Biocon Limited's Q3 FY15 Earnings Conference Call
January 23, 2015

Key Participants from Biocon Group's Senior Management Team

- Kiran Mazumdar Shaw: Chairperson and Managing Director
- John Shaw: Vice Chairman
- Arun Chandavarkar: Chief Executive Officer & Jt. Managing Director
- Siddharth Mittal: President, Finance - Biocon
- Abhijit Barve: President, R&D
- Ravi Limaye: President, Marketing
- Peter Bains: Director, 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 Q3FY15 Earnings Conference Call of Biocon Limited. 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. Thank you. And over to you, sir.

Saurabh Paliwal: Thank you, Mallika and Good Afternoon, everybody. Welcome to Biocon's earnings call for the third quarter of FY'15. Last night we released our results and hope you have received them, the same have also been posted on our website.

This afternoon to discuss the business performance and outlook, we have with us Ms. Kiran Mazumdar-Shaw – Biocon's Chairperson and Managing Director and the senior leadership team at Biocon.

Before we proceed with this call, I would like to remind everyone 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 for the call shall be available soon on the company website.

I would 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 contains 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 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. First and foremost I would like to start by wishing everyone a Happy New Year.

I welcome you to the Biocon's earnings call for the third quarter of fiscal 2015 ended 31st December 2014.

Let me start by presenting the key financials for the quarter.

- Group revenues were at Rs.779 crore, a growth of 8%.
- The Biopharmaceutical segment sales were Rs.541 crore and within this segment, the core Biopharma sales were at Rs.436 crore, which is a modest 4% year-on-year growth.
- Branded Formulations grew 6% to Rs.105 crore.
- Research Services, which was the best performing segment, grew to Rs.220 crore, delivering 20% growth.
- We have earned Rs.10 crore from various Licensing deals in emerging markets this quarter.
- Group EBITDA was at Rs.170 crore, with EBITDA margins at 22% for this quarter.
- Group net profit for the quarter was Rs.91 crore, PAT margin stood at 12%.
- There was a net FOREX loss of Rs.5 crore this quarter on account of premium payments made towards hedging contracts and adverse movements with respect to the Malaysian Ringgit-USD parity.
- Long-term borrowings for the group at the end of Q3 stood at Rs.797 crore, coming from drawdowns made for the construction of our Malaysia facility.

I would like to highlight some of the key aspects of the financials as follows:

Our **R&D spends** have seen a sharp increase this quarter where we have incurred a total spend of Rs.66 crore, of this amount, Rs.47 crore was reported in the P&L, which is approximately 9% of the Biopharmaceuticals segment sales. We capitalized an amount of Rs.12 crore, while the balance amount was offset against deferred revenue. We expect these spends to rise going forward as more biosimilar programs advance in the clinic. The decrease in EBITDA therefore needs to be viewed in context of this sharp increase in R&D expenses together with other factors which include a modest forex loss, CSR spends and some Malaysia-related expenses.

The increased R&D expenses clearly highlight the advancement of our research programs in the clinic. And therefore, the core margins i.e. EBITDA margins excluding the effects of other income, licensing, and R&D spends actually stood at 25% for Q3 and 26% for the nine-month period which actually reflects strong underlying operations.

I would like to emphasize here that R&D is an integral and important part of our business. Our investing in R&D is about investing in our growth engines and growth drivers of the future and therefore we believe that R&D is a very critical growth engine for us which we will have to keep investing in, in order to really generate the growth which we will see delivering on all cylinders in the very near future.

In our **Biopharma business**, we continue to work towards shifting sales lost from our Middle East markets, not on account of lack of demand but really due to the high credit risk that prevails in these parts of the world. The regulatory process for qualifying our products in these newer geographies is ongoing and we expect approvals to come through in the coming quarters. We are confident that the expected regulatory approvals in many of our LATAM countries and other emerging markets together with increased capacity once Malaysia kicks in will help us deliver double-digit growth in this business. Branded Formulations India and Research Services will continue to be the growth drivers for Biocon until then.

Our **R&D** pipeline is progressing well. The global Trastuzumab and Insulin Glargine trials continue to advance. I am happy to share that two additional global Biosimilar programs have entered the clinic. Recruitment of patients for the India clinical trial of biosimilar bevacizumab has commenced. And all

this basically points and positions Biocon as a leading player in biosimilars globally with one of the largest portfolios of biosimilars in the clinic. This, as you can see, is a very important optic that people need to understand as the biosimilars opportunity starts becoming a very large and now visible opportunity with not too many players in a position to address this very important and increasing opportunity.

Our **Branded Formulations business** is being developed as a Specialty franchise and we have made several strategic calls in terms of product rationalization. Nine month growth for this business stood at 11%, which is in line with industry and we are confident to deliver low mid-teen growth for the full year. It is important for me to mention here that this product rationalization and portfolio rationalization has actually enabled us to increase profitability of this business vertical significantly. It is now becoming an important contributor to EBITDA and PAT.

Our flagship brands across divisions, particularly in Metabolics and Oncology continue to do well. CANMAb™, our Biosimilar Trastuzumab has been very well received in the market in India and has the distinction of being one of the most successful product launches in the Oncology segment in the country.

Our **Research Services segment** had the best quarter so far and we are confident that this performance will continue in Q4.

The Board yesterday gave its consent to initiate the listing process for Syngene which will commence with the appointment of merchant bankers for the purpose of preparing for the IPO. Listing of Syngene is an important and much awaited event which will help us unlock value of this business that is not fully captured at the moment. The proceeds from the Offer for Sale will help fund Biocon's requirements for cash, both for its R&D and CAPEX programs.

Our Oral Insulin program (IN-105) continues to progress well in clinical trials which are ongoing in the US and we expect some critical readouts by the end of this fiscal. This will pave the way for the next phase of development which is key to unlocking the enormous potential of this asset.

I am also pleased to say that our Malaysia project is nearing completion and is on track to be commissioned by the end of this fiscal. This will herald the start of a series of operational processes required for regulatory inspections.

I would also like to comment that we are making progress in licensing of our anti-CD6 monoclonal antibody, Itolizumab. Our potential licensee requires certain regulatory clearances which is delaying the conclusion of this licensing arrangement. We expect that this will take a little more time, certainly I do not think that this will happen by this fiscal.

In conclusion, I would like to mention that Biocon continues to invest in its uniquely differentiated business model. Our efforts are reflected in the progress made by our research programs in the clinic. As we move towards taking these products to various markets across the globe, we are confident that our focused approach will help us drive long-term value creation.

I will now stop here and open the session for question-and-answers.

Moderator: Thank you. Ladies and Gentlemen, we will now begin the question-and-answer session. The first question is from the line of Ranjit Kapadia from Centrum Broking. Please go ahead.

Ranjit Kapadia: Ma'am, I have two questions: My first question is what is the order book for Syngene and Clinigene currently? And my second question relates to domestic formulations business, which has shown a growth of 5.5%. Now, even if we take a 6.3% growth which is the price increase the companies have taken even if you consider all the products under price control, you could have got about 6.3% increase in the price, but this growth is lower than that also. So, what is the reason for this, and if you can elaborate on growth of our domestic business going further?

Kiran Mazumdar-Shaw: So let me answer the second question and I will get Peter Bains to answer the first question. As I mentioned earlier on, our focus now in branded formulations is about profitability, not just top line. We have actually shed a number of products. So when you look at the growth, please do not look at the growth as measuring it to market growth, because we have actually let go of a number of products; we have intentionally and deliberately actually curbed back on many of our products; we have actually rationalized the products, much of our top line that was coming from many of these products have actually been knocked off. However, the profitability that I am not in a position to share, has more than tripled in this vertical by doing so. I hope you understand the strategy we are taking to actually focusing on specialty products, making big brands out of them, rather than just going after the large number of products that are not delivering high profitability to us. So, we are not really going to focus on top line growth, but we are going to focus on bottom line deliverable, but at the same time we believe by doing this our top line will henceforth grow robustly.

Ranjit Kapadia: How many products are there currently approximately and how many have been rationalized?

Kiran Mazumdar-Shaw: All I can say is we have actually shed 30% of our products.

Ranjit Kapadia: 30% of the products have been rationalized?

Kiran Mazumdar-Shaw: Yes.

Peter Bains: With regard to your question on visibility of order book for Syngene, as we reported, we have seen a strong pick up in Q3, delivering 20% growth on the comparable quarter and we have good visibility on order book to see that momentum continue through Q4 and on track to deliver the guidance of full year revenues in the high teens.

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

Girish Bakhru: First one on the rh-insulin. We have the strategy of harmonized filing both in the EU and US. With FDA giving some kind of green light to release insulin in US market also, so how are we looking at the US for this year filing for the rh-insulin along with Europe?

Abhijit Barve: Girish, as we have said on multiple occasions, Lilly's glargine filing definitely has been of significant help to us in terms of understanding the requirements. Having said that, we are talking to the regulators and seeing how we can make sure that we can have a combined filing that would also coincide with our Malaysia plant going onstream.

Girish Bakhru: So this would happen by end of this calendar year as per the track earlier?

Abhijit Barve: I think we cannot give an exact date, but we are working closely towards seeing how quickly we can get this filed.

Girish Bakhru: I am just trying to understand, because the FDA is viewing this product not exactly as Biosimilar for Lilly's case. Does that kind of give you a different kind of picture as to whether the rh-insulin per se can be filed as a branded product or would it have to be a biosimilar filing, what is your understanding on that?

Abhijit Barve: Since glargine was approved under the old 505 pathway versus the biologics pathway, both glargine as well as rh-insulin will be viewed as filing not as in a true biosimilar perspective, but if you look at how they have been looking at these molecules, some of the concepts related to biosimilarity will apply to these molecules as well.

Girish Bakhru: Again on the US side. You have plans to file ANDAs. I understand it has been of course happening. When do you expect the first ANDA launch in the US market?

Arun Chandavarkar: We have just started filing ANDAs this fiscal and clearly the molecules we have picked are molecules that from a patent expiry perspective would be a few years down the road, because this is typically how we normally view the market. So, we do not expect commercialization of any of these in the US say in the next two years.

Girish Bakhru: So, your filing none of the products which are already generic, is that correct interpreting?

Arun Chandavarkar: That is correct. Our strategy in ANDA is a little different from what you would typically hear in the generic space, because our strategy of getting into these ANDAs filing was largely to be a vertically integrated player, so that we could add value to a lot of our differentiated APIs, like whether it is in the Immunosuppressant side or Oncology side or any of these kind of specialized molecules. It was not so much about driven by getting into a race of filing a large number of ANDAs.

Girish Bakhru: So, when you file these ANDAs which are patented right now, most of these filings you would wait for patent to expire, right? And you would partner in every ANDA with somebody for distribution of products?

Arun Chandavarkar: I cannot talk about the IP strategy, as you know, IP strategy is a key part of not just us, any company's ANDA strategy, so I cannot comment about patent expiry, Para-IV and things like that. In terms of commercial strategies in the US, once we are closer to commercial launch of our first products, at that time we would be in a better position to come to you with the commercial strategy, whether we are going through a partner or not.

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

Surya Patra: Just wanted to know, since you have already indicated about the Malaysia plant's commissioning before March, which is on the scheduled timeline, so, what are the kind of initiatives that you are planning to take the Insulin little aggressively in the emerging market, can you discuss at least on this front, which will provide some visibility about the Biopharma side?

Arun Chandavarkar: In terms of taking our Insulins to emerging markets, you recognize that we have publicly said in earlier calls, that our recombinant human Insulin is registered in over 50 countries and glargine registered in over 10 countries and we will continue to add countries to this list of approvals. It is very clear that our Malaysia facility was built primarily to cater to the developed market. Having said that, pending approvals from many of the developed countries, we will be of course qualifying Malaysia in many of the emerging markets where we already have approvals for example from our Bengaluru facility.

Surya Patra: But again, can you add anything else which will give some visibility about the insulin strategy going ahead in the emerging market because possibly commissioning of the Malaysia plant is key to the growth in the insulin front as we have been seeing capacity constraints at times?

Arun Chandavarkar: I did not get your question. If you mean commercial strategies in emerging markets there is a mix of retail strategy, tender strategy, mix of partnering with the local people. So there are various options of how we approach the emerging markets. It is country specific, very often; different countries have different ratios of retail and institutional business.

Surya Patra: Is it fair to assume that okay at least second half of '16 will see some revenue implication of the new plant commissioning?

Arun Chandavarkar: We will see capacities accruing incrementally, I think there are two kinds of capacities. If you look at it, the immediate constraint was also the drug product capacity and that we are trying to bridge through various means to address some of these markets and we hope some of the strategies will kick in, in FY16.

Surya Patra: On Fidaxomycin, as of now we are not getting any business out of the Fidaxomycin API supply because of the fact that getting acquired by Cubist, but again, there is a development on that front; Cubist being acquired by Merck again. So, on that front what kind of future that you are anticipating for the Fidaxomycin, particularly for the next year?

Ravi Limaye: So the acquisition as you rightly put of Cubist by Merck has just happened, in fact, it is actually in the process; integration has not even happened. It is too early to make any comment on how this will merge going forward. So we would wait to see how Merck takes up the new product and how they commercialize it and then accordingly, we will be able to be in a position to respond, but at the moment a bit too early.

Surya Patra: So, based on our existing contract with the partner either Optimer or Cubist, so there is a future of this product, right?

Ravi Limaye: We cannot comment on it at this stage.

Surya Patra: On Itolizumab, it seems that you have already tied up with somebody for licensing and the partner is awaiting for some regulatory approval. So, does that mean something has already happened and it is just that we have not announced it for public that is what we are trying to say?

Kiran Mazumdar-Shaw: No, what we are saying is that this is something that we are looking forward to concluding with a potential partner, but the partner requires to get some regulatory clearances on account of certain aspects of the asset. So until they get that we are not in a position to conclude the

deal. So, it could happen now, it could happen in a few months' time, but there is no certainty as to what is the time in which they can get that approval.

Surya Patra: Is it linked to some developmental aspect in terms of asset?

Kiran Mazumdar-Shaw: No, it is not linked to that, this asset has got a Cuban origin. Cuba had certain issues dealing with US, of course now fortunately, the Cuba-US relations are improving significantly and therefore because of that they have to go through some formalities. We are just awaiting that.

Surya Patra: We have worked for two indications for this molecule, right?

Kiran Mazumdar-Shaw: Right now in India we have basically worked on Psoriasis and we are actually about to start a clinical trial for RA and we have done Phase-2 in RA. So this is now going to be a Phase-3 in RA in India.

Moderator: Thank you. The next question is from the line of Dheeresh Pathak from Goldman Sachs. Please go ahead.

Dheeresh Pathak: In the segment breakdown of the financials, the margins for the Contract Research are in the (30% +) range, but there is a large part of unallocated corporate expenses as well. You give a segment breakdown, but when we look at that, the EBITDA margins on a segment basis were very high and the reason of course is that there is a large unallocable corporate expense also, which is almost 50% of the EBITDA pre-tax. I am trying to just think of the underlying EBITDA of the Syngene business which you are trying to list separately, so how to sort of allocate this unallocable corporate expense into the two different revenues that you report?

M.B. Chinappa: The Research Services business margins as we have maintained in the past, is 30% plus, so the balance would be attributable to Biocon.

Dheeresh Pathak: All the unallocated expenses go to Biocon, is that you are trying to…?

M.B. Chinappa: More or less, because you can take the Research Services at 30% plus margins and then allocate the difference to Biocon.

Dheeresh Pathak: Just trying to understand that what R&D program is being capitalized, I know you explained this in the past, if you can just refresh that which program costs are being capitalized?

Siddharth Mittal: Only costs relating to Trastuzumab are capitalized.

Dheeresh Pathak: What is adjusted through deferred revenue, is rh-insulin?

Siddharth Mittal: rh-insulin, glargine, lispro and aspart.

Dheeresh Pathak: What runs through P&L is basically the ANDA?

Siddharth Mittal: ANDA, all other monoclonal antibodies and biologics, small molecules, and a part of oral insulin runs through the P&L.

Dheeresh Pathak: You would have had a choice of using the 351(k) which is biosimilar pathway or the 505(b) (2). We are seeing that FDA is approving some through the biosimilar pathway. Can you again walk us through briefly that why not go through the biosimilar pathway because the insulin are first-generation Biosimilars?

Abhijit Barve: I think the FDA's thought process on this is very clear. If you look at insulins and glargine, these were the molecules that were approved before the BLA and those pathways were well established which really runs into what we call as now as the 351(k) pathway for biosimilars. So the molecules that were approved before that, including some of the old molecules like growth hormones, etc., all of them actually fall under the 505(b)(2) or a 505 pathway. That is how we have been approaching it. The requirements are not dramatically different in terms of the expectations of the regulators. FDA has actually mentioned that after 10 years since the BPCI has been approved, all the molecules, whether they were approved under 505 or 351k or 351 pathway, will flow through the 351. So, I think it is more of a technicality, I do not think it anyway changes. There are definite advantages of 505 because interchangeability is well-defined path within the 505 pathway vis-à-vis the 351 pathway.

Dheeresh Pathak: But, the study that you are doing, is a crossover arm also designed in the study?

Abhijit Barve: I would not like to get into the design of the study, but I think as our partner, Mylan has said with glargine, that the goal is to get to a product that is going to be interchangeable or satisfy the requirements of interchangeability.

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

Sameer Baisiwala: I am not quite sure whether you are talking about it, you mentioned that there are two other biosimilar programs having entered clinical globally. Which are these two candidates?

Kiran Mazumdar-Shaw: We cannot name them, but you know that we have a pipeline of biosimilars. So, some of these have now entered the clinic globally. So that is why we are just mentioning that.

Sameer Baisiwala: Because you have disclosed the others like glargine or…?

Kiran Mazumdar-Shaw: Correct, wherever we can disclose we have disclosed it, because the moment it comes into the public domain we can certainly disclose it.

Sameer Baisiwala: But these are out of your partnership with Mylan?

Kiran Mazumdar-Shaw: Yes, these are all partnership with Mylan.

Sameer Baisiwala: On Itolizumab. As and when the outlicensing deal gets concluded what would it mean, I am assuming this is for regulated markets, so would it be the full grown clinical trials or the fact that you have done a fair bit of work here in India is going to make it quicker to get launched in those markets?

Kiran Mazumdar-Shaw: There is a lot of confidentiality to it, so I do not think I can share more than what I have said.

Sameer Baisiwala: One final clarification – I think you mentioned in the call that it is possible that the Malaysian facility will start generating sales even in FY'16, if you can just clarify on that?

Kiran Mazumdar-Shaw: No, I think what we are saying is that by the end of this fiscal we will be ready to start the whole validation and the regulatory processes that are required for approval. It all depends on the regulatory timing; if it happens sooner than later, then we can capture some sales from that plant, but it all is dependent on regulatory inspection events. You know how this is; you cannot actually predict exactly when this can happen, and that is the nature of the business. If we could predict exactly when something can happen, I think we will have far more predictability in the business, but these are basically something that is left to the regulatory agencies to decide the time of inspection and things like that.

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

Surya Patra: So far how many ANDAs that we have filed in USA?

Arun Chandavarkar: We have not disclosed the number, but as I said it is very few, we are not chasing large numbers.

Surya Patra: One thing what I am observing is the primary sales and the secondary sales growth, what we see from AIOCD or any other data points, those are not matching, any specific reason?

Ravi Limaye: I do not think you can compare primary sales internally and secondary sales from IMS or somewhere, I do not think that is a comparison of AIOCD any third-party database. So, we have our own internal secondary sales data, we would rather go by that. There is obviously some correlation but it cannot be exactly compared.

Surya Patra: Possibly, the rationalization what you said 30% of product that you have rationalized because of the profitability factor or whatever. So, that is the reason for the mismatch.

Ravi Limaye: Maybe, may not be, depends on which products because not all products get reflected in IMS or AIOCD because there is a hospital component and there is a retail component. So I do not think these are exactly comparable. For example, our Oncology business will never get reflected in IMS or AIOCD; Oncology is one of our star businesses.

Surya Patra: Any number that you have sharing for Trastuzumab in India?

Ravi Limaye: We would not share the numbers, Kiran already mentioned, it is one of the most successful products in Oncology.

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

Bhavin Shah: Could you just outline the CAPEX plan for the year next?

Siddharth Mittal: CAPEX excluding Malaysia and any Greenfield expansion which we will commit to will be around Rs.200-250 crore.

Bhavin Shah: Will this run rate sustain FY17 onwards, do you probably want to keep this going?

Siddharth Mittal: I said that this would be the annual maintenance CAPEX, does not include any Greenfield or large expansion we might have or Phase-2 of Malaysia.

Bhavin Shah: And just on the Syngene part of the business, on the margin front, given the pipeline that we have, do you see incremental addition thereof, we will probably sustain the run rate that we have currently?

Peter Bains: I think the position is looking to sustain the margins that we have. We have seen margins stability very firm around the guidance ranges that we have given of low-to-mid-30s EBITA and high-teens in PAT. We see that being a firm outlook.

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

Abhishek Sharma: Regarding the rationalization of the domestic portfolio, I was just wondering if there was a possibility to divest the rationalized part of the portfolio, which could have created some possibility of monetization?

Ravi Limaye: We did not rationalize it from the point of view of divestiture, the rationalization was more a strategic decision to focus on some of the key products. So the decision was more strategic, it was not tactical in that sense, and I do not think we are in that kind of business. We would rather focus on growing our star brands and we hope that over a period of time whatever we rationalize we will be compensated with the growth in the star brands.

Abhishek Sharma: No, so there would have been some brands, which you have shed, right, and did you consider a possibility of divesting them?

Ravi Limaye: The reason in rationalization is because they were low profitable brands, they are not really brands which were growing. So, making a divestiture of these brands may not make any strategic fit for the buyers I am saying.

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

Nitin Agarwal: On the small molecule business, if you can probably highlight what would be the drivers for this business over the next two to three years?

Ravi Limaye: We have said this before; our strategy is to move from our old business to the new profitable specialty products like Immunosuppresants, etc. So that strategy continues, it is giving us results and we will continue to follow this.

Nitin Agarwal: Do you still see enough opportunities in that category to grow because of the not too many products are going to go off patent?

Ravi Limaye: In the Immunosuppressants category?

Nitin Agarwal: Yes.

Ravi Limaye: Yes, and other specialty products as well.

Nitin Agarwal: This would be largely what you are doing small molecule API sales to regulated as well as non-reg markets?

Kiran Mazumdar-Shaw: Remember Biopharma sales also includes few more products, like Insulins and things like that.

Nitin Agarwal: Insulin I guess would be more a function of how your Malaysian facility takes off because what we heard in the past is the Bengaluru facility is at reasonably high capacity utilization right now?

Kiran Mazumdar-Shaw: Yeah, but if you look at our small molecule portfolio, I think we have quite a nice portfolio of products which goes beyond Immunosuppressants.

Nitin Agarwal: On the Contract Research business, could you shed some light on, if you have added some more service lines over the last couple of years and how has the business really evolved over the last couple of years and how do you see it going forward qualitatively as a mix of different service offering?

Peter Bains: So, the Syngene growth story is based on a number of dimensions. A piece of it is in expanding capability. So, as you described, adding in new elements of discovery and development to build a stronger integrated capability. Another dimension of growth would be to expand capacities and we have seen the results of that play through in the growth rate that we are providing. From the customer perspective, we are building existing customers and we are attracting new customers, and we are seeing increasing longevity of those customers building in, longer-term visibility in terms of contracts. So, the growth story is robust and multifaceted.

Nitin Agarwal: What kind of growth would you have seen in your commercial manufacturing part of the business which is booked under Syngene?

Peter Bains: So, we have no sales from commercial manufacturing at present, but we have aspirations and hope that this will come based on a strong pipeline of assets where we are supplying partners with clinical trial materials, and if those clinical trials result in successful approvals, we are very well placed to continue from supplying clinical trials to supplying commercial manufacturing.

Nitin Agarwal: How many such candidates would we have in late-stage trials right now?

Peter Bains: We have 6-7 assets in late-stage clinical trials.

Nitin Agarwal: And that would be Phase-III trials?

Peter Bains: Phase-II and Phase-III.

Nitin Agarwal: We did mention about the CAPEX plans, can it get escalated if we have any new Greenfield capacity expansions in mind. So, are there any thoughts towards that, so what kind of the areas you are looking at for committing fresh Greenfield CAPEX?

Peter Bains: So, we have a quite a broad ranging capital spend plan and that is best looked at over a range of years. So, over the next 4 to 5 years, we would be looking at a plan that would be in the $200 million range. But of that, only about 40% is currently committed, where we have clear visibility of expansion opportunity or new capabilities and the other 60% is in plan but not yet committed, and we will look at the business visibility and triggers before we would commit that.

Nitin Agarwal: What would be the major Greenfield plans for the overall business excluding contract manufacturing business?

Siddharth Mittal: I think in the last call we had mentioned that one, we are setting up a formulation facility; this is oral solid dosage facility for our ANDAs. Apart from that, we are also adding a formulation line for Insulin in India, would be evaluating a Greenfield facility for monoclonal antibodies and at some point of time Phase-II expansion of the Malaysia plant.

Nitin Agarwal: And will you probably see some crystallization happening around these areas over the next few quarters?

Siddharth Mittal: I think over the next two years, we should commit and a lot also depends on how the molecules progresses in clinic.

Moderator: Thank you. Next question is from the line of Nitin Gosar from Religare Invesco. Please go ahead.

Nitin Gosar: I just wanted to understand on this rationalization program that we have conducted in domestic market. So does that mean 30% has gone up during this particular year or it has been happening over a period of say 2-odd years or 3-odd years?

Ravi Limaye: So, it is a continuous process. So, it has happened over the last say, a few months and it will continue to happen in future as well. The intention as we said is to focus on a few strategic brands which we believe will drive the growth of this business and take us into the future and that focus is on specialty business.

Nitin Gosar: But I am trying to understand the A-point to B-point where you calculated the 30% drop in?

Ravi Limaye: You can say approximately about a year.

Nitin Gosar: Same would have happened with the MR strength for the domestic market?

Ravi Limaye: Yes, but we would not like to go more into those details.

Nitin Gosar: Since you are talking about the profitability, could you give a kind of ballpark understanding where does our profitability stand like in terms of it is way below the consol number or the consol margin or it is very much closer to consol margin?

Siddharth Mittal: It is below the consol margin, I think we have mentioned again in the past that it is a low single-digit number for the Branded Formulations, and with the rationalization effort, the aim is to get it closer to the company margin.

Nitin Gosar: That could happen over a period of…?

Siddharth Mittal: Very difficult to give a period, but if you look at our FY'18 target, we do expect a lot of revenue to come from the biologics and the biosimilars; these biosimilars would definitely be more profitable than some of the other products, and as Ravi mentioned, the idea is to have some key anchor brands and these anchor brands would contribute to good profitability. So, I would say that by FY'18, we should aim to reach the company target average for this division.

Nitin Gosar: We continue to maintain that 20% growth rate for domestic Branded Formulations or that gets changed because of the event?

Siddharth Mittal: We have said mid-teens, and we do feel confident even for FY'15 we will come out in the same range.

Nitin Gosar: On the ROCE, keeping in mind currently you are investing heavily through P&L as well as balance sheet, when do you see the reported ROCEs to cross the 20% benchmark – 3-years, 5-years down the line?

Siddharth Mittal: A lot depends on Malaysia, as you know that we have invested a huge amount in that plant, and also some of the other biologic plants in India. If you look at our billion dollar target by '18, a lot of that is going to come from biologics. So, we definitely expect the margins to improve and the ROCE to improve starting FY'17-18. But unless you reach optimal capacity utilization on Malaysia which would probably be beyond FY'19 timeframe, you will not see huge ROCE improvement from that plant.

Moderator: Thank you. The next question is from the line of Tushar from IndiaNivesh. Please go ahead.

Tushar: Given that now that R&D cost is going to increase, so just would like to have guidance on the tax rate?

Siddharth Mittal: The guidance has been around 22-23% in general. This year, we do expect to do better than that. We expect tax rate to be somewhere between 18-21%, which will be 200 basis points lower than our guidance. However, for next year again, a lot of the benefits we get is dependent on whether we are doing research in SEZ or non-SEZ, so we would maintain 20% to 23% for next year.

Moderator: Thank you. Next question is from the line of Ranvir Singh from Sharekhan. Please go ahead.

Ranvir Singh: First on a clarity on CAPEX. You said Rs.250 crore. This is apart from what has already been done on Malaysia or that includes…?

Siddharth Mittal: Yes, this is apart from what has been done in Malaysia and this is apart from any Greenfield CAPEX that we might have in, some of which Peter spoke about it; he did an estimate of what Syngene is looking at doing. I mentioned some of the other Greenfield spends we would have.

Ranvir Singh: Where this Rs.250 crore would be spend – towards expansion of formulations facility?

Siddharth Mittal: It is a routine CAPEX, for our existing Bengaluru facility

Arun Chandavarkar: This goes into things like lab infrastructure, debottlenecking existing product lines, existing facilities, replacement of old equipment and things like that.

Ranvir Singh: Can you give guidance on R&D expenditure for the full year?

Siddharth Mittal: We have said 10% of the Biopharma revenue. It would fluctuate at any point of time by 200 to 300 basis points but that is a broad trajectory if you look at a longer period of time.

Ranvir Singh: What we are experiencing in MENA region, I think situation not going to change immediately and we have capacity constraints also. Malaysia facility also at least 1-1.5 years away. So what would be boosting growth in between in next couple of quarters, any hints if you can give?

Arun Chandavarkar: I think in the earlier quarters we had mentioned that the near-term growth drivers are basically 2 or 3. Clearly, Research Services as a group, will be a key growth driver, it has already shown growth of 20% and they are guiding for closing the year in the mid-to-high teens, so, which means that it does look promising. Branded Formulations clearly is a growth driver for us. The dip in Q3 is partly the rationalization that we have gone through, but there again as Siddharth mentioned earlier, we should close the year out in the low-to-mid teens, and going forward, we will drive profitability in this business. So, these two are clear near-term growth drivers. The other growth drivers, I think Kiran alluded to, is regulatory approvals in emerging markets. So, as and when we get regulatory approvals in emerging markets, we would enter them with many of our biosimilars as well as some of our other formulations.

Ranvir Singh: About Syngene, now Board has approved to go public, if you can give some timeline when we can expect that listing coming here?

Kiran Mazumdar-Shaw: The board has given its approval to go ahead with the listing process, and typically, this has a certain time duration, and we believe that we will be able to list Syngene in the first half of next fiscal.

Moderator: Thank you. Next question is from the line of Dheeresh Pathak from Goldman Sachs. Please go ahead.

Dheeresh Pathak: Just one clarity on the MENA region, if you just give more granular details in terms of which countries, what are the exact issues, I think you said credit issues?

Ravi Limaye: These are countries like Syria for example, Iran, Egypt, where we already said that the issue is not demand but issue is credit risk which you can very well imagine when I name the countries.

Dheeresh Pathak: So is it a particular distributor that is bad or is it overall …?

Siddharth Mittal: Earlier we used to have ECGC, underwrite the credit for most of the countries and then if the customer did not pay, the insurance used to pay. Now insurance has stuck off these countries from the covered list. So, you have to sell at your own risk and there are very tough banking regulations in some of these countries; most of our buyers have to first deposit the amount of purchase with the government, and then government transfers the money on less than what is the amount of invoice and then it takes them almost 6 months to one year before you realize the money. So, it is just the risk of which we thought is not worth taking at this stage.

Dheeresh Pathak: Just to have a better clarity, as per the footnote, it sort of talks about that when the Mylan deal was signed about Rs.215 crore from deferred revenues came through the P&L as an exceptional income related to the analogs development. Why would then analog development cost be netted off through deferred revenues?

Siddharth Mittal: When Pfizer exited in 2012, they had paid us on account of two things; one for rh-insulin and the second for the analogs. When Mylan came in, they also paid us $20 million for the analogs, and at that point of time the corresponding amount that was lying from Pfizer was taken as an exceptional income pertaining to analogs. The amount paid by Mylan was put to deferred. Currently the amounts have been utilized against that.

Dheeresh Pathak: Mylan had a one-time payment of $20 million and they are not making recurring payments which goes into deferred revenue. So, you are netting off against the $20 million?

Siddharth Mittal: They are sharing in the co-development costs. So, this was only one-time upfront payment. Apart from that there are no milestone payments.

Dheeresh Pathak: This money that you received is in dollar or you convert?

Siddharth Mittal: All in dollars.

Dheeresh Pathak: So when you market-to-market, do you run the gains or losses through the P&L?

Siddharth Mittal: If you are talking about the translation, the translation goes to the balance sheet, because the money is all lying in dollars with our Swiss entity and because of the rupee-dollar fluctuation, any positive or negative goes to the balance sheet.

Moderator: Thank you. The next question is from the line of Nitin Gosar from Religare Invesco. Please go ahead.

Nitin Gosar: Just one follow-up on this Malaysian facility; If I were to exclude the CAPEX related to Malaysian facility, then broadly we are doing around 18%, 20% kind of ROCE on the existing business. Do we build in this kind of understanding for our Malaysian CAPEX or Malaysian CAPEX could fetch us a better ROCE?

Siddharth Mittal: As we said, Malaysian facility is primarily being constructed for the developed markets for US and Europe, and definitely, the margin from these markets are going to be much higher than our current business in the emerging markets. However, we have to reach optimal capacity utilization from Malaysia for the ROCE to be higher than what we are doing now, and as I had mentioned sometime back that even though we have given guidance for '18, it will take a couple of more years after that to reach that optimal capacity utilization.

Moderator: Thank you. As there are no further questions from the participants, I now hand the conference over to the management for their closing comments.

Saurabh Paliwal: Thank you everyone for joining us in this call. We look forward to hosting you next quarter.

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.

Note: This document has been edited to improve readability