Biocon Limited's Q3 & 9M FY14 Earnings Conference Call
January 23, 2014

Key Participants from Biocon Group's Senior Management Team

- Kiran Mazumdar Shaw: Chairman and Managing Director
- John Shaw: Vice Chairman
- Arun Chandavarkar: Chief Operating Officer
- Murali Krishnan: President, Finance
- Abhijit Barve: President, R&D
- Siddharth Mittal: Vice-President, Finance
- Satish Arunachalam: Associate Vice President, Finance
- Peter Bains: Director, Syngene International
- M.B. Chinappa: President, Finance, Syngene International
- Manoj Nerurkar: Chief Operating Officer, Syngene International
- Shukrit Chimote: Business Unit - Head, Branded Formulations (India)
- Sandeep Rao: Business Unit - Head, Insulins
- Paul Thomas: Business Unit - Head, Biosimilars
- Prasad BSV: Business Unit - Head, Small Molecules
- Akash Puranik: Vice President, Marketing
- Saurabh Paliwal: Head, Investor Relations

Presentation Session

Moderator: Ladies and gentlemen, good day and welcome to Biocon Limited Q3 & 9M FY14 Earnings Conference Call. As a reminder for the duration of this conference, all participants' lines will be in the listen-only mode. There will be an opportunity to ask questions at the end of today's presentation. Should you need assistance during this conference, please signal the operator by pressing '*' and 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 of Biocon Limited. Thank you.

Saurabh Paliwal: Good afternoon everybody, and welcome to Biocon's quarterly conference call for Q3 and 9M FY14. I am Saurabh Paliwal from the Investor Relations team. We had released our results last night and the same are available on our website. We have with us on the call today Ms. Kiran Mazumdar-Shaw, Biocon's Chairman and Managing Director and our colleagues from the senior management team. We will begin this call with opening remarks from Biocon's management followed by an interactive Q&A session.

Before we proceed with the call, I would like to remind everyone that this call is being recorded and a replay will be available for the next few days. The call transcript shall be available on our website soon. I would like to add that today's discussion may be forward-looking in nature and must be viewed in conjunction with the risks that our business faces. The safe-harbor contained in our press release also pertains to this conference call. After the end of this call, please feel free to get in touch with the investor relations team with any additional queries that you may have. Now I would like to turn the call over to Ms. Kiran Mazumdar.

Kiran Mazumdar Shaw: Thank you Saurabh. Good afternoon and a very Happy New Year to all of you. I welcome you to Biocon's investor call for the 9 months ended 31st December 2013. Let me begin with our key financial highlights for this period:

- Group sales have risen by 18% to Rs. 2,130 Crs.
- Our Biopharma business grew by 14% to ~Rs. 1,600 Crs. versus Rs. ~1,400 Crs. last year and within this segment:
  - The Biopharma sales grew by 14% to ~Rs. 1,300 Crs. and
  - The Branded Formulations business grew by 14% to approximately Rs. 300 Crs.
- The Research Services segment has registered a stellar growth of 35% delivering Rs. 526 Crs. to the top-line.

The growth has been partly supported by the rupee depreciation and at constant exchange rate, our Biopharmaceuticals business has grown by 9% and the Research Services element has delivered 22% YoY growth. Group EBITDA was at Rs. 550 Crs. which is a growth of 17% YoY and EBITDA margins were at 25% for the 9 months. If we exclude R&D spends, licensing and other income, our core EBITDA margins stood at 27%.

I must highlight here that we have seen our Bio-pharmaceuticals business grow modestly in Q3FY14 from Rs. 495 Crs. last fiscal to Rs. 517 this fiscal. Our Biopharma business within this segment, has grown from Rs. 409 to Rs. 418 and our Branded Formulations India business has grown from Rs. 86 to Rs. 99 Crs. Contract Research has continued to deliver strong growth, growing from Rs. 140 Crs. to Rs. 183 Crs.

We had 10 Crs. of net forex loss this quarter, which appears under other expenses. The forex losses in Q3 are largely due to hedging costs involved to protect us from currency fluctuations and I would like to emphasize here that all the lower price forex contracts for the BMS engagement had expired last quarter.

Group net profit for the first 9 months has grown 16% to Rs. 301 Crs. and PAT margins stand at 14%. We are net cash positive with a balance of Rs. 481 Crs. at the end of Q3FY14. Our total debt for the group at the end of Q3 stood at Rs. 537 Crs. largely coming from draw-downs made for construction of our Malaysia facility, which is at a very low interest rate.

Moving on to the individual vertical performances:

The portfolio optimization initiatives in our **Small Molecules** vertical continues, with Immunosuppressants and specialty molecules gaining further prominence. We are witnessing headwinds in our statins basket and we are working towards rejigging the product mix to balance these out. In order to fuel further growth in this vertical, we are investing in the development of molecules as part of an ANDA focused strategy. We look to file our first application later this year. In the coming years, launch of these products in the developed markets should add additional revenues in this vertical and take us up the value curve from the presently commoditizing API business.

Coming to the **Biosimilars** vertical, our generic Insulin business continues to do well on the back of sustained demand from the emerging markets. We have expanded our Insulin capacity in Bangalore

earlier this fiscal and will continue to enhance the same with incremental process and facility enhancements. However, the increasing demand for development batches to support our clinical programs limit the capacity available for commercial supplies and we can expect further strong growth from our global Insulin business when our Malaysia facility comes online. So until then, we can only expect incremental additions to our Insulin business which is right now a very attractive business, even when it comes to margins. Our Malaysia facility is expected to be fully commissioned by the end of FY15.

Moving to our Biosimilar MAb program, as you know, we received regulatory approvals for the commercial launch of Trastuzumab from the Indian regulators in Q3 FY14. This is the world's first Trastuzumab to be commercialized, and with be launched under the brand name CANMAb™. The important differentiator of this particular product is that it will be available in two presentations of 150 mg and 440 mg in order to provide affordable access to this drug in India. To put the pricing in perspective, the innovators' products in India retails at about a third of its international price and our product will be at least 25% more affordable than this price. Thus, our drug is effectively at an 80% discount to the innovators' international price. In addition, we will also have compassionate use programs and relevant trade discounts to further address the affordability challenge and this will significantly lower the treatment burden on patients. The drug will be available in the market early next month.

Our **Branded Formulations** vertical grew at 14% for the first 9 months against the industry growth of 5%. With the market stabilizing after the NLEM rollout, we expect the industry to return to its growth path. Our recent launches Alzumab™ and CytoSorb™ have done extremely well, with strong uptake from both doctors and patients. We will strengthen our portfolio further with products like CANMAb™ and other in-licensed molecules for key emerging market diseases. In line with this strategy, we have entered into a development partnership with Advaxis for their novel cancer immunotherapy to treat HPV-associated cervical cancer. I would like to highlight here that India accounts for ~25% of the cervical cancer patients worldwide.

As molecules from our R&D pipeline gets commercialized, we are engaged in strengthening our **Novel Molecules** pipeline further with new alliances. We have partnered with Quark Pharmaceuticals for a molecule that is based on a novel siRNA technology which will be developed for an ophthalmic condition. This partnership will help us gain access to a novel platform technology which will also be leveraged for other unmet medical needs.

The **Research Services** segment grew by 35% for the first 9 months to deliver Rs. 526 Crs. of revenue. The growth has been driven by the increasing penetration of our services across our partners supported by sustained investments to support their R&D programs. We have strengthened several engagements by offering customized programs and expect this momentum to continue. A comment on taking Syngene to the market- we will certainly look at this post the general elections.

In summary, I would like to highlight that Biocon has delivered consistent quarterly performance in this year; however, two things stand out this quarter. First, the top-line performance this quarter has been lower than the previous quarters due to the absence of large global tenders which had boosted our performance in the earlier period. In addition, there has been a phasing issue with some orders which will

get reflected in Q4. Second, our R&D expense numbers were significantly lower this quarter against the average run rate seen earlier. R&D expenditure is inherently lumpy nature and depends on a number of external factors like regulatory approval and activity initiation. However, one factor that did impact lower R&D spends is the current clinical trial environment in the country. In conclusion, I would like to say that we have a strong order book for Q4 and are confident of ending the year on a strong note. With this, I would now like to open up the session for question-and-answers. Thank you.

Q&A Session

Moderator: Thank you very much ma'am. Participants, we will now begin with the question-and-answer session. We have the first question from the line of Alok Dalal from Motilal Oswal Securities. Please go ahead.

Alok Dalal: Just one question Kiran, what is the restructuring that is going on? I believe McKinsey is involved in some restructuring. So when did it start, what is McKinsey proposing to the company and how you are going to implement it?

Kiran Mazumdar-Shaw: First and foremost this exercise was done almost a year ago. We have created strategic business units (Verticals) that we believe will be our strong growth drivers for the future. In fact, we have gone live with the new structure from 1st April 2013; which has been developed by McKinsey in close partnership with our leadership team.

Alok Dalal: So essentially, you are trying to create separate SBUs for each units going forward?

Kiran Mazumdar-Shaw: Yes and this is beginning to play very well for us.

Alok Dalal: Who is heading the marketing part, now that Rakesh has moved on to Mylan?

Kiran Mazumdar-Shaw: We are looking for replacement for Rakesh and we hope that this will happen soon.

Moderator: Thank you. We have the next question from the line of Milind Bhangale from Dolat Capital. Please go ahead.

Abhay: This is Abhay from Dolat Capital, on behalf of Milind. Kiran, you made an observation on the Malaysian facility starting in end FY15. So I presume this is a delay of 3 months?

Kiran Mazumdar-Shaw: We had earlier mentioned end of CY14, but this basically continues to be the same kind of timeline.

Abhay: The Biopharmaceutical division has had probably one of the lower numbers that we have seen in recent times. So is it now fair to say that it is probably the inflection point and the growth will probably return to more like mid-teens….

Kiran Mazumdar-Shaw: Well as I mentioned in my comments, we have seen a steady run rate of our Biopharmaceuticals business. The spike you have seen in Q2 pertains to a couple of large global tenders that we had supplied, which has not been the case in Q3. As I mentioned, Q4 seems to have a very good order book. So I think you will see a better set of numbers next quarter.

Abhay: Last quarter you had mentioned that we had received the approval for Sirolimus-- so have we launched during this quarter?

Kiran Mazumdar-Shaw: So I think that is another thing that has added to the sales last quarter, which was pipeline filling for Sirolimus.

Moderator: Thank you. We have the next question from the line of Sudarshan Padmanabhan from Sundaram Mutual Fund. Please go ahead.

Sudarshan Padmanabhan: Ma'am, this time your R&D spend has been substantially lower. You had indicated about the clinical trial climate in the country. Can you elaborate a bit on what is actually happening on the ground level with respect to this and how much we can R&D spend can we expect for the full year and for FY15?

Kiran Mazumdar-Shaw: First and foremost, I think that the R&D spends this quarter is a bit of an aberration. The clinical trial environment in the country has severely impacted some of our plans for initiating certain clinical trials, which has led to a lower spending this quarter. We have taken some of these trials offshore, but it takes time to then recognize the funding and the expenses of such trial which are about to start. Our R&D spends are expected to increase going forward and you will probably see larger spends next quarter and beyond.

Sudarshan Padmanabhan: Thanks. Also, there has been a substantial jump in your long-term debt. Is it primarily because of the Malaysian unit?

Kiran Mazumdar-Shaw: Yes, there is now a debt of Rs. 537 Crs. which is largely on account of the Malaysia facility which is going to come on stream in FY15.

Sudarshan Padmanabhan: Can we expect additional debt going forward or this is the debt that we can expect?

Kiran Mazumdar-Shaw: There will be additional debt, as we will be drawing down the loan in line with the progress of our Malaysian facility.

Sudarshan Padmanabhan: What should be the peak debt that we can look at?

Siddharth Mittal: The total debt that we planned to draw on this project is roughly $120- $130 million, of which we have already drawn ~$70 million.

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

Girish Bakhru: Just wanted color on Syngene's EBITDA and profit?

Peter Bains: The guidance on EBITDA margins remained consistent with that was given before, which is low to mid 30% range.

Girish Bakhru: With the hedges winding off in the last quarter, the losses on the Syngene have reduced. Have you seen expansion in the margins of Syngene?

Siddharth Mittal: At the group level, we had forex losses of 19 Crs in Q2 which has declined to 10 Crs in Q3. So yes, we have had some benefit from the losses on Syngene going away. The base operational performance ex-forex, as Peter mentioned, continues to be strong.

Girish Bakhru: On the Biopharma side, I know you mentioned probably some of the tenders not being there in this quarter. But excluding that, the business in the statins and the normal emerging market Insulin-- is that in steady state?

Kiran Mazumdar-Shaw: If you compare it to Q1, you will see that it is fairly steady state.

Girish Bakhru: Lastly on the oral Insulin part, you had commented earlier that Bristol has retained the asset despite the AstraZeneca-Bristol deal. So, would Bristol only have the oral Insulin in the diabetes portfolio?

Abhijit Barve: As of now, BMS continues with the arrangement that we had with them on IN-105. As is widely known, the BMS-AZ deal is largely for BMS' late stage and commercial assets. Apparently, Bristol continues to work on some early stage programs including our oral Insulin.

Moderator: Thank you. We have the next question from the line of Surya Patra from Philip Capital. Please go ahead.

Surya Patra: Couple of questions. Firstly, on the USFDA inspection at Syngene. Is this the first ever USFDA inspection for the Syngene? How important is this, what is the kind of revenue implication that we should be seeing and when would that start?

Peter Bains: We are very pleased to clear the USFDA inspection with no observation or 483s. It is really a reaffirmation of the world class quality systems that underpin Syngene's service platform. It was triggered by our client. So there is no immediate inflection point.

Surya Patra: Will it lead to some sort of incremental Research Services revenues in the future?

Peter Bains: I think it clearly demonstrates the quality of our service platforms which is extremely important to all clients looking for manufacturing services. So I think it amplifies a very important aspect of our business.

Surya Patra: The next question is with regards to the progress of rh-Insulin penetration in ROW markets. What is your thought process regarding this and how are you progressing on this front?

Arun Chandavarkar: I think we had mentioned in the last quarter that we had approvals in ~ 46 countries. Now we are over 50 countries in terms of rh Insulin approvals. There are two focus areas for us: increasing our footprint in terms of the number of countries we are present in and increasing our presence in the countries where we already have approvals. So both efforts are very much underway. Currently the emerging markets are the key opportunity for us in rh-Insulin, because we are yet to be approved in the regulated markets, but once that happens there could be significant opportunities there as well.

Surya Patra: Will this be the same story for biosimilar trastuzumab as well?

Arun Chandavarkar: It is similar to the Insulin strategy. Our approval in India will help us in reaching out to some of the emerging markets as well.

Surya Patra: What would be the kind of margins that you would be looking in the medium term because on the one hand you are talking about increasing R&D spending, and on the other you are saying product rationalization for enhancing margins?

Kiran Mazumdar-Shaw: I think one has to offset the other and as you can see, we have been building our margins pretty steadily upwards. I think we should be able to sustain these levels by better product rationalization and product mix. While we are realizing much higher values and margins, we are fully cognizant of the increased R&D spends and hence we are very confident that we will be able to deliver on these margins going forward.

Moderator: Thank you. We have the next question from the line of Krishna Prasad from Kotak. Please go ahead.

Krishna Prasad: The first question is on the tenders that you spoke about. If I understood correctly, you are talking about tenders which happened in 2Q FY14. Could you elaborate what are these tenders all about, what are the products or the markets, maybe if you can give us some sense on that?

Arun Chandavarkar: As Kiran mentioned, these were one-time spikes due to tenders. We cannot disclose further specifics on the nature of these contracts, but this does not imply that we cannot win these again in the future. Let me just say that these tenders largely pertain to the emerging markets.

Krishna Prasad: And you meant it happened in the second quarter of FY14 right?

Arun Chandavarkar: Q2 FY14 is when the peak supplies for the tenders took place.

Krishna Prasad: Got it and just with respect to the lower R&D cost-- if I look at the 9-month R&D number, you actually had a decline of 17% in the R&D expense. Beyond the issues relating to the clinical trials in India, has there been anything else which is contributing to this decline. You have not had the kind of scale up that you talked about in the early part of this year.

Arun Chandavarkar: R&D expenses consist of multiple expense items. The clinical part tends to be the biggest share of that expense. As you know, some of our recent trials have culminated into commercialization approvals from DCGI (Alzumab and CANMAb). Last year, we had our global Insulin trial

happening in Europe which we have concluded with successful results. So these were all significant contributors in the earlier period. Likewise, there are ongoing trials in our partnered programs with Mylan and as more molecules get into the clinic, there can either be a smoothening out or a peaking of expense, depending on whether multiple peak expenses on certain clinical trials happen in sync or in phases. So it is hard to predict this. That is why we keep advising R&D expenses tend to be lumpy.

Krishna Prasad: On the launch of CANMAb in India, could you talk a little bit about the pricing because it appears fair from a discount point of view. How do you expect volumes to shape up, do you think this is the appropriate discount to the brand and how do we see that evolving over the period of time?

Kiran Mazumdar-Shaw: I think this is a very important product for us and we are focusing on various strategies to address access and market expansion with a discounted price. The announcement of our launch has actually seen the innovator take certain preemptive measures and they themselves have slashed the prices. If you remember for the last 10 years and more, the innovator had priced this product at almost double of what the present MRP is. This product was sold anywhere between 1.25 - 1.6 lakhs because it was linked to the Swiss Franc. Now they have of course reduced this to 75,000 and we have offered this product in the market at a discount of almost 25% to this MRP, which effectively makes our product at an 80% discount to their international price. In addition just like the innovator, we are also willing to pass on trade margins to the patients which will obviously then discount it further. I think there is a very interesting piece in Bio Century which talks about how the 150 mg presentation which we have very innovatively offered to Indian patients is going to drive affordability even further. In addition, we are going to look at various ways of increasing access to patients via various compassionate use and patient assistance programs.

Krishna Prasad: Got it. Also, once we are done with the Malaysia facility expansion, would that mean we would have just maintenance CAPEX going forward and if you could talk about any CAPEX plans that we have beyond that?

Arun Chandavarkar: We have mentioned earlier, that we have an ongoing CAPEX on an annualized basis for debottlenecking opportunities. For example, we have an ongoing CAPEX plan to build and commission our devices facilities in Bangalore. So there will always be a continuous CAPEX requirement beyond the big one in Malaysia. The annual range for this has generally been 100-150 Crs at the group level.

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

Nitin Agarwal: What would be the CAPEX that we are looking at on a consol basis for FY14 including the Malaysian CAPEX?

Murali Krishnan: Malaysia is not going to be calculated this year, as it will get completed only next year. So other than that, it will be in the region of about Rs. 150 Crs.

Nitin Agarwal: Because if we look at the gross block….

Murali Krishnan: The gross block includes capital work-in-progress as well.

Nitin Agarwal: What is the spend on Malaysia this year? I am asking this as our gross block ex of depreciation, seems to be up by almost Rs. 500 Crs. from March to now.

Siddharth Mittal: Malaysia has added ~Rs. 400 Crs. from April 1 till 31st December, and the remaining addition is on account of Research Services and Biopharma maintenance CAPEX and upgrade CAPEX.

Nitin Agarwal: Secondly Kiran, you mentioned about the ANDA filings – could you please repeat some of those comments regarding the formulations in the developed markets.

Kiran Mazumdar-Shaw: We have a pipeline of ANDAs under development and we expect to file a few ANDAs during this coming fiscal. The actual market opportunities for those ANDAs is a few years later, but this will be opening our account with our own filings.

Nitin Agarwal: And lastly on trastuzumab, given the price cuts that you had to take in reaction to the innovator dropping prices; does it remain a profitable product-- material relevantly given the fact that our volumes initially will be low and we competing with the innovator with its own scale to operate at.

Kiran Mazumdar-Shaw: We are pretty experienced at competing with the innovator on the Insulin front. We will do the same on this front. And by the way it is not us reacting to the innovator. The innovator has reacted to us coming into the market. So I think you have to get your facts right.

Nitin Agarwal: My point is they can do it because they have got the volumes to do it...

Kiran Mazumdar-Shaw: I think there are more complex issues than just the price aspect. I think innovators also have to consider other global aspects in terms of how they price the product. So I think this is a space which we understand very well. I think we have done extremely well on the Insulin front where we have seen fierce competition and how the innovators have fought back, but I think we have held our own very strongly and I think we expect to do the same for the Biosimilars as well.

Moderator: Thank you. We will take the next question from the line of Bino Pathiparampil from IIFL. Please go ahead.

Bino Pathiparampil: Can I get the constant currency growth rate in Biopharma for the third quarter and also the 9 months?

Siddharth Mittal: This quarter, it is (-2%), although 9 months is up by 9%.

Bino Pathiparampil: Does this include the India Branded Formulations?

Siddharth Mittal: Yes.

Bino Pathiparampil: Second question, the domestic business growth this quarter was 16%. There has been some disruptions like last time you said related to the trade channels, margins, etc. How are those issues going on? Are they kind of settled? Are we on a steady growth path now?

Arun Chandavarkar: These seem to have settled down, pertaining to our products.

Bino Pathiparampil: So in that case, I would have expected a better growth like north of 25% rather than 16% or is there some effects still there in this quarter?

Kiran Mazumdar-Shaw: This particular quarter we have seen a much higher growth rate of 16% vs. the industry growth rate of 5%. We should see further improvements going forward.

Bino Pathiparampil: Going to R&D expense, the sharp drop in R&D expense when couple of trials were postponed in India seem to suggest to me that your fraction of R&D expense related to the regulated market Biosimilars in the Mylan partnership is relatively a low percent of R&D expense as of today. Is that a correct reading?

Arun Chandavarkar: No. We cannot make any of these assumptions because unfortunately we have multiple development programs. We have 8 partnered programs with Mylan and outside of that, we have a Recombinant Human Insulin which we are doing on our own plus we have all our ANDAs, some of which we will file by end of this year. Then we have a novel biologicals portfolio where we are conducting trials for oral Insulin as well as global studies for our Alzumab. In addition there is sustained support for developing a new product portfolio in our small molecules business. So when you look at the various business units we have and the number of products in each of those business units, it is a very complex scenario to analyze and deduce that the spending is attributed to this or that. But by and large, clinical spends do tend to outspend process development investments. That is why it is said that R&D spends are more hooked on to the clinical trials than to things like process developments.

Bino Pathiparampil: One final question. As per your latest presentation, roughly little higher than 50% of your revenues comes from small molecules. Now could you briefly tell us which are the major contributors and how much statin is in there?

Arun Chandavarkar: We have maintained that statins as a percentage has come down over the years, but the bigger underlying message is the change in our statin portfolio mix with lower dependence on our older statins like Simvastatin or Lovastatin. For example, Lovastatin is practically off the radar now. Although the statins portfolio as a percentage is lower, what it reflects is the significant growth in our other molecules like the Insulins, Orlistat and Branded Formulations.

Bino Pathiparampil: Earlier you had said statin is one-third of the top-line or so, would you be able to…

Arun Chandavarkar: It has decreased and is now in the 20% ballpark range.

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

Sameer Baisiwala: I am looking at slide #17 on the presentation and it looks like over last 5 years in the emerging markets for your Insulin, the market share has moved up from 4% to 11%. So while it is doing good versus the other players, my key question here is does this pace of market share gains surprises you on the down side and where exactly is the challenge in winning the patients?

Kiran Mazumdar-Shaw: I don't know what you are saying Sameer because I think we are actually making a lot of gains. In fact remember we are getting 11% of a bigger pie now and you can see that we have actually eaten into both the innovators and others. So I think what you have to take into consideration is that when you look at the 4% market share we had in 2009, I think it was a much smaller pie and where the innovators enjoyed a big market share and the others actually had a bigger market share than us.

Arun Chandavarkar: To expand on what Kiran said, we have said that the shift from 4% to 11% was over a 4 year period (2009 to 2013). You should remember that many of our approvals in some of these markets have also been more recent. Those markets which are very recent are currently not at the 11% range. So they all represents growth opportunities going forward. The market share of 11% is in some of the markets where we have been present for a longer period of time. Also, some of these markets are not necessarily branded for us because some of them would tend to be like tender opportunities which we referred to earlier.

Sameer Baisiwala: Where is the bigger challenge in getting more patients on board? Is it the doctors, is the physicians?

Arun Chandavarkar: As I mentioned to you, some of these are tender markets. We do not have our own retail salesforce in any of these markets. Most of them are through partners who are either strong themselves or through institutional or government procurement.

Sameer Baisiwala: Fair enough. Would you think that the older patients who are already diabetic and taking innovators or someone else's? Are you wining the new diabetic patients as your customer or is it the older patients?

Arun Chandavarkar: It is both. We are doing both switchability as well as getting new patients.

Sameer Baisiwala: Sir one final question on this point. What is the price differential in Insulin versus innovator in India and emerging markets?

Kiran Mazumdar-Shaw: We compete very seriously with innovators.

Arun Chandavarkar: In India, it is under price control.

Kiran Mazumdar-Shaw: And we compete in tender markets with the innovators and win those tenders. So there is no question of discount in that kind of case.

Sameer Baisiwala: And if you can update us on the Phase-III global clinical trials both for Glargine, I guess this should be starting sometime and Trastuzumab. When are we expected to complete both these studies?

Abhijit Barve: The Trastuzumab study is going on as per plan and with regards to Glargine, the Phase-III study will start in first half of this calendar year. We have not given any indications in terms of the completion and we would not like to do that, as there are multiple external factors that affect us. Also, as these are partnered programs, usually there is a discussion in terms of what we can share with the wider audience.

Moderator: Thank you. We have the next question from the line of Mahesh Sarda from ING Vysya Life Insurance. Please go ahead.

Mahesh Sarda: Last two quarters you have seen the Biopharma segment growing decently on a constant currency basis whereas in this quarter we have seen about (-2%) growth. So can I understand it is also because of the constraints which we are facing on the capacity which is leading to this or it is only a one-off which has led to this kind of de-growth in the quarter.

Kiran Mazumdar-Shaw: It is one-off, and we should see growth come back in Q4

Mahesh Sarda: Second question is on Syngene. We have been seeing the growth rate being much better in first half where it grew about 25% constant currency growth. The rest in this quarter the growth rate has come down to about 15%. So any specific reason why are we seeing the momentum coming down in this?

Peter Bains: This is very largely due to the comparison with a very strong third quarter last year and a little bit of slowdown on the clinical trial side. The fourth quarter outlook remains very robust and in line with the year-to-date number of 22%.

Mahesh Sarda: You have done couple of in-licensing deals. Any specific payment we are supposed to make to have the technology tie-ups in both of the deals which you have done.

Siddharth Mittal: In-licensing deals would not have a revenue impact in the short-term. There has not been any significant cash outflow either.

Mahesh Sarda: And on R&Ds again, I lack clarity on what would be your run rate going forward. Earlier we were guiding for about Rs. 160 Crs. on a yearly basis. So do we still maintain that or we see some slowdown in FY15 over to sustain that kind of Rs. 160 Crs. run rate.

Arun Chandavarkar: We would like to maintain it at 7%-8% of Biopharma revenues.

Moderator: Next question is from the line of Nisarg Vakharia from Lucky Investments. Please go ahead.

Nisarg Vakharia: Is it possible to share the value of the one-off tender business that you got in quarter 2?

Arun Chandavarkar: No.

Nisarg Vakharia: Is it possible to share the contribution of statins business in terms of value or percentage of the Biopharma business as of now?

Arun Chandavarkar: We have mentioned it earlier in the call that it is around 20%.

Moderator: Thank you. We will take the next question from the line of Ranjit Kapadia from Centrum Broking. Please go ahead.

Ranjit Kapadia: Celltrion from South Korea has also announced an approval for their biosimilar trastuzumab in South Korea and they have roped in Hospira as a partner for the global commercialization. So how is going to affect our competitive scenario in the global market?

Arun Chandavarkar: We have Mylan as our partner—a US based organization, which is the 3rd largest generic company worldwide.

Ranjit Kapadia: Can you elaborate about statin pricing scenario globally?

Arun Chandavarkar: We have continued to maintain that some of our older statins continue to be under pricing pressures. The newer statins are doing well, the statins basket is still largely stable.

Moderator: Thank you. We have the next question from the line of Anand Rawani from Horizon Research. Please go ahead.

Anand Rawani: As you are pointing out the difficult clinical trial environment in India and Biocon had to conduct the clinical trials offshore, do you believe that it is a temporary phenomenon and if it is not, then you will have to continue conducting trials offshore. How it affects our EBITDA margin going ahead?

Kiran Mazumdar-Shaw: First and foremost, we hope that this is a temporary phenomenon because there have been several announcements recently that the concerned authorities are trying to resolve these issues. This challenge affects not only Biocon, but also the whole industry. We hope that the issue is resolved at the earliest, but obviously we are watching this space and we will keep evaluating what we need to do to mitigate this problem.

Anand Rawani: But is it costly to conduct research outside or in India?

Kiran Mazumdar-Shaw: Obviously it is very expensive to conduct this kind of clinical research outside.

Arun Chandavarkar: The trials that we have taken out are largely early stage trials. Of course trials required for an India approval will continue to be done in India.

Moderator: Thank you. We have the next question from the line of Chirag D from HDFC. Please go ahead.

Chirag D: Can you try and explain to me how this supply chain for our Insulin manufacturing works. Where do we make the API and where do we make the formulation?

Arun Chandavarkar: Both are manufactured at our facility in Bangalore.

Chirag D: And Malaysia has API capacities?

Arun Chandavarkar: Malaysia is primarily for the Insulins basket- both API and drug product.

Chirag D: And secondly on the insulins side. Is there an yield advantage or a process advantage that we have vis-à-vis the innovators where we can take out market share or we can be more competitive than them, etc., what is the plan here ?

Arun Chandavarkar: I do not know how to compare ourselves with the innovator in terms of process yields and all of that, but overall the rationale for us to enter the Biosimilar phase is precisely to win market share on price against the innovator. The whole nature of the game in Biosimilar is quite similar to that in generics except that we do not expect the very high erosion in price that you see in small molecule generic, but it is obviously a part of anyone's business strategy for Biosimilars. The expectation is that you need to be at a lower price than the innovator.

Chirag D: Do we know how our yields compare with other competitors?

Arun Chandavarkar: No, that is not something that would be available in the public domain.

Moderator: Thank you. We have the next question from the line of Purvi Shah from Dalal & Broacha. Please go ahead.

Purvi Shah: My question relates to Advaxis. If you could give some more clarity on as to what stage it is currently and then we already have few vaccines in market for cervical cancer. So how would it differentiate from the rest of the products?

Abhijit Barve: The announcement that we made today on our collaboration with Advaxis pertains to the platform which is primarily being targeted for HPV and specifically cervical cancer. The data that has been generated in India clearly shows that the drug has got a much better safety profile compared to the current chemotherapeutic agents and has similar efficacy. So we are very excited. One of the biggest challenge is that many of the women are not able to tolerate chemotherapy and have got significant side effects. This would offer them a safe and effective alternative.

Moderator: Thank you. We have the next question from the line of Bhagwan Choudhary from India Nivesh. Please go ahead.

Bhagwan Choudhary: My first question is on Insulins - other than Biocon do we have any other generic player in these emerging markets?

Arun Chandavarkar: There are some local competitors. The number varies from country to country and they may not necessarily be backward integrated into the API.

Bhagwan Choudhary: If I look at pure Biopharma business (biopharma excluding licensing income) in constant currency terms from Q1FY14 to Q3FY14, the numbers are in declining trend by $1 or $2 million. Is that a right assessment?

Saurabh Paliwal: Can we take this offline since we have to go deeper into what you are trying to say.

Moderator: Thank you. We will take the next question from the line of Vipul Shah, an individual investor. Please go ahead.

Vipul Shah: My question is regarding your Malaysian facility. So once it becomes operational, is it only for Insulin and how much top-line addition we can expect from that facility once it becomes fully operational?

Murali Krishnan: The Malaysian facility right now is meant only for Insulins, but we would not be able to share top-line guidance on the plant, when it goes into operation.

Moderator: Thank you. We have the next question from the line of Srihari from TCS Securities. Please go ahead.

Srihari: My question for this is to Syngene. Could you please tell how many Phase-III projects you have on hand right now?

Peter Bains: So we have 5 clients moving into Phase-III now. We are in discussions with them for commercialization support.

Srihari: Can you please give the therapy lines for this 5 molecules?

Peter Bains: No, we cannot disclose our clients' therapeutic areas.

Moderator: Thank you. The next question is from the line of Sachin Shah from Emkay Investment Managers. Please go ahead.

Sachin Shah: Just wanted to understand if you can throw some color on your drug which you launched in India for Psoriasis. How it has been doing in the last few months?

Shukrit Chimote: We launched Alzumab a few months ago and the response rates with the physician community and the patients has been extremely encouraging. More than 100 patients have had the benefit of the drug and more than 50% of all biologics prescribers in India have now written this product. There are early encouraging signs on the clinical trial and the in-market outcomes.

Sachin Shah: Can you give us some sense of what is the size of this drug currently in India and how do you see it in for the next financial year shaping it up for you?

Shukrit Chimote: The Psoriasis opportunity in the market is close to Rs. 150 to 200 Crs. So we will continue to play within that and look to expand the patient pool and the market. I cannot give you brand level guidance.

Moderator: Thank you. We have the next follow-up question from the line of Alok Dalal from Motilal Oswal Securities. Please go ahead.

Alok Dalal: Just wanted to understand the ANDA strategy a bit better. So are these products which will be filed, are these are own filings or for the partner?

Arun Chandavarkar: These are our own filings.

Alok Dalal: Sir don't you think that when you start now, you will take lot of time to build the meaningful pipeline for a market like US.

Arun Chandavarkar: Yes, but that is why at some point we have to make a beginning if one wants to add value to the API portfolio. We have decided to make a beginning in a small way and we have been judicious about the products we have selected. We have selected products where we feel we have competitive advantage. The first filings will happen this calendar year, in FY15

Alok Dalal: And then in the next 2 or 3 years, my question is that would not it take a lot of time for scale up and then the payback period also would not it take a lot of time here in this market?

Arun Chandavarkar: As Kiran said, the revenue opportunities for this come few years later. It typically takes at least 3 years or so for revenues to start kicking in post filing. So definitely you will not see revenues from these opportunities from US market before that. Prior to that, revenues from such opportunities can only be in emerging markets.

Moderator: Thank you. We have the next follow-up question from the line of Surya Patra from Phillip Capital. Please go ahead.

Surya Patra: Just one single question. After BI & Lilly's filing Glargine in US, what is our thought process regards initiating our filing activities there in US for our Glargine?

Arun Chandavarkar: We think it is a good development because it is endorses the kind of strategies we have had internally for this program.

Surya Patra: So at least for now the pathway is finalized right for Glargine?

Arun Chandavarkar: It looks like.

Moderator: Thank you. We have the next follow-up question from the line of Bino Pathiparampil from IIFL. Please go ahead.

Bino Pathiparampil: Just one follow-up question on the capacity of the Malaysian facility. I understand you cannot give a top-line, but this Malaysia facility would be increasing your Insulin capacity by how much like doubling it, tripling it?

Arun Chandavarkar: All we can say that the Malaysia facility is much larger than the Bangalore facility and secondly the Malaysia facility, like Bangalore one, is designed in phases. So what we are targeting about investment and commissioning right now is only the Phase-I and Phase-I itself is expected to be bigger than the Bangalore facility.

Bino Pathiparampil: So the Phase-II, III can be for other Biosimilars as well right, not necessarily….

Arun Chandavarkar: It can be for the Insulins and the analogs.

Bino Pathiparampil: But do you have the infrastructure in the current facility for future expansion?

Arun Chandavarkar: We have the space.

Moderator: Thank you. We will now take the last question which is a follow-up one from the line of Bhagwan Choudhary from India Nivesh. Please go ahead.

Bhagwan Choudhary: This is regarding this tender into the emerging market. As you said that we supplied that product into the previous quarter, but tender won was earlier than that. So if can you please elaborate what kind of process is there. How long before you apply for the tender and one tender can supply for what period?

Arun Chandavarkar: We cannot give specifics, but generally the tenders tend to be lumpy and are a win/ lose kind—so there are rarely any partial wins. So when you win, you get a spike; if you lose, you do not get that. The duration of the tender varies. Many of you, for example, are familiar with AOK tenders in Germany. Emerging market tenders also are like that, but the periods vary. Something could be one year, something even could be a spot tender.

Moderator: Thank you. I will now hand over the floor back to Mr. Saurabh Paliwal for closing comments. Thank you and over to you sir.

Saurabh Paliwal: Thank you everybody for joining us in today's call. We look forward to hosting you next quarter. Thanks.

Moderator: Thank you. Ladies and gentlemen, on behalf of Biocon 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