdar-Shaw: In my opening comments I did mention that the better product mix has actually realized better earnings and this is clearly coming from newer products like Immunosuppressants. The dependence on Statins is obviously reducing and we are seeing a better contribution from products like Immunosuppressants. So that basically tries to give you some indication. That is one shift that you are seeing and there we believe that the competitive intensity is far less than in Statins. We are also seeing that today compliance is also helping us in a big way because some of our Chinese competitors are getting warning letters and that is also helping us.

Abhishek Sharma: In terms of pipelines would you continue to focus on these two categories or is there any other class that you are currently working on?

Arun Chandavarkar: You would have seen in our press release and on our call earlier today that we announced construction of our potent Oral Solid Dosage Formulations facility and we have said that this is part of our vertical integration strategy. So that should give you an indication that we are looking at potent APIs as well.

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

Shraddha Patil: My first question relates to conceptual understanding about the R&D. So I was just reading the 'annual report' and I wanted to understand the rationale behind why there is a separate heading of R&D, where we directly charge it to the P&L and we also carve out certain the R&D expenditure from other heads of expenses. So what is the reason behind this?

Siddharth Mittal: How the numbers are presented can be discussed offline.

Shraddha Patil: My second question is regarding Tregopil. So I understand that BMS has divested their portfolio to AstraZeneca. But, would it not be a better idea for us to continue our portfolio with AstraZeneca as well?

Kiran Mazumdar-Shaw: We will be exploring that option as well.

Shraddha Patil: So we have not yet completely decided on continuing on all our own?

Kiran Mazumdar-Shaw: As I mentioned it is very important for us to progress this asset in terms of validating some of our first wave findings and after that we have many options and therefore we believe that these options will include approaching companies like AstraZeneca.

Shraddha Patil: So you will continue the development from your side but you will also explore the other options?

Kiran Mazumdar-Shaw: Yes.

Shraddha Patil: Any update on the Malaysia plant as to the regulatory approvals of the locals or any other markets?

Shreehas Tambe: As you know we have commissioned the facility in Q4 of FY15 and at this point we are in the process of validation of our products. We have received the GMP certification from the Malaysian authorities already and as we look to validate these products we will next get the manufacturing license within the next quarter or so. Once we do that we would be looking at making applications towards other emerging markets to begin with along with the other processes that we follow.

Shraddha Patil: So maybe a period of two quarters where we will see the filings to begin for the product?

Shreehas Tambe: From a Malaysian standpoint, yes, you would see that.

Shraddha Patil: You mentioned that the total filings for the ANDAs are in single digit. So, I understand that the first filing had begun in 2015. So what is your anticipation of starting to receive the first ANDA approval?

Arun Chandavarkar: We expect the first ANDA approvals to start coming in the latter half of FY17.

Moderator: Thank you. The next question is from the line of Charulata Gaidhani from Dalal & Broacha. Please go ahead.

Charulata Gaidhani: I wanted to know your new launches that you have planned like the Hepatitis C launch and revenues expected from new launches?

Ravi Limaye: We have already launched as you know two products in our Virology segment -- Sofosbuvir and Sofosbuvir plus Ledipasvir - CIMIVIR and CIMIVIR-L. One more product will be launched very shortly. So you will hear about it soon and one more product will follow. So with that we will almost have the entire portfolio of Hepatitis C covering all the relevant genotypes.

Charulata Gaidhani: Why is the interest cost lower in this quarter?

Siddharth Mittal: For year to date, the difference is very small from Rs.10 crore to Rs.9 crore. Some of finance charges also include charges on account of the hedges that we take.

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

Prakash Agarwal: Just trying to understand this licensing income stream. So since we said that we tied up and we expect to launch in three of the markets of the 15. So I understand there is still a lot of markets to be covered. So can we expect this licensing income to be ongoing event?

Arun Chandavarkar: Licensing is a part of how we monetize the assets in emerging markets on top of product sales. One is of course there are markets to be covered in terms of licensing. There are also additional products in our portfolio that would be covered going forward. So combined with geographic expansion and portfolio we would see on an ongoing basis, but it will be lumpy. We cannot say what will happen in which quarter or which year.

Prakash Agarwal: Tregopil, I think you have explained enough, but just trying to understand, so we were till Phase-I with BMS and now we are seeing the positive data we are going solo with this and in future we might look at another partner, correct?

Arun Chandavarkar: Correct.

Prakash Agarwal: So any particular reason why BMS is not going forward?

Kiran Mazumdar-Shaw: I mentioned to you that this deal was struck with BMS prior to their divestment of their diabetes franchise to AstraZeneca.

Prakash Agarwal: Is there a FOREX gain in the other income?

Siddharth Mittal: There is a FOREX loss of Rs.4 crore included in other expenses.

Prakash Agarwal: So EBITDA would have been better?

Siddharth Mittal: Yes.

Prakash Agarwal: On 4Q last year, if I look at your Biopharma base currently above Rs.450 crore and ex of domestic, so there was some spike in 4Q last year. So was there any one-off or is there a seasonality that happens in 4Q, if you could help us understand?

Ravi Limaye: Last year in the last quarter there was some business you probably may recall Fidaxomycin that was there. That may not be there now.

Moderator: Thank you. The next question is from the line of Surya Patra from Phillip Capital. Please go ahead.

Surya Patra: Just one point; in recent past we have already seen a kind of acquisition of API manufacturing plant with high potency capability and we are now setting up the Formulations unit in that same space. So could you just throw some light on the kind of a product that we are targeting in that particular space?

Arun Chandavarkar: If you look at it in the API business, Biocon would like to leverage the capabilities on high science that we have built largely around Biosimilars and now extend that to Small Molecules portfolio. This would cover molecules that are complex, difficult to make, molecules that require containment. Our compliance record with our Injectables facility also is something that we would like to leverage on the Small Molecules side and as you know potents would require a high degree of containment. So this is the space that we would like to work in and the announcement of the construction of our potent solid facilities is one piece while we had earlier announced acquisition of manufacturing facility for APIs in Vizag. So clearly these two are linked towards building our capacities and capabilities in that space.

Surya Patra: Basically, does that mean we are trying to complement our targeted therapy products targeting cancer and all that? Having our small molecule cancer molecules in the portfolio, that is what we are trying to have or …?

Arun Chandavarkar: Correct. Our Small Molecule focus is also around our key disease areas of Oncology, Autoimmune in those kind of segments.

Surya Patra: May I ask, what is the kind of market share that we have gathered for CANMAb and HERTRAZ put together in India?

Ravi Limaye: It is over 30%.

Surya Patra: On the Insulin front, though we have been talking about the four Biosimilar set for commercialization and filing in the advanced market. You possibly are not highlighting anything or not indicated anything on the RH Insulin for the European market. So any change in the strategy?

Arun Chandavarkar: Our stated strategy remains on track. But of course in terms of our priorities our energies are focused on getting these four molecules out the gate first.

Moderator: Thank you. We would be taking the last question from the line of Nitin Agarwal from IDFC Securities. Please go ahead.

Nitin Agarwal: On the US business, where do you see opportunities in the ANDA side, are you looking at essentially Immunosuppressants and some of those APIs where you are strong on or are there you see more opportunities out there?

Arun Chandavarkar: In terms of ANDAs, we are entering the space but the space is well known to you and is well established space. So we clearly need to identify differentiators in this space which align with our capabilities and our strengths. As I mentioned in response to an earlier question we believe this is focusing on one, disease areas which we are familiar with; two, high science, characterization, complex, compliance, containment. Those are the kind of spaces that we would operate in. We have mentioned in earlier quarter calls that we are not going to be chasing vast numbers; so we are not going to be filing 30-40 ANDAs annually like many other companies, we would be filing single digit numbers ANDAs, but cumulatively over the next four to five years, it will become a very nice portfolio for Biocon which would take us up the value chain in small molecules. This is part of our concerted effort to move away from products that can get easily commoditized and get into a space where we believe the competitive intensity will be less.

Nitin Agarwal: What Formulations facilities do we have right now which you are referencing for these filings?

Arun Chandavarkar: All of our Formulations facilities currently are on the Injectable side. Oral Solids and other presentations clearly is missing in Biocon's portfolio and that has resulted in us triggering this first CAPEX of potent Oral Solids. For other molecules in our portfolios, we are currently adopting an outsourced model in the near-term and we will take a strategic call as to when some of these outsourced products will be brought in over in the medium-term.

Nitin Agarwal: Do you have FDA-approved Injectable facility right now?

Arun Chandavarkar: Yes, I mentioned that we had two inspections this calendar year and they covered our Formulations Injectable facility as well.

Nitin Agarwal: Secondly, on the CANMAb you mentioned about (+30%) market share. Is the market share the context of the overall market including the innovators or the 30% Generic market?

Ravi Limaye: Including the innovator. For the moment it is and us, Mylan and Roche.

Nitin Agarwal: Herceptin was Rs.100 crore plus market in India, right, and we have (+30%) market share in that?

Ravi Limaye: Yes.

Moderator: Thank you. I now hand the conference over to Mr. Saurabh Paliwal for his closing comments.

Saurabh Paliwal: Thank you everybody joining us in today's conference all. We look forward to connect again in the next quarter. Good day.

Moderator: Thank you very much, members of the management. Ladies and Gentlemen, on behalf of Biocon Limited that concludes this conference call. Thank you for joining us and you may now disconnect your lines.