Biocon Limited's Q1 FY16 Earnings Conference Call
July 24, 2015

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
- Narendra Chirmule: Sr. Vice President, R&D
- Peter Bains: CEO, Syngene International
- Saurabh Paliwal: Head, Investor Relations

Presentation Session

Moderator: Good Day, Ladies and Gentlemen, and welcome to the Biocon Limited Q1FY16 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. Thank you and over to you, sir.

Saurabh Paliwal: Thank you. Good Morning, everybody, and welcome to Biocon's earnings call for the first quarter of FY16. This morning, to discuss the business performance and outlook, we have with us Ms. Kiran Mazumdar-Shaw – Biocon's Chairperson and Managing Director, along with the senior leadership team at Biocon.

Before we proceed with this call, I would like to remind you that this call is being recorded and a replay will be available for the next few days immediately after the conclusion of this call. The transcript of the call would be made available as soon as possible on the company website.

I would like to add that today's discussion maybe forward-looking in nature and must be viewed in conjunction with the risks that our business faces. The Safe Harbor language contained in the press release also pertains to this conference call. I would like to emphasize here that the disclaimer regarding Syngene International Limited in relation to its proposed IPO applies to this conference call. After the end of this call, in case you have any additional questions, please feel free to get in touch with the IR team.

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

Kiran Mazumdar-Shaw: Thank you, Saurabh. Good Morning, everyone. I welcome you to Biocon's earnings call for the first quarter of this fiscal.

Let me present the key financial highlights for the quarter:

- Group sales for Q1 were Rs.825 crore, which is a growth of 15% year-on-year.
- Biopharma sales were Rs.489 crore for this quarter, a growth of 12%.
- Branded Formulations sales were flat at Rs.112 crore in Q1. However, there was a sequential growth of 14% in this vertical.
- Given that we are currently in the silent period post the filing of our Red Herring Prospectus with the RoC in Bengaluru, we cannot make any statements regarding our subsidiary, Syngene, or its proposed initial public offering. Hence we are not providing any details with respect to the standalone performance of Syngene in this earnings call.
- Group EBITDA was Rs.236 crore for Q1, with EBITDA margins at 28%. The improvement in EBITDA is attributable to a one-time fee of Rs.45 crore received from Merck towards capacity reservation for Fidaxomicin, plus a forex gain of Rs.6.5 crore. I would also like to mention here that the contract with Merck is further extended by 7-years for Fidaxomicin.
- Group Net Profit for the quarter was Rs.126 crore, with net profit margin at 15%.
- We incurred a total spend of Rs.93 crore on R&D this quarter which is reflective of the advancing clinical programs, globally. Of this amount Rs.50 crore is reported in the P&L. We capitalized an amount of Rs.13 crore while the balance of Rs.30 crore was offset against deferred revenue.
- Long-term borrowings for the group at the end of Q1FY16 stood at Rs.761 crore on account of loans taken for construction of our Malaysia Insulins facility.

Now, moving on to discuss individual businesses:

Biopharma: We saw improved performance in our Biopharma business in Q1, benefiting from a strong performance of our Insulins and Biosimilars business in emerging markets. The performance was also driven by a one-time money received from Merck on account of the capacity reservation fee for Fidaxomicin. This payment frees them from future guaranteed offtake commitment towards API supplies; however, we have extended the contract with Merck for Fidaxomicin for an additional 7-years and they remain very committed and optimistic on the prospects of this product. Excluding the one-time fee, Biopharma products sales and licensing revenues have been relatively flat. However, I must mention here that we took a planned maintenance shutdown in Q1 of our drug product facility which lasted approximately 45 days. The facility is now up and running and back to normal operations. The shutdown certainly affected availability of certain products and we partly mitigated this through the use of CMOs who have recently been qualified by the regulatory agencies.

Talking about Drug Product Facility, I am very pleased to share with you that our Insulin Drug Product facility in Malaysia underwent a cGMP audit by the National Pharmaceutical Control Bureau (NPCB) in Malaysia. We expect to receive the formal certification from them in a few weeks, and this will then be followed by the initiation of validation batches for the drug product. This is extremely good news, it is certainly advancing our original plans, expectations around the commissioning of this plant and we expect this to result in sales in calendar year 2016.

Branded Formulations performance was as planned fairly flat this quarter compared to last year. However, based on our efforts to rationalize our product basket and focus on key brands and profitability, we have seen a strong sequential growth of 14% led by Metabolics, Nephrology and Market Access divisions. We expect an improved performance from this vertical in the coming quarters.

Our **Generics Insulins and Biosimilars programs** continue to advance in the clinic. I am indeed extremely pleased to announce that the recruitment for two global clinical trials for Generic Insulin Glargine, initiated in 2014, has been completed this quarter.

Recruitment for the RoW-focused phase-III clinical trial for Bevacizumab continues and we have also initiated a phase-I Pharmacokinetic comparability study for Bevacizumab in the Netherlands. Our Trastuzumab and Pegfilgrastim global phase-III clinical trials are progressing well and in fact very near completion. With the unique portfolio comprising a rich pipeline of Generic Insulin, Insulin Analogs and Biosimilar Antibodies and Recombinant Proteins, Biocon is well placed to tap the Biosimilars opportunity in the coming years. We do have one of the largest portfolios of these molecules globally and we are indeed very excited with the prospects that this particular portfolio holds in terms of both growth and market share opportunities globally. We expect sales from Biosimilar products will become a predictable engine of growth for the Company in the coming years. We are certainly seeing that we are making strong inroads with Biosimilars in many emerging markets. We have also realized licensing income from licensing Trastuzumab in some of the key emerging markets and we continue to look at other emerging markets in which we will continue to license a very lucrative and attractive Biosimilar Molecules.

Novel Molecules: IN105, which is our oral insulin program is keenly being watched by everyone including patients, doctors and of course, analysts. In April 2015, we completed the first wave of trials in the US with our oral insulin. The data from the first two studies that aimed at answering questions around Pharmacodynamic i.e. PD impact on drug absorption and intra-subject variability and food effects look extremely positive. The data from the third study related to the amount of drug absorbed and the PD impact as evaluated by euglycemic clamp in type-1 patient is still being complied. The study itself is completed but the data is still being received. Since BMS has an option to this molecule, the public release of this data when completely ready will be done in discussion with them through an appropriate plan. Subsequent to these studies just discussed, a basal bolus non-Inferiority study versus rapid acting insulin in type-II patients already receiving basal insulin will be conducted.

Itolizumab: While the recent improvement of relations between US and Cuba augur well, we hope that the process of licensing Itolizumab will now pick up pace. Meanwhile, we continue to develop this asset focusing on rare neurological indications with significant unmet medical need.

There was also recently a very important publication in the Journal of American Association of Dermatology for the long-term efficacy of Itolizumab which indeed is an important profiling of the efficacy data of this particular molecule and we remain very-very excited with what this molecule has to offer.

So, I will end there and open this up for Questions-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 Manoj Garg from Healthco. Please go ahead**.**

Manoj Garg: Two quick ones; one is can you update us on the timelines for the Mylan partnerd products in terms of expected data readout?

Arun Chandavarkar: In terms of the partnerd programs, we have said that we have four molecules in global phase-III trials and one of them in an ROW focused phase-III trial in India. What we can share with you is that recruitment has been completed in the Glargine trial and the follow up phase is in progress. The Trastuzumab as well as the Pegfilgrastim trials have made substantial progress and are nearing completion. The Adalimumab trial has just recently commenced and recruitment is in progress. Of course, in terms of Bevacizumab, we have also initiated a PK study in Europe. In terms of anticipated specific completion timelines we cannot disclose that at this point in time but you can see from the progress that we have made and which has also of course reflected in the ramp up in our R&D expenses, these initiatives are progressing quite well.

Manoj Garg: Do any of these products have a change in control position that would allow you to regain control of the asset in the event of a successful Teva pursuit?

Arun Chandavarkar: We would not like to comment on confidential contractual clauses related to our partner agreement.

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

Ujwal Shah: Just wanted to understand more about the Branded Formulations business. Has the rationalization activities completed and we can foresee growth coming in probably from the second half, can you throw some light on that?

Ravi Limaye: So the rationalization activity is to a large extent completed. However, we continue to look at opportunities to further prune products and reduce our tail end. But that is unlikely to have an impact on our growth going forward. Branded Formulations is definitely coming on track and we believe that in the coming quarters you will see the underlying growth visible in the Branded Formulations business, in fact, even in this quarter the underlying growth is good.

Ujwal Shah: The impact on the margins as well because that was something which we were keen on?

Ravi Limaye: The impact on the margins will only be positive because we are reducing the tail end because those products are low both in margins as well as sales. So, that is in fact one of the objectives of reducing the tail.

Ujwal Shah: Can you share the numbers, what kind of margins we are …?

Ravi Limaye: We would not like to share the exact details of margins but they are going to improve.

Ujwal Shah: Some further light on the Malaysian unit. Madam just specified that probably from 2016 we might start seeing some revenues out of it. So, is it that initially we would be using that facility for the emerging markets and then we might possibly pursue the regulated markets once we get the approvals, how do we see the Malaysian facility ramping up?

Arun Chandavarkar: We certainly expect quicker approvals in the emerging markets. So you are right that we expect commercialization to begin initially in the emerging markets and subsequently in the developed markets, although our qualification strategy would cover both jurisdictions.

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

Surya Patra: Just wanted to clarify on the kind of Rs.45 crore that you have received. What is the nature of that – whether it is for non-offtake for the Fidaxomicin during this quarter or during this year or something like that? We are also talking about 7-year extension of the supply arrangement with Merck. So, that means whether we will see the resumption of supply of Fidaxomicin this year itself or whether it would happen next year, can you give some timeline, some indication about it?

Arun Chandavarkar: To answer the question, the contractual agreement with Merck entailed capacity reservation fee if the offtake did not meet a certain threshold level. So, in discussion with Merck, we decided mutually to encash this opportunity of capacity reservation which frees them from future obligation. However, from a business outlook perspective, the signal is clear that they have renewed the contract for 7 more years which means they still have confidence in the product. As to when exactly that confidence will translate into us renewing supplies to Merck, we cannot at this time have precise answer to that question. We are certainly encouraged by the fact that they chose to renew the contract despite paying out the capacity reservation.

Surya Patra: But after the discussion, did you get any sense that the product potential would be even larger with a larger hand like Merck or anything on that sense?

Ravi Limaye: We have been talking with Merck and they remain optimistic about the product, in fact, they have renewed their focus on the product I believe with a separate sales force. So, they remain optimistic and obviously Merck as you know is a much bigger player in US as well as across the world.

Surya Patra: The similar kind of a product in a similar pipeline will not impact the visibility of this product?

Ravi Limaye: At this stage we cannot comment on that but Merck remains optimistic about the product.

Surya Patra: On the Glargine side, the licensing income that we have talked about, it is relating to Mexico and Colombia, right?

Kiran Mazumdar-Shaw: This is not licensing, this is actual launch of the product in Mexico and Colombia.

Siddharth Mittal: Licensing is for other biosimilars in emerging markets.

Surya Patra: This is kind of a continuing stream kind of revenue or income that one should expect considering there are a lot many products are there to be out-licensed for the emerging markets, is that the kind of sense one should have?

Kiran Mazumdar-Shaw: Yes. As you know, Biocon's approach to global reach is through licensing these programs and assets with local and important partners in different regions. So this is going to be a continued stream of revenue for us but I think what is important in answering your question is that we have seen a very good launch of our Glargine in both Mexico and in Colombia. As we are addressing a market size of almost $50 million between these two markets alone. So I think that is what is very exciting.

Surya Patra: Any progress that you are seeing in other emerging markets, like you have already indicated 20-odd countries that you have got approval for Glargine?

Kiran Mazumdar-Shaw: We are continuing with our efforts to make sure that we are in key emerging markets, we are going to be very focused on the kind of markets we choose because we do not want to spread ourselves too thin, we want to focus on key markets that will actually deliver both revenues and good profitability.

Surya Patra: On Glargine again, is it possible for you to share which are the key markets that we are targeting initially or which are the key emerging markets that is there on our radar?

Ravi Limaye: The focus is on the top 10-12 emerging markets, I can give you the list, and those are the usual suspects.

Siddharth Mittal: Mostly Latin American markets.

Arun Chandavarkar: This information you can get from IMS data of what are Lantus sales for example and that will tell you what the top markets are.

Kiran Mazumdar-Shaw: I think what you should also bear in mind is that Biocon has one of the very few Biosimilar Glargine available in the emerging markets. So at this point in time really only three key contenders in the emerging markets for Biosimilar Glargine which of course is Sanofi, Lilly, and Biocon. I think you should keep that in mind that we are poised in a very good position for all these markets.

Ravi Limaye: Here is the list of the top-5 emerging markets – China, Russia, Turkey, Algeria, and Brazil.

Surya Patra: But China, we are targeting that we can commercialize the product in the near future?

Ravi Limaye: I do not think we will go into those details. I told you the five top markets and you can be rest assured we will focus on the top markets.

Surya Patra: Ma'am, wanted to have a sense from you, this Biocon Pharma what we have created, though in the past we have talked in bits and pieces about our ANDA plans and our Formulations plans for the advanced markets, and since you have created the company, can you talk something more about it, what is the kind of plans and when can we really start filing and whether this will not impact our business, some API businesses what it has been on with the other various customers?

Arun Chandavarkar: In terms of our ANDA strategy, we have articulated it in previous analyst calls as well. Historically, Biocon has been an API supplier when it came to small molecules and a very credible API supplier because our facilities have been compliant to global regulatory standards now for almost 14-15 years ever since we first got into this. Unlike other companies which got into formulations, our initial formulations foray actually happened on the biologics side, not on the small molecule side. And when we saw the kind of value that we can capture by getting into formulations, we certainly decided to leverage our expertise in injectable fill finish that we gained in Biologicals and extend that to the API business as well in the anticipation that will capture a bigger piece of the value chain. So that is our foray. But playing to Biocon's strengths in Biosimilars and the R&D capability that we have set up, we clearly are trying to focus on some of the more complex molecules, some of the specialty molecules. We are not in our portfolio targeting products where we expect a very high competitive intensity. So, this part we have articulated in the past. We have said that do not expect very large number of ANDAs from us, but do expect a focused portfolio that will generate value for Biocon. To answer your question, although we have not given the numbers we did commence filing ANDAs last fiscal.

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

Girish Bakhru: Following on that, has the activity picked up significantly in terms of ANDA filings, like in this fiscal would there be a significant number?

Arun Chandavarkar: As I mentioned that our strategy is not to necessarily chase numbers, but identify niche products that play to our strengths and target them. So, yes, certainly, the ANDA strategy is continuing this fiscal also and we should expect additional filings this fiscal.

Girish Bakhru: But, in terms of the mix, would it be largely to say that earlier sort of filings would be more in the Immunology products or there are some diabetes products that you are targeting, can you give some color on that?

Arun Chandavarkar: All I can tell you is that we try to play to our strengths on specialty molecules, of course, from a disease segment you know that we specialize in Oncology, Immunology, Diabetes. So it certainly plays to again those kind of chronic therapy areas.

Girish Bakhru: Second one was on the regulatory inspection of Malaysian unit. Do you have a date for like EMEA visit or FDA visit to the Malaysia plant?

Arun Chandavarkar: No, it is premature, because as we have told you that this was a local regulatory of cGMP audit which will then allow us to commence qualification of the product, this was a facility audit. The product validation batches we have clearly said will commence shortly and it is only when you file the product dossiers in these jurisdictions that it will trigger some of those inspections from foreign authorities.

Girish Bakhru: So, one would assume inspection in say mid-next year or late next year?

Arun Chandavarkar: We cannot comment on that. But as Kiran said, from emerging markets we expect some revenues to kick in calendar 2016 which means that those markets that require inspection, it will probably happen next year.

Girish Bakhru: On the oral insulin side, you said of course there is some data that may come out this particular year after the completion of the first study. Would that be say a precursor for beginning the second study? Basically trying to get a bit handle on what exactly triggers the option or is the option partly linked to even the outcome of the first study?

Arun Chandavarkar: I think the way our development strategy which we have worked out jointly with our partner Bristol-Myers Squibb on the oral insulin Molecule is that, we were going to do two sets of studies – in the first set of studies we said that we are doing three studies of which in two studies the readouts have happened and we are waiting for the readouts of the third study which is a clamp study. Based on these readouts, we would of course discuss with BMS the next step and we have broadly outlined to you the nature of the next step which is basically a competitive study, a basal bolus study with the basal insulin and rapid acting insulin. In terms of the option agreement, the option agreement continues until all of these studies – the Wave-I and the Wave-II studies, are completed. BMS of course has the right to convert the option into a license agreement anytime. They do not need to wait for completion of the study. But, our expectation is that they would probably like to wait to see the readouts. Having said that, we are conscious of the fact that some of these studies do take time, especially the second one because we have not decided things like how many patients, duration of the study, where we will do the study. So, all that is yet to be discussed.

Girish Bakhru: On the second wave of the study, what is the timeline, where it will end?

Arun Chandavarkar: All we know is that we want to do a basal bolus study and basal being a long acting insulin typically Glargine, rapid acting insulin could be either an Aspart or Lispro or equivalent molecules. So that is a basal bolus regime. The reason we are targeting that is because our data to-date does indicate that our oral insulin is a prandial insulin and would probably give patients the best benefit if the oral insulin is given as the prandial which is the bolus and combine that with the basal which is a long-acting insulin.

Girish Bakhru: On the markets that you mentioned are say big markets, say Mexico, does it feature in the top-10 markets for Glargine?

Arun Chandavarkar: Yes, typically the BRIC-TM markets would be there.

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

Shradha Patil: I just wanted to have an idea regarding the Branded Formulations. A couple of quarters back, you had said that with the way of rationalizing you expect the margins to improve in the Branded Formulations to maybe around a consol level. So, I just wanted to have some light on if it is maybe around 10 or what kind of margins does it have, any color on that?

Ravi Limaye: As I said earlier, we would not like to comment specifically on margins, but certainly, the endeavor is to improve the profitability and we are in the right direction.

Siddharth Mittal: What we had also said earlier that the margins were in high single-digit and our endeavor was to move close to the company average and at least we can say that we have moved to double-digit.

Shradha Patil: Another question is regarding the Branded Formulations again now. Your long-term outlook for FY19 which says that you expect $1 billion sales. So, out of that Branded Formulations would be around 20%. So, I just wanted to know that is it still on the right path because it was coming to CAGR of around 29%?

Ravi Limaye: Branded Formulations will continue to be our key growth driver and we are strategizing appropriately to move in that direction, we remain confident that we are in that direction.

Shradha Patil: Regarding the Trastuzumab out-licensing, out of the Rs.19 crore that you have booked in this quarter, does it all pertain to Trastuzumab?

Arun Chandavarkar: We can just tell you it pertains to our Biosimilars portfolio. We would not like to give molecule specific break-up.

Shradha Patil: So it is a combination of multiple out-licensing?

Arun Chandavarkar: Yes.

Shradha Patil: So not just Trastuzumab?

Arun Chandavarkar: I cannot be specific because certainly partnering our Biosimilars portfolio is a key strategy for us in terms of commercial presence in emerging markets, and as Kiran mentioned in her opening remarks, our revenues would have a mix of product sales and licensing. So, it is largely molecules which are advanced like Trastuzumab.

Kiran Mazumdar-Shaw: But just to answer your question, yes, the revenues are largely attributable to Trastuzumab.

Shradha Patil: Any update on Rh-insulin for Europe?

Arun Chandavarkar: There is no further update other than to say that we have continued with our stated objectives that is mentioned in the past about trying to bring in Malaysia on stream and trying to bridge the requirements for the US.

Shradha Patil: But any further emerging markets country registrations like last time it was around 55?

Arun Chandavarkar: That I think right now our focus is not further registration pick up, it is already registered in 60 which include the top 10-15. So, our focus is now on actually getting approvals and commercialization.

Shradha Patil: So as for now it is where it was last quarter?

Arun Chandavarkar: Yes.

Shradha Patil: I just wanted to understand better that Rs.45 crore from Merck, I could not understand exactly what is it. So could you please explain it once again?

Siddharth Mittal: As Arun had mentioned earlier that there was an annual capacity reservation fees, if the minimum volumes were not sold to Cubist. But as one time settlement to absolve Cubist from future capacity reservation, we agreed on the $7 million number.

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

Nitin Agarwal: My question is regarding the two biosimilars – Pegfilgrastim and Trastuzumab – where we said we are almost finishing our global phase-III trials. So the data that we are going to have from these trials, will it be good enough for us to file for the regulated markets or do we need another additional some other trials for filing in the regulated markets?

Arun Chandavarkar: These are designed for global filings, including the regulated markets.

Nitin Agarwal: So post the readouts you should at some point in time be in a position to file its products over the next few quarters as far as regulated markets are concerned?

Arun Chandavarkar: That is correct.

Nitin Agarwal: On Malaysia, what portion of the CAPEX will get capitalized this year, on which you will probably start bearing the depreciation charges and all going forward?

Siddharth Mittal: Most of the costs this year would be capitalized.

Nitin Agarwal: That would be how much roughly?

Siddharth Mittal: It will be in the range of $10-15 million. These are primarily the expenses incurred towards validation batches which would be capitalized.

Nitin Agarwal: What proportion of your gross block will start booking depreciation charges going forward from here on once the facility becomes commercialized?

Siddharth Mittal: While we have not technically assessed the life of the plant but typically these plants are anywhere between 15-20-years. So, we will depreciate let us say around $250 million over a period of 15-20-years.

Nitin Agarwal: One housekeeping question; there seems to be a pretty sharp reduction in our other expenses. Anything specific which drove this quarter, any sustainability to it?

Siddharth Mittal: Last quarter, there was a FOREX loss of Rs.20 crore which was in other expenses, this quarter we have FOREX gain of Rs.6.5 crore which is in other income. So, that is the reason for the shift.

Nitin Agarwal: Other income is pretty sharply higher. So, Rs.6.5 crore you mentioned is the FOREX gain. Is there anything else which is there or the rest of it is all sustainable?

Siddharth Mittal: Rest of it is all sustainable.

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

Dheeresh Pathak: I have a few questions; first is how much of our India Branded sales is coming from Insulin and Analogs?

Ravi Limaye: It is substantial, approximately 30%.

Dheeresh Pathak: On Glargine, did I hear you correct that you said trials are over in the regulated markets?

Siddharth Mittal: Recruitment is over.

Dheeresh Pathak: So, in terms of just thinking through the timelines, how much time as a base case for trials from here on and then post that for submission and then approval, because you have a precedence of I think Lilly getting tentative approval. So based on that precedence can you just walk us through what your base case assumptions for the timelines are for Glargine?

Arun Chandavarkar: All that we have said that is the recruitment is over, certainly, there has to be a long extended follow up phase. It will be a few quarters before the actual clinical study report is available.

Siddharth Mittal: We have publicly announced earlier that we expect to file in 2016. There is no change to that plan.

Dheeresh Pathak: I am just thinking in terms of the Lilly experience, how much time did it take them from filing to getting the tentative approval?

Kiran Mazumdar-Shaw: I think you should look at Lilly as the forerunner. And once they clear the way we believe that we will be in a better position to get the approval, probably in the same if not shorter time than Lily. That is our expectation.

Dheeresh Pathak: In terms of patent landscape for this, when does the main blocking patent expire for Glargine in US?

Arun Chandavarkar: I do not think that should be an issue. That will be discussed with our partner, Mylan, they would drive the IP strategy in terms of how to navigate if there is any residual patent.

Dheeresh Pathak: The other question is in the biopharma sales, if you can just share what is the size of the biosimilar sales that we do in the emerging markets?

Siddharth Mittal: A very small base, we have just started registering Trastuzumab in emerging markets and it is picking up.

Dheeresh Pathak: But, Insulin, will you be selling a large part of Insulin and Analogs as well right in the emerging markets?

Siddharth Mittal: We already sell Insulin in emerging markets. As you know that we have capacity constraints in India and till we get new capacities approved in Malaysia, that business will remain largely flat. Once we receive new approvals like we received for Mexico and Colombia, we will try to manage within the available capacity. In terms of percentage, what we have said is around 10% to 15% of our Biopharma revenue.

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

Bharat Seth: Regarding renewal of this contract with Merck, but still this reservation clause is there or they do not lift, can you clarify further?

Kiran Mazumdar-Shaw: I think we have been clarifying it saying that originally they had to give us an annual capacity reservation fee if their offtake did not cross a certain threshold. Now, we have freed them of this particular obligation. Now going forward, they do not have to give us the capacity reservation fee but they have still committed to pick up the product. So that is the only difference. So, the product supply still remains, but, if they do not pick up a certain quantity they do not have to pay us a fee any longer. That is all it means.

Bharat Seth: Then how do we plan that capacity utilization suppose if they do not pick up for whatever reasons?

Siddharth Mittal: The plant that was manufacturing Fidaxomicin was a dedicated asset and we have now got release to use that plant for other products and we would be using the facility to manufacture other products.

Moderator: Thank you. The next question is from the line of Manoj Garg from Healthco. Please go ahead**.**

Manoj Garg: Just two quick questions again; one, a macro question maybe for Kiran. Just would like to get your perspective on how competitive you would expect the biosimilar landscape to be by the time you guys get to market in the US? How many players do you think would be there that have the capabilities that you do?

Kiran Mazumdar-Shaw: To answer your question, I think right now we are tracking about 5 companies who will be strong players in biosimilars and I would say that Biocon-Mylan are very well positioned to be very competitive in this space; I think you can understand why we are so confident because of our cost and capability base that we have in India which we believe is very competitive.

Manoj Garg: Would you be willing to share the names of the other four?

Kiran Mazumdar-Shaw: I think you can look at it, this is public domain knowledge, so I think if you just sort of look at the names of the leading companies in this space, it is there, it is Hospira, Celltrion, Pfizer, Amgen, Merck, Sandoz, Samsung, some of them are of course combined partners but these are the sort of the names that we are tracking.

Manoj Garg: And then on your aspirational goal of 200 million plus of Biosimilar revenues in fiscal ’19, about how much of that is originating in the US?

Kiran Mazumdar-Shaw:I do not think we can really give you too much granularity on that front, but suffice to say that we expect at least some revenues to come from the US and European markets. I also want to say that in the interim, the emerging markets themselves offer a huge opportunity which we are now beginning to understand.

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

Dheeresh Pathak: Just to understand the out-licensing deals that we do for the biosimilar programs in emerging markets, once you get this money then you are entitled to only manufacturing margins or do you get some profit share or royalties on an ongoing basis, can you without giving the specifics, just give the underlying thought process and how the deals are structured?

Siddharth Mittal: In emerging markets, the deal works differently compared to the developed markets and mostly we agree on a fixed transfer price or a supply price. In certain cases, we also try and get royalties, but there is no profit share model like we have with Mylan for emerging markets.

Dheeresh Pathak: And the brand that is established in these markets, is the partner brand or the brand…?

Siddharth Mittal: It all depends; some markets it would be Biocon brand, that is our desire but in certain cases where partner has a strong brand in the local market they would want to have their brand.

Moderator: Ladies and Gentlemen, that was the last question. With this we conclude the conference call. Thank you for joining us and you may now disconnect your lines.

Note: This document has been edited to improve readability