Biocon Limited's Q2 FY16 Earnings Conference Call
October 21, 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
- MB Chinappa: President, Finance, Syngene International
- Saurabh Paliwal: Head, Investor Relations

Presentation Session

Moderator: Ladies and Gentlemen, Good Day and Welcome to the Biocon Limited Q2FY16 Earning Conference Call. As a reminder, all participants' lines will be in the listen-only mode and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing '*' then '0' on your touchtone phone. Please note that this conference is being recorded. I would now like to hand the conference over to Mr. Saurabh Paliwal – Head of Investor Relations at Biocon. Thank you and over to you sir.

Saurabh Paliwal: Thank you, Karuna and Good Evening, everybody. First of all apologies from our side for keeping you on wait for 15 minutes over the scheduled time because of run over from our previous conference call of Syngene.

Moving ahead, I would like to welcome all of you to our second quarter FY16 earnings call. Today to discuss the business performance and outlook we have Ms. Kiran Mazumdar-Shaw -- Biocon's Chairperson and Managing Director and other colleagues from the senior management team at Biocon. Before I proceed with this call I would like to remind everybody that the call is being recorded and the replay will be available for the next few days. The call transcript shall be made available on the website in the coming days as well. 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 our press release also pertains to this conference call. After the end of this call if you have any further questions please feel free to get in touch with me.

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

Kiran Mazumdar-Shaw: Thank you Saurabh, and Good Afternoon, Everyone. Welcome to Biocon's Earnings Call for the quarter ended 30th September 2015.

Let me start by wishing every one of you a Happy Dussehra.

Let me begin with to share with you the Financial Highlights for this quarter:

- At a consolidated level, total revenues were at Rs.861 crore, growth of 12% year-on-year.
  - Biopharma sales were at Rs.459 crore;
  - Our Branded Formulations business sales were at Rs.119 crore; and
  - Syngene delivered a stellar performance at Rs.250 crore at a consolidated level, a 30% year-on-year growth. On a standalone basis, Syngene sales were Rs.256 crore.
- Depreciation of the rupee resulted in a forex gain of approximately Rs.2 crore at the group level and this is reported under 'Other Income'.
- Group EBITDA was at Rs.222 crore for this quarter with an EBITDA margin of 26%, which is an improvement over 24% on a year-on-year basis. The improvement in margins is despite a 64% 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 was at Rs.306 crore. Adjusting for exceptional items, i.e. the Syngene IPO receipts net of IPO expenses and tax, book value adjustment for 11% Syngene stake dilution and an impairment charge for one of our novel assets, Itolizumab, the net profit was at Rs.103 crore.
- Gross R&D spends were Rs.90 crore this quarter, representing a 12% year-on-year increase. Net R&D spends as reported in the P&L statement were at Rs.57 crore, which is an increase of 64% year-on-year. We have capitalized an amount of approximately Rs.25 crore while the balance amount of Rs.8 crore was set off against deferred revenue. Clearly, the increase in spends in R&D is a reflection of the very strong progress we are making at the clinical level with five of our biosimilar molecules being in advanced Phase-3 clinical trials, of them four in global Phase-3 clinical trials. This puts us in a very strong position to be amongst the early wave of entrants in the developed markets with our Biosimilars.

Moving on to discuss Individual Businesses:

The **Biopharma** business has been stable this quarter. A better product mix led to higher profitability as evidenced from the improvement in EBITDA margins and this is on top of increased R&D spends reported at the P&L level. There are of course challenges on pricing in the legacy statins business but there continues to be improving opportunities with higher margins in Immunosuppressants and Insulins which has kept the overall business on an even keel.

Just as we have unlocked huge value in our Research Services business which you have seen through the Syngene IPO, there remains a huge untapped value in our Biosimilars portfolio. Biosimilars continues to offer a huge opportunity and we are very confident that once we enter the developed markets, this unlocking of value will be realized. This offers a great opportunity for Biocon as a company to realize a very large benefit in terms of both revenues and profitability.

We continue to target emerging markets in the interim which also is a very large lucrative market and we have already made some entries into emerging markets with our Recombinant Human Insulin, Insulin Glargine and soon with our Trastuzumab in several emerging markets.

Branded Formulations this quarter realized overall sales of Rs.119 crore. We were constrained in terms of larger growth potential on account of certain product and Institutional business constraints due to certain tender challenges that we had in realizing some of the tenders that we had won. However, efforts around rationalization of the portfolio and an increased focus on key brands continue to yield significant improvement in profitability in this business.

In terms of our **Generic Insulins and Biosimilars programs**, we have currently five programs in Phase-3 clinical trials, of which 4 are global trials -- Trastuzumab, Pegfilgrastim, Adalimumab and Insulin Glargine. The fifth trial is a RoW focus Bevacizumab Phase-3 trial, but Bevacizumab has also recently entered global Phase-1 and is nearing completion. The clinical advancement of these Biosimilar programs has now put us on track for regulatory filings, some of them which we expect to file next fiscal. This is a very exciting time for Biocon because Biosimilar is a very large opportunity, the programs that are in Phase-3 clinical trials address ~$40 billion market opportunity in terms of revenues that are today enjoyed by the innovator companies. We are very confident that the Biosimilar opportunity is going to be large with a few players in the first wave of entry and Biocon and Mylan are well placed to take advantage of this opportunity.

Coming to **Novel Molecules**: Our Oral Insulin program which is often referred to as IN-105 which henceforth be referred to as "Insulin Tregopil". This is the INN name that we have obtained from WHO. We have completed the first wave of trials in the US with our Insulin Tregopil and the complete study report for these trials has now been received. Data gleaned thus far clearly indicates an important role played by Insulin Tregopil in post prandial glycemic control. These are very encouraging indicators. We will discuss with our partner BMS, the next steps of developing this very exciting molecule. We also propose to submit several research papers for publication in peer reviewed international journals based on some of these very important findings through these clinical studies.

In terms of Itolizumab - Based on recent feedback we believe that it is unlikely that we will obtain certain regulatory waivers from the US authorities related to the Cuban origin of this molecule. If you recall, we have shared with you challenges that we face in commercializing this asset in the US on account of these governmental regulatory permissions. Although the Cuban relations are vastly improved with the US, we still do not have any clarity on how expeditious these governmental waivers will be. Based on that we have decided to take an impairment charge for the US and Canadian marketing rights in view of this uncertainty and in keeping with good governance. But meanwhile, we continue to develop the molecule for non-US markets. We have already commenced this effort in conducting certain key clinical trials in Australia, which will be initiated almost imminently and we expect to revisit the opportunities for the US market at an opportune time in the future.

When it comes to **Syngene**, for those of you who participated in the Syngene conference call, you would have seen that Syngene has posted a very strong set of numbers this quarter; a 30% year-on-year sales growth on a consolidated basis. On a standalone basis, Syngene's total revenues grew 28%,

delivering Rs.262 crore in Q2; EBITDA was at Rs.87 crore and Net Profit was at Rs.52 crore. Adjusting for minority shareholding, Syngene contributed Rs.39 crore to the Rs.103 crore net profit that Biocon has posted at a consolidated level this quarter.

The business performance for Syngene was broad-based and all three verticals - Discovery Services, Dedicated Centers and Development and Manufacturing Services have delivered on growth and performed extremely well. We expect the business momentum to continue in the second half of this fiscal.

Syngene will be a contributor to Biocon's growth in the near-term, but Biocon also sees some near-term growth triggers in the form of Biosimilars especially the Insulins and Trastuzumab. We continue our transformation to be a leading global Biosimilar player with emerging market opportunities in the near-term and the developed market opportunities later on.

Biocon today is extremely well positioned to be a very unique company in this space coming from India. Together with our partner, Mylan, we believe that we are very well placed to tap into this very large and lucrative Biosimilars opportunity that is emerging globally. Given the cost-base and our ability to develop a very robust and large pipeline of Biosimilars, we believe gives us a very large opportunity to play in this space. Biocon and Mylan have today perhaps the largest portfolio of Biosimilars in advanced clinical development. This is again a matter of great pride for us and gives us the kind of confidence with which to approach this very large opportunity. So watch this space, it is a very important segment for Biocon. The opportunities in terms of Biosimilars, both in terms of growth and regulatory filings are becoming extremely visible for Biocon and is something that we would like you to track.

So with that I would like to open this up to Question-and-Answers.

Moderator: Thank you very much. Ladies and Gentlemen, we will now begin the Question-and-Answer Session. The first question is from the line of Surya Patra from Phillip Capital. Please go ahead.

Surya Patra: Could you elaborate more on your amortization on Itolizumab?

Siddharth Mittal: Surya, this is impairment and not amortization. As Kiran mentioned we had purchased the marketing rights for US and Canada from CIMAB in 2010 for a total consideration of $15 million and we were looking to license this product for commercialization in the US. Again, in the past we had mentioned that we had hit certain regulatory hurdles because of requirements of OFAC approval from the US government since this asset has a history and linkage to Cuba and Cuba being a sanctioned country. We were looking at obtaining wavers from this approval; however, the discussions did not progress as expected thereby creating an uncertainty on licensability of this asset in the US. Given that we had to take an impairment charge since we do not have near-term visibility of commercializing this asset.

Surya Patra: So with this US potential for say molecule getting eliminated…?

Kiran Mazumdar-Shaw: It is not eliminated. Since we do not have a near-term waiver - we thought that we might get a waiver on governmental regulatory norms, but the policy has not changed thus far. So whilst the Cuban relations have greatly improved, this has not yet translated into trade policy. Since we have not got any clarity on this, we believe that we should take an impairment on this asset. But as I mentioned it is not a question of eliminated, it is a postponement.

Surya Patra: Can you elaborate on your aspect on capacity constraint and lower API offtake and is it related to Fidaxomicin?

Kiran Mazumdar-Shaw: No, Fidaxomicin does not feature in our business as I mentioned last quarter. We had shared with you that we got a capacity reservation free from Merck which absolved them from guaranteed offtake. So until they re-launch this product we are not depending on Fidaxomicin. So it is not Fidaxomicin that has resulted in lower revenues of our Biopharma business, it is our deliberate policy to focus on high margin products as opposed to just getting top line from some of the low margin products. I think that is what has actually generated higher profitability but not necessarily higher revenue.

Surya Patra: Can you give your progress on your Glargine launch in Mexico and other emerging markets?

Kiran Mazumdar-Shaw: Glargine has done extremely well in Mexico, it continues to do well. We are very confident that Mexico will be a very large market for our Insulin Glargine.

Surya Patra: Also, you indicated about some of your Biosimilar filing in US and Europe in FY17. So you are talking about your Rh-Insulin, Herceptin? Is this a product basket that you are looking for?

Kiran Mazumdar-Shaw: Yes, some of these programs have already been shared with you - Insulin Glargine, Trastuzumab, Pegfilgrastim, Adalimumab - all these are advancing very rapidly in Phase-3 clinical trials and we expect that few of these will definitely be filed in the US and Europe next fiscal.

Siddharth Mittal: If you have followed the press release we have said that Glargine recruitment was complete last quarter and Trastuzumab recruitment is nearing completion.

Surya Patra: Are things related to US filing for commercialization of Biosimilars in US are clear?

Kiran Mazumdar-Shaw: Certainly for G-CSF there has been clarity and Glargine also there has been clarity. Those two molecules certainly have got a nod from USFDA and EMA. So I think we are confident that as we move towards a regulatory filing, there will be greater clarity.

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

Girish Bakhru: Just following on the last comment actually on the clarity regarding some of the Biosimilars in terms of the regulatory aspect, wanted your thoughts on how the other applicants,

including you and Mylan, will approach when you file for say, Glargine or Pegfilgrastim, would you also choose not to basically disclose the information of your dossier with the innovator?

Kiran Mazumdar-Shaw: We are not in a position to make any comments on this because we are bound by confidentiality. All I can say is that given the nod that companies have got for Glargine and Filgrastim, we feel quite confident that we will be able to address this opportunity.

Girish Bakhru: From the overall partnership level, if you can comment who will take that call -- will that be Mylan?

Kiran Mazumdar-Shaw: That will be Mylan because Mylan has the exclusive rights to these markets.

Girish Bakhru: On the overall margin part, this quarter you mentioned that the overall margin got impacted, it had better mix overall because of largely Syngene, but within Biopharma, when do we see higher traction, say from the Insulin in the emerging markets basically, would that be a feature of the second half of this fiscal?

Kiran Mazumdar-Shaw: I want you to also look at this quarter in context of the higher R&D spend. If you look at it in that context profitability has been much higher than previous quarters and last fiscal. I think you should look at it in that context. I think all of you are just looking at PAT numbers but I think you are not factoring in the much higher R&D spends that we have incurred this quarter and half of this year. If you look at this quarter our R&D spend has increased 64% to Rs.57 crore over last fiscal Rs.35 crore. So that means additional Rs.22 crore of R&D spend has been factored this quarter. Then if you look at the half year level we have actually spent Rs.183 crore at a gross level. In the P&L, you can see that even at a half year level, spends are 62% up. So when you look at these kind of numbers and then look at profitability, we are actually delivering very strong set of numbers. To play in the Biosimilars game, you have to make these investments. You would have seen the articles in the very recent past where they are actually saying that except for Biocon and Mylan they do not see any participation in the Biosimilars story from other Indian companies. So it places us in a very unique spot. We are in the first wave of companies addressing this very large global opportunity and we cannot do that without investing in developing these programs. So I think you should look at it in that context.

Siddharth Mittal: And Girish, I would just like to add two more things to what Kiran said -- one is while our R&D has gone up by Rs.22 crore, licensing income compared to last year has been down by Rs.7 crore. Licensing income is something that goes straight to the bottom line and in spite of having only Rs.2 crore of licensing income this quarter we have been able to maintain similar level of profitability. And second, last year same quarter we had higher forex gain compared to this quarter and lastly in Q2 of FY15 Biocon held 86% of Syngene stock compared to 73% this quarter because of which we have an impact of 12% on consolidated PAT this year versus last year. So in spite of factoring in the effect of all the increased R&D, lower licensing, lower forex income, lower consolidation effect of Syngene, we have been able to maintain the margins. That is what we have guided- that our main endeavor while we get Biosimilars to the market would be to maintain the core margins.

Girish Bakhru: No, the point is very well taken, but my question was more on the front that like with the launch in Mexico and some markets, have you already started seeing significant growth in the Insulin business in the emerging markets?

Kiran Mazumdar-Shaw: Yes. I have mentioned even in my comments that the large part of the improvement in margins has come from a better product mix. And this product mix certainly is being contributed to by Insulin and Glargine, Immunosuppressants and Branded Formulations (which have also improved in profitability). So I think you need to look Biocon's business in context of all these various factors.

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

Harith Ahamed: Harith this side. On the recent development related to Eli Lilly's filing for Insulin Glargine, I would like to know what is your read on that where Sanofi announced a settlement allowing Lilly to launch. So, is that something which could be read as a positive for Biocon as well?

Kiran Mazumdar-Shaw: Yes, absolutely, I think this is a positive. We have always maintained that Lilly's entry into the Glargine market in the US and Europe is obviously a positive signal for Biocon and Mylan.

Harith Ahamed: Another related question is Lilly had filed 505(b)(2). So is there any thought around what approach Biocon and Mylan would be taking?

Kiran Mazumdar-Shaw: It has to be the same approach.

Harith Ahamed: Moving on to the Domestic Formulations business, you mentioned about some profitability improvement in that business. So, where does thing stand now in terms of profitability – is it close to the corporate average now the Domestic Formulations business in terms of margins?

Siddharth Mittal: It is getting closer to the corporate average. For the Biopharmaceutical segment, we focus on the core EBITDA margins which exclude licensing income, R&D expenses and forex. These margins have improved from 26% to 30% on the back up of improved margins from Branded Formulations, Insulin and Immunosuppressants.

Harith Ahamed: On the growth front, we have been seeing muted growth in the last few quarters and that can be attributed to some of the restructuring work that is going on. So when do we expect growth to return to industry average levels?

Kiran Mazumdar-Shaw: That I think we are looking at getting to those industry level growth numbers by the end of this fiscal.

Harith Ahamed: On the recent Disposable Pens launch that you have done, how many Glargine Pen products are there in the market today?

Kiran Mazumdar-Shaw: Today, if you look at it you have got Sanofi's Disposable Pen and you have got Novo has Disposable Pen… of course Biocon has now entered the fray with Disposable Pen and I think there is one more who have Disposable Pen.

Harith Ahamed: The Glargine market in India, the split between Vials and Pen is it a 50:50 split?

Ravi Limaye: Disposable Pens is about Rs.380 crore market, out of which the analog market is about Rs.304 crore and the Vials market is about Rs.657 crore out of the total Rs.1800 crore Insulin market. Just Glargine Vials market is about Rs.40 crore. Analog is about Rs.304 crore and Lantus is about Rs.63 crore which is Disposable Pen.

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

Ujwal Shah: Ma'am, just getting some sense from what you just said, so can we assume that by FY18 we would at least have one or two products approved for the developed markets on the Biosimilars?

Kiran Mazumdar-Shaw: Yes, that is the expectation.

Ujwal Shah: In terms of the Malaysian plant, how are the regulatory approvals moving there and what amount of cost have we started already incurring in our P&L from the Malaysian plant?

Arun Chandavarkar: The regulatory approvals in Malaysia right now is largely to do with the local approvals to allow us to commence batches there. We have commenced batches. And as we have mentioned these batches will be put on stability and we will file in various jurisdictions including in both emerging markets and developed markets. These filings will probably begin by end of this year.

Ujwal Shah: In terms of the cost that are being incurred at the Malaysian plant -- what percentage or how much quantum is being transferred to the P&L as of now?

Siddharth Mittal: Right now, there is a very small component of cost in the P&L for Malaysia. For the full year we expect the total cost that would hit the P&L to be around Rs.20 crore. The majority of the costs have been capitalized.

Ujwal Shah: What would be the amount that is being capitalized?

Siddharth Mittal: That we have not disclosed.

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

Prakash Agarwal: On Lilly's entry that we just spoke about, just trying to understand what our understanding is or make us understand in terms of substitutability. So this 505(b)(2) product, my understanding is they would need to get their own marketing and get some market share, if you could help us understand better?

Arun Chandavarkar: In terms of our filing strategies I think Mylan mentioned in one of their earlier public comments that we are of course targeting to file with necessary data required to get inter-changeability. Whether inter-changeability will be granted by the USFDA is of course up to them, but our aim is to target inter-changeability.

Prakash Agarwal: Any comment on Lilly's product?

Arun Chandavarkar: No, I cannot comment on Lilly's product. All I can tell you is the fact that they have got approval means that they are there, but I do not think they have got approval as an inter-changeability.

Prakash Agarwal: There was a comment made now on Malaysia that initial costs have been started with the filings of the local Malaysian qualifications. When do we start fully expensing it out -- is it with the regulatory filings which is expected '17-18?

Siddharth Mittal: As per the current accounting standards which are going to change as you know from next fiscal year, we would have capitalized costs till we received local approvals, which we are expecting by end of this fiscal year. However, as per the new accounting standards, we still have to evaluate till when we can capitalize the cost.

Prakash Agarwal: Nothing to do with the regulatory market that is what I am trying to understand.

Siddharth Mittal: No, we are not going to wait till the approvals from the regulated markets (USFDA and EMA) to stop capitalizing. We will stop much ahead of that.

Moderator: Thank you. The next question is from the line of Sai Prabhakar from Karvy Stock Broking. Please go ahead.

Sai Prabhakar: My question is again on the Malaysian facility. So for the debt and interest expense, when can we expect it to be reflected on the P&L? I believe the depreciation will start once emerging market sales begin.

Siddharth Mittal: The depreciation would begin once the developed market sales begin, and interest would be in the P&L once we stop capitalizing the expenses. As I just answered the previous question that we would stop capitalizing all expenses including interest at the time we receive the local approvals and we would have qualified the plant. With that approval we would be filing for approval with FDA and EMA. So, in the interim period while we have filed and are waiting for the approval from FDA and EMA is when the expenses would be in the P&L, including the interest expense. However, depreciation on the plant would commence when we launch the product in one of the developed markets.

Sai Prabhakar: So for emerging markets, the facility will be minimally used?

Siddharth Mittal: This plant as you all know has been set up with the main intention of commercialization of the product in the developed markets. Emerging markets revenue, though important for us, will not be significant enough to fill the entire capacity.

Sai Prabhakar: With regards to the capacity constraint, is the recent acquisition aimed towards easing of the capacity or is it still reserved for our Formulations business?

Siddharth Mittal: The facility that we have acquired is for products where we did not have in-house manufacturing capabilities till date. It was more a buy versus build decision. We are developing certain ANDAs where we were procuring APIs from third party manufacturers. Now those APIs would be manufactured through this in-house facility.

Sai Prabhakar: So the capacity constraint will not be eased significantly by the recent acquisition?

Siddharth Mittal: Not due to the facility we have acquired in Vizag. However capacity constraints that we have in our Small Molecule business are getting addressed as we have already triggered capacity expansions. We have also triggered expansion of our Insulin Formulations facility in Bangalore. Necessary steps have already been taken and we do not think that this capacity constraint would last for long.

Sai Prabhakar: Also, we have diversified from Middle East. So that should ease up some capacity as well?

Siddharth Mittal: We have not diversified the Middle East business. We continue to do business in the Middle East. The issue was relating to credit. The terms of credit instead of being post the delivery earlier is now being moved to LCs or advance. We have lots of customers who are not able to arrange for advance or LCs, and as a result we deny supplies to them.

Moderator: Thank you. The next question is from the line of Jayesh Parekh from JMC Capital. Please go ahead.

Jayesh Parekh: You had some issues regarding Institutional tender participation due to a couple of reasons. Is that now being addressed?

Kiran Mazumdar-Shaw: When we say Institutional business issues, there are two issues - one is that in an Institutional tender that you win they do not allow you to use CMOs for supplies. And this was actually a challenge that we had to face because our current capacities were actually booked out and committed for other markets and obviously we like to address the markets or opportunities that give us better returns. But having said that we have addressed those issues and we are beginning to free up some capacities. But this capacity free up will really take place only when Malaysia becomes fully operational. The second issue about Institutional business is that you might win tenders, but by the time you really translate these tenders into orders, it takes a bit of time. So it is a phasing issue. So that is what has affected us this quarter. So we did win quite a few tenders which we could have supplied this quarter, but obviously, many of these tenders take time before the formalities translate

into the orders. So that is what has given us a phasing challenge this quarter which we hope will be corrected in the coming quarters.

Jayesh Parekh: Can you throw some light on Oncology division keeping in mind our recent business assets acquisition?

Kiran Mazumdar-Shaw: Yes, that is a very good question you have asked. We have acquired a plant from Acacia, an asset which is really a potent facility. We have done this because we are very focused on these potent molecules especially from the ANDA opportunity point of view. So right now we have quite a few of these Oncology molecules under development and we have had to outsource a lot of these molecules. And now with this facility we will have an in-house capability of providing these ANDAs in a vertically integrated manner. Apart from that it is extremely important for us because we do have a very strong Oncology focus and with that in mind having a potent facility is extremely important. We did not have a potent facility in the past so we felt that this was one gap that we needed to plug.

Jayesh Parekh: This particular business asset have adequate capacity?

Kiran Mazumdar-Shaw: Yes, it has for the time being but we will be expanding it.

Siddharth Mittal: This facility currently manufactures API intermediaries and we would be investing in capex for manufacturing finished APIs.

Jayesh Parekh: What was the contribution of Basalog One in Q2?

Siddharth Mittal: A very small number.

Kiran Mazumdar-Shaw: We have just launched it, but it will start contributing in the quarters ahead. But I would also like to mention that we have done extremely well in the Metabolics and Oncology divisions.

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

Shraddha Patil: I wanted to know that would it be fair to assume if the Branded Formulations margins have reached to mid-teens?

Siddharth Mittal: Close to that.

Shraddha Patil: Could you give some more clarity on how do you wish to achieve your 2018 target of $200 million for the Branded Formulations?

Ravi Limaye: So there are a number of areas on which we are focusing. These are all specialty areas plus we are also adding a few specialty areas to this. Our Oncology pipeline will also materialize in the next three years. We have a couple of important launches coming from our own pipeline and we

continuously keep on looking for new products in areas which are of interest to us and where we have strength. In addition our existing Metabolics and Oncology business will continue to drive growth. We will continue to invest in that. We have also recently entered a new business area of Virology. We are seeing good traction in that. So all these growth drivers will eventually help us to reach our goal.

Shraddha Patil: Would there be any meaningful contribution from any in-licensed molecules?

Ravi Limaye: So when I mentioned to you new products I am also factoring in in-licensing initiatives which are under discussion. Obviously, I cannot give more details about it at this stage.

Shraddha Patil: So you remain fairly confident of achieving the target for 2018?

Ravi Limaye: Yes.

Siddharth Mittal: $200 million at Rs.50.

Shraddha Patil: My next question pertains to the MAbs capacity. So I just wanted to know is this a Greenfield capacity for the MAb?

Arun Chandavarkar: We have an existing facility in our Bangalore which will suffice us for our near-term, but going forward we would be looking at a new facility for drug substance.

Siddharth Mittal: What Kiran mentioned was for drug product which is a part of our existing facility expansion.

Shraddha Patil: I just wanted to know that the new capacity for the MAbs apart from the existing augmentation that you are undertaking, would it come in before FY18?

Arun Chandavarkar: No, unlikely.

Kiran Mazumdar-Shaw: The drug capacity will come in before FY18 but the drug substance capacity might take additional year.

Shraddha Patil: So any idea about the capex outlay for the drug product?

Arun Chandavarkar: It is about $25 million.

Shraddha Patil: Is this the same as what you mentioned that expansion of drug product facility in Bangalore has been initiated?

Arun Chandavarkar: Yes, same thing.

Shraddha Patil: Lastly on the ANDAs. So when we had started off in fiscal 2014, we had expected filing around 20 ANDAs. So I wanted an update on roughly where do we stand as for the filings today - have we filed all of them?

Arun Chandavarkar: No, we have mentioned that our numbers annually will be very small, cumulatively we said that in the three to four year timeframe we are targeting to have the numbers that we talked above 20 which you mentioned. But, annually the numbers will be small at this point in time because we start small and as the pipeline adds it sort of snowballs into a larger number as we go ahead. The conscious decision to keep it small at the moment is partly because we are just entering this space, more importantly because we do not have internal manufacturing facilities for drug product. I think we mentioned that Oral Solid facility is also under construction. So once we become fully integrated and we have our own facilities, we will ramp up these ANDA filings.

Shraddha Patil: So maybe less than 10 have been filled till now?

Arun Chandavarkar: Yes.

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

Sudhakar: This is Sudhakar here. A couple of questions. My first question is on your Insulin business. How do you see this business scaling up over next three to five years?

Kiran Mazumdar-Shaw: Insulin has been a very successful product for us and we look at this as a very large global opportunity. Right now, of course, our opportunities are really in the emerging markets, but in the next three to four years we believe that even the developed markets could be quite attractive as a business opportunity for us. Glargine as you know has been very an important molecule for us. This is a product that we believe will enter the US and European markets sooner than later. We are expecting to file for this program next fiscal and we already have a pretty growing presence in the emerging markets which we believe will really ramp up in the years ahead.

Sudhakar: For FY18 you have guided around $1 billion of revenue and I understand that around $200 million of this would come from the Biosimilar business…

Kiran Mazumdar-Shaw: Yes, and we remain very confident that we can deliver on that number.

Sudhakar: How do you see the margins panning out over the next 3-years? Right now your EBITDA margin is (25%+). Do you think your margins can substantially improve from here?

Kiran Mazumdar-Shaw: Our core margins if you exclude R&D, licensing and forex and if you just look at base business we are confident that our margins will grow. I think you have to factor the R&D spend which is really an investment in growth. And this R&D spend is really to address the Biosimilars market that we talked about. So obviously if you include R&D spends it might impact the margins that you are looking at. But if you exclude R&D spends and treat it as an investment then the margins will definitely look better.

Sudhakar: On your R&D spend, would that increase substantially as a percentage of revenue or would it be like more or less at similar levels?

Kiran Mazumdar-Shaw: I think it would be at similar levels because we have done large part of the investments already because as I mentioned, a large part of our programs are in Phase-3 clinical trials and so a large part of the R&D spend have been incurred. There are still of course another set of molecules under development. But I think it will be at the same level, I do not expect it to be significantly higher.

Sudhakar: Again, coming back to your guidance of $1 billon, how confident are you of achieving this?

Kiran Mazumdar-Shaw: I think we are very confident because you can see that all our growth verticals are capable of delivering on what we have talked about.

Sudhakar: In terms of risk, if you could highlight one or two risks which can come against your guidance?

Kiran Mazumdar-Shaw: Delayed regulatory approvals for some of our Biosimilars could pose a risk for us. But having said that we still can balance that risk with very large emerging market opportunities which we had not factored in at the time of really coming up with a billion dollar guidance.

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

Shraddha Patil: I just wanted to understand that the emerging market supply from the Malaysia plant. So when do we expect it to start?

Arun Chandavarkar: Because we mentioned that we will file for approvals end of this year. So then really it is about approval time - some countries might take six months to approve, some countries might take longer. So I would definitely say maybe middle of next fiscal.

Shraddha Patil: I wanted an update about how ALZUMAb is doing in Domestic Formulations because when you launched it, we had expected to do at around Rs.100 crore?

Kiran Mazumdar-Shaw: In ALZUMAb what is happening is that the doctors do not prescribe Biologics for psoriasis treatment in a very big way in this country as yet. So we are trying to work with the prescriber base to see how we can get them more familiar with Biologics. I think that is the biggest challenge we have in India because most of the prescribers are treating their patients with non-Biologics. We want to work with the prescribers to get them more comfortable and familiar with Biologics. So I think all Biologics have the same challenge when it comes to psoriasis treatment because they prefer to use even cosmetic kind of treatment methodologies like creams and things like that. Biologics is last on their list of treatments and we are trying to bring it to the fore. There has been a challenge. We are very optimistic about the molecule because it works very well, but India is not a country that is very familiar with the use of Biologics for this treatment.

Shraddha Patil: This is only for psoriasis. So we do not think you will get such a problem in any other?

Kiran Mazumdar-Shaw: No, we will. We are also going to start a trial for Rheumatoid Arthritis, so that also is another opportunity for us.

Shraddha Patil: But when we had launched this molecule, so had we not we seen such a problem coming in?

Kiran Mazumdar-Shaw: No, we had hoped they would actually be more receptive to Biologics. When you do a survey, when you ask doctors about whether they are prepared to prescribe Biologics, of course they all answer in the affirmative, but then the ground reality when you actually launch such products you realize that they need a lot of hand holding.

Shraddha Patil: So how long you think it may take more for your molecule to actually…?

Kiran Mazumdar-Shaw: As you know, ALZUMAb is not a drug that really is something that we need to really grow in a big way in India. I think the biggest opportunity for ALZUMAb is really globally in terms of the kind of indications we are developing it for. That really is the biggest opportunity for ALZUMAb. But, what is important is that once you get it launched in the Indian market you can generate a lot of safety and efficacy data which helps in global development. That is very important because when a drug is used in a number of patients in India and you can generate data, it is very valuable as you develop the drug for the global markets.

Shraddha Patil: So you do not see you facing such a problem in the emerging markets when you…?

Kiran Mazumdar-Shaw: No, I do not mean that. When you are developing this asset for global markets, if you can show the safety and efficacy data from India, it helps to develop the product faster in the US and Europe. That is what they look for. If you can show very good safety data which is what this drug is all about, the regulatory approval when they look at this drug becomes easier.

Shraddha Patil: But at the acceptance level from the doctors side, you do feel that there might be some resistance in the emerging markets as well?

Kiran Mazumdar-Shaw: It depends which emerging markets you are talking about because there are some advanced emerging markets and there are some markets which are not so developed. For instance, if you actually go to some of the more advanced markets like say for instance, Mexico and others, there I think they accept such drugs much more readily. But when you go to some of the other markets you might find that they need the same kind of handholding that Indian prescribing doctors need.

Shraddha Patil: On Sovaldi, any update on that on how it is going on?

Ravi Limaye: We are making good progress in sofosbuvir. I would say it is one of our successful new product launches and this is a stage where we need to invest and continue to consolidate, but we have seen good traction.

Shraddha Patil: We have launched it only in India, right?

Ravi Limaye: At the moment, yes, in India.

Shraddha Patil: Any plans to launch it in any other…?

Ravi Limaye: We have rights for about 80 odd countries and we are working out plan how to enter those markets, but at this stage it is India.

Moderator: Thank you. The next question is from the line of Abhishek Yadav from Quadria Capital. Please go ahead.

Abhishek Yadav: I wanted to understand the company's outlook on the Small Molecule API business over the next 3-5-years just from a perspective of what are the therapies that company would focus and outlook of the company in this business segment?

Arun Chandavarkar: I will make a comment and then I will hand it to Ravi. In terms of our guidance for the calendar 2018 we have shown small molecules showing a muted CAGR going up to $300 million dollars from a level of about $250 million currently. So it has been a muted projection in terms of revenue top line growth. Of course we expect erosion of prices on our legacy products to be replenished by new products such as Immunosuppressants and some of the potent molecules that we have talked about and other such opportunities, should opportunities like Fidaxomicin, revive or come by. So the outlook as an API business has been projected by as being muted with the strong growth drivers really coming from our Biologics, Branded Formulations, and, of course, from Biocon's consolidated point of view, from Syngene.

Ravi Limaye: Just to add to what Arun said, while the revenue may remain flat, the strategy is to migrate to a more profitable portfolio which will mean Immunosuppressants, specialty products, potent molecules as Arun mentioned, some new products. We have some very interesting products in our pipeline. So that would be the broad strategy.

Abhishek Yadav: So the focus would be on launching new more profitable products?

Ravi Limaye: Focus will be to migrate to a more profitable portfolio.

Abhishek Yadav: The expectation is the existing products that the companies already selling, their quantities would taper off or remain at the same level?

Ravi Limaye: In the API business you often see erosion in prices, especially in old products, which we intend to offset with a profitable product mix. So by doing that we expect there will be at least some small single digit growth to make sure that overall there is no erosion.

Abhishek Yadav: To check on how the company on track with the completion of the Oral Dosage facility - is it still on track for the calendar year 2017?

Arun Chandavarkar: That is right. For completion, yes, then of course the question is about when we get USFDA inspections and approvals so that we can use it to support our ANDA business.

Abhishek Yadav: In the first phase, the plan is to do Oncology and Immunosuppressants?

Arun Chandavarkar: Yes, it is a potent facility, it also has a non-potent side to it, but our commercial strategy in the near-term will leverage both our in-house facility and the existing outsourced manufacturing capacity that we have contracted.

Moderator: Thank you. As there are no further questions from the participants, I would now like to hand over the floor back to Mr. Paliwal for his closing comments. Thank you and over to you, sir.

Saurabh Paliwal: Thanks, Karuna. Thank you everybody for joining us in today's conference call. Hope we have addressed all your queries. If there are still any additional questions you may have later, please get in touch with me. With that I wish you all Happy Navaratri, Dussehra and Durga Pooja. Good Evening.

Moderator: Thank you very much, sir. 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