

## Q3 & 9M FY13 Post Earnings Conference Call January 25, 2013

## Participants from Biocon Group's Senior Management Team

- Kiran Mazumdar Shaw: Chairman and Managing Director
- John Shaw: Vice Chairman
- Arun Chandavarkar: Chief Operating Officer
- Abhijit Barve: President, R&D
- Rakesh Bamzai: President, Marketing
- Satish Arunachalam: General Manager, Finance
- Kiran Kumar: Deputy General Manager, Finance
- Peter Bains: Director, Syngene International
- M.B. Chinappa: President, Finance, Syngene International
- Manoj Nerurkar: Chief Operating Officer, Syngene International

## **Presentation Session**

*Moderator:* Ladies and gentlemen, good day and welcome to the Biocon Limited Q3 FY13 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 Ms. Urvashi Butani of CDR India. Thank you.

*Urvashi Butani:* Thank you. Good afternoon everybody and thank you for joining us on Biocon Limited's Q3 FY13 conference call. We have with us on the call today Ms. Kiran Mazumdar-Shaw, Biocon's Chairman and Managing Director and her colleagues from the senior management team. We will begin this call with the opening remarks from Biocon's management followed by an interactive Q&A session. I would like to add that some of the statements made in this call may be forward-looking in nature and a note to that effect is stated in the release sent out to you earlier. Now, I would like to invite Ms. Kiran Mazumdar Shaw to briefly discuss the company's performance for the period ended 31st December 2012.

Kiran Mazumdar- Shaw: Thank you Urvashi. Good afternoon and welcome to Biocon's investor conference call for the nine months ended 31<sup>st</sup> December 2012. I would like to start by wishing everyone a very happy, prosperous and rewarding 2013. I am pleased to report that we have started this year by announcing a very strong performance. We have delivered a robust 23% consolidated top line growth both for Q3 as well as for the 9M FY13. On a YoY basis, our revenues have grown from 536 Crores to 660 Crores for the quarter and from ~ 1,540 Crores to ~1,900 Crores for the nine months. EBITDA has also grown by 18% this quarter from Rs. 142 Crores to Rs. 167 Crores and 11% at the nine months level to Rs. 472 Crores. This growth is attributable to a combination of increased volumes, price increases as well as better export realization. PBT has also been strong this quarter at Rs. 118 Crores which is a 23% increase over the last year. PBT for the 9 months stood at Rs. 331 Crores, which is a 17% increase compared to the previous fiscal.



Taxation has risen sharply both this quarter as well as at the 9M level as many units came out of the scope of tax benefits under the SEZ and EOU scheme. Subsequently, the PAT level is slightly muted compared to PBT. However, it remains strong. We have seen PAT level at 260 Crores for the nine months period and 92 Crores for Q3.

For the first nine months of this fiscal, R&D investments have risen 44% to 121 Crores compared to 84 Crores last year. This, I believe, is indicative of the good progress being made by various programs in the clinic, which in turn is indicative of the approaching approvability of many of these programs. One such successful outcome of R&D investments has been the recent regulatory approval of our novel first-in-class molecule Itolizumab for Psoriasis. We plan to launch this molecule in the Indian market around mid-2013 and expect to recoup R&D investments for our India development within four years. I will also touch upon other programs that are progressing well in the development pathway later in my comments. R&D is integral to our business model and we are confident that the incremental investments that we are making in R&D will provide large and sustainable growth for the future.

I would now like to provide greater granularity on our various businesses for the nine months ended 31<sup>st</sup> December 2012.

- Small molecules and Biosimilar Insulins have grown by 25% from 894 Crores to 1,120 Crores. This growth has largely come from business expansion of Insulins and APIs in the emerging markets and Tacrolimus and Fidaxomicin sales to the US.
- Branded Formulations have grown 35% from 194 Crores to 263 Crores.
- Research Services added about 100 Crores and grew 34% from 292 Crores to 391 Crores for the nine months this fiscal. At a profit level, Research Services have grown 35% from 49 Crores last fiscal to 66 Crores this fiscal reflecting strong earnings.

As mentioned earlier, R&D investments have risen significantly this fiscal and reflect the progress being made by our various Biosimilars and Novel Molecules programs in the clinic, including a global and an Indian Phase-III clinical trial for Biosimilar Trastuzumab. I would also like to state that we have completed the treatment phase for the second part of our European Phase-III trial for recombinant human insulin for the evaluation of immunogenicity and safety over a 12-month period. We are currently compiling the data and once the results are available we will have a presubmission interaction with European Health authorities and proceed with the filing.

Another important milestone this quarter was the receipt of marketing approval from DCGI for our 2nd Novel biologic, Itolizumab which has a differentiated mechanism of action. It has demonstrated an excellent efficacy profile with very low incidence of opportunistic infections. We will introduce this molecule under the brand name of Alzumab in the coming fiscal once we receive manufacturing approvals. This important event enhances the licensability of this late-stage asset where we intend to file an IND with USFDA later in the year. Itolizumab has shown promising preclinical and clinical efficacy in other auto-immune diseases like rheumatoid arthritis and multiple sclerosis. The Psoriasis trial also generated very valuable positive data for psoriatic arthritis which is a very large unmet need globally. We will thus evolve a strategy for global development, based on all the data available to us.



Our Novel Molecules business continues to progress well during the reported period. We have concluded a key Option Agreement for IN-105, our Oral Insulin program with BMS. As per the agreement, BMS will fund and help us design certain clinical trials to address the placebo effect that was observed in the earlier trials carried out in India. We expect to initiate the first of these trials shortly. We have also initiated patient recruitment for Phase-I of our novel, Anti CD 20 program, BVX 20 for Non-Hodgkin Lymphoma. R&D, therefore, continues to be a key thrust area to drive exponential growth in the future.

Coming to expenditure: imported raw materials, power and personnel costs have increased by 27%. However, our EBITDA has remained strong and has grown by 11% from 423 Crores to 472 Crores and PAT, despite the higher taxation, has grown 8% from 241 to 260 Crores for the nine months period. Our net cash position is a robust 695 Crores which shows that we have a very strong balance sheet. Our Malaysia project is making good progress and is on track to deliver additional insulin capacity by FY15 which will enable us to address growing global needs by that time.

Our outlook for the remainder of the year is optimistic and we expect to end this fiscal on a strong note. We are confident about accelerating growth across all our business verticals. I would like to mention here, that our carefully thought-out business model based on business growth verticals is delivering very well for us. Going forward, you will see a higher contribution from Biosimilar Insulin, Research Services and Branded Formulations apart from our core business of small molecule APIs in the next few fiscals. Our increasing R&D investments are reflective of the progress being made in this direction with all our research assets of Novel Molecule and Biosimilars progressing well on the development pathway.

I think I should stop at this point and open it up for the Q&A. Thank you.

## **Question and Answer Session**

*Moderator*: Thank you. We will now begin the Q&A session. The first question is from Ravi Agarwal from Standard Chartered Securities. Please go ahead.

**Ravi Agarwal:** My first question was on the rh-insulin program for Europe. You were mentioning that you are compiling the data there. Could you give some indicative timelines for this and the larger program on Glargine?

Abhijit Barve: The Phase III trial for rh-Insulin was a two-part study divided at the 6 month interval. We have just finished the second part. It typically takes a couple of months to compile the data; to ensure that the data is clean and all the queries on the data are resolved. We will then have a discussion with the regulators to get a feedback on the data package that we generate. This usually takes another couple of months. Based on all our earlier interaction with the regulators, we feel that the data package that we have generated to-date is sufficient. We are reasonably confident that we should be able to file it, once we get the requisite feedback. So we are talking about another 8-9 months for this entire process.



**Ravi Agarwal:** I presume that a discussion for getting the marketing partner is an ongoing process. We should see that getting announced in the next couple of months-is that correct?

**Rakesh Bamzai:** Yes, we are discussing with two contenders right now and the discussions are going on. We have not concluded anything yet.

Ravi Agarwal: The other question was on the BMS tie-up for IN-105. Kiran was alluding to some R&D payments which BMS might be making to the company for conducting the global trials to evaluate the placebo effect. Could you quantify that, what are the timelines and how much it could come to?

*Kiran M. Shaw:* BMS will be funding those clinical trials to a large part. There will be no material impact on the P&L with respect to those particular studies.

**Ravi Agarwal:** Our run rate of R&D essentially will be the run rate for our Biosimilars MAbs. There will be no additional cost coming from IN-105...

Kiran Kumar: That is correct.

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

Girish Bakhru: Kiran, you mentioned in one of the conferences that you expect about \$300 million top line from small molecule segment by 2018. Just wanted to know what are the clear drivers? If you can share the growth details between API and Insulin for the quarter and nine months that will be helpful.

*Kiran M. Shaw:* I would say that the key product segments in APIs are Insulin, Immunosuppressants and Statins. All these three are growing well. Each one of them occupies a very significant share of the API pie. However, Insulins is not just pure API play. We are talking about Insulin finished dosage sales to ROW market.

*Girish Bakhru:* Lastly on Statins, has any benefit of the disruption in the Atorvastatin market flown to Biocon?

**Rakesh Bamzai:** In the US statin market, Simva maintains ~40% market share; Atorva ~30%; Pravastatin ~15%; Rosuva ~10% and Lovastatin ~5%. So while we have significant market share in that 40% slice of the pie, we are also gaining market share in other statins. We have a significant market share in Prava; however in Atorva we are a new player, so it will take some time.

*Moderator:* Thank you. The next question is from Sudarshan Padmanabhan from HDFC Securities. Please go ahead.

**S** Padmanabhan: I was looking at the Biopharma export sales. This quarter has shown a substantial jump over the previous quarter. I wanted to know whether this run rate is sustainable



and whether this growth is because of Atorvastatin coming up or better upsides from Fidaxomicin...

*Kiran M. Shaw:* I think this growth rate is sustainable and we have seen growth in all the products that you mentioned.

**S** Padmanabhan: Coming to your Biopharmaceutical branded business, there has been a slowdown which is more or less in line with the industry slowdown as well, but I wanted to know what is exactly happening on the ground, in a sense that has there been any fewer launches and what has really caused this slowdown, not necessarily for Biocon but even for the entire industry?

**Kiran M. Shaw:** There has been a slight slowdown in the last quarter. That is largely because of the uncertainties around the drug pricing policy. We are very confident that the fourth quarter will not have this kind of slowdown and we hope that the entire industry will also pick up because unfortunately the government has been sending very confusing signals. I think there has been a wait and watch approach from several quarters but we are seeing that easing up.

Rakesh Bamzai: Adding to what Kiran said, you would be aware that the months of September to December are supposed to be healthy for the patients leading to a cyclical slowing of growth in this quarter. In addition to that, because of the pricing uncertainty, approval delays and other industry wide phenomena, the overall industry did not grow as much; it was around 9%. Biocon on a nine month basis has grown at 35%. This quarter was slower than the initial growth but this growth will come back in the next quarter.

**S Padmanabhan:** Did we see lower launches this quarter?

**Rakesh Bamzai:** We did not have a lot of launches planned in this quarter; we will have more launches happening in the next six months.

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

**Bhavin Shah:** You mentioned about Insulin market share gains- is it specific to any market or is it across the board?

**Rakesh Bamzai:** Overall Insulins have grown a lot for us. We currently have approval in 44 countries, we have 30 countries under registration and it is growing in India as well. We have seen substantial growth and we expect it to continue.

**Bhavin Shah:** The price increases that you mentioned, are they specific to Immunosuppressants or any category?

**Rakesh Bamzai:** We always aim to increase our gross contribution, at the same time there has been an impact on the raw material because of exchange fluctuation. So, across the board we have had better realizations.



**Bhavin Shah:** So it is really well pattered across segments that you are referring to?

Rakesh Bamzai: Yes.

**Bhavin Shah:** And on Herceptin (Trastuzumab), do you think you will be there at the time of market formation or probably a little later than expected?

**Abhijit Barve:** We have just announced the start of the global study. We intend to complete it in a timely manner and hope to be at the market formation day but it also depends on the time it takes for the regulators to review the file.

**Bhavin Shah:** I believe that Synthon and Celltrion have advanced in this specific molecule. So just trying to get a little bit more insight on how Biocon could be placed when the market opens up in Europe?

**Abhijit Barve:** Barring any regulatory delays, we should be there in time.

**Bhavin Shah:** On research services, any new client additions in a meaningful way that has happened in this quarter?

Peter Bains: Yes, we had some important new client additions in the last nine months.

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

**Ranjeet Kapadia:** My question relates to NPP- the New Pharma Policy's effect on Biocon brands. And second question relates to market size of recombinant human insulin in Europe?

**Kiran M. Shaw:** To begin with, NPP does not have a significant impact on any of Biocon's products and as far as European registration is concerned, we have earlier explained the dynamics in terms of the market size. It is a shrinking market for the innovators because they are trying to move the market towards analogs but for Biocon this will continue to be a very large addressable opportunity.

Ranjeet Kapadia: Which year will you be reaching the plateau?

*Kiran M. Shaw:* Based on when the approval comes in, we expect to be in the market by about 2015 and we hope to ramp up over the next five years thereafter to peak sales.

**Moderator**: Thank you. The next question is from the line of Monica Joshi from Avendus Securities. Please go ahead.

*Monica Joshi:* Kiran, just some clarification on the BMS deal. If we understand correctly, you said that all the clinical trials from now on will be funded by BMS. Is that correct? Or is it a part of the trial cost that will be reimbursed by BMS?



*Kiran M. Shaw:* As of now, the clinical trials that are being planned will certainly be funded by BMS. If we need additional clinical trials then that will be discussed between the partners. As of now, BMS will be able to fund most of the work that is required to answer certain questions.

Monica Joshi: And these trials are proposed in the US, is that correct?

*Kiran M. Shaw:* Most of these will be conducted overseas but some of them will also be conducted in India.

*Monica Joshi*: And you carry this through to the Phase-II, post which BMS has an in-licensing option?

Kiran M. Shaw: Yes.

*Monica Joshi:* Is the in-licensing value predetermined or is it a function of what data is generated during the trials?

*Kiran M. Shaw:* It is pre-determined; it is a pretty large licensing opportunity if we come to that stage.

*Monica Joshi:* What is your time-frame for completing Phase-II trials before you hit that kind of benchmark?

Kiran M. Shaw: Approximately two years.

*Moderator:* Thank you. The next question is from the line of Krishna Kiran from ICICI Direct. Please go ahead.

Krishna Kiran: Any FOREX loss in the first guarter?

Kiran Kumar: There has been a marginal, low single digit FOREX gain in the quarter.

*Krishna Kiran:* Rakesh, you were talking about a marketing partner. Is that only for rh-Insulin or for all four products?

Rakesh Bamzai: All 4 biosimilar insulins & analogs for US & EU.

*Krishna Kiran:* We have seen increasing raw material costs. Any particular one-off in this, or will this be the rate going forward?

*Kiran M. Shaw:* Given the depreciation in the rupee, we have seen an increase in our raw materials prices which depend on factors like oil prices, power costs & solvent costs.

Krishna Kiran: Have we hedged anything in terms of our raw materials?

Kiran Kumar: No, we do not hedge raw materials separately. We hedge our net FOREX exposure.



*Moderator:* Thank you. The next question is from the line of Meeta Shetty from AMSEC. Please go ahead.

*Meeta Shetty:* You are talking about a 20% growth, so are we looking at 700 Crores plus run rate for FY14 on a quarterly basis? We already have a base of Rs. 611 Crores for Q4. So just trying to...

*Kiran M. Shaw:* When you look at our annual growth that certainly seems to be the number. However, we do not have to look at it on a Q-on-Q basis. We expect to attain ~\$700 million revenue, taken at an exchange rate of 50, by FY15.

**Meeta Shetty:** Secondly, on the R&D, we currently have a run rate of sub 45 Crores. Now that we have other programs excluding IN-105, like Anti-CD6 and others which we plan to take to US; how much would that inflate your R&D going ahead?

*Kiran M. Shaw:* I think you must expect R&D investments to increase going forward. We cannot quantify it at this point, because it is dependent on regulatory approvals, development progress, how we design the trials, recruitment rates etc. For the global development of our programs, we will try to get a partner on board. So I do not think the entire impact will be on Biocon.

*Meeta Shetty:* And on the tax rate, we have seen some increase particularly in the last two quarters. So where do you think the tax rate would be for the next two years?

Kiran Kumar: You should take it at ~20% level.

*Meeta Shetty:* I believe that is what we had been guided at the start of the year. So it still remains at 20%?

*Kiran M. Shaw:* We maintain those numbers because we have other SEZ units which will come to some kind of tax benefit.

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

**Surya Patra:** We have already discussed about the growth that we have delivered in Biopharma, which has grown almost 30% in the quarter ex-licensing. I think most part of this has been driven by the insulin launches in the various emerging markets. So can you please add some color to that: the key markets that we have entered, the kind of potential of those markets or what is our market share in that Biosimilar Insulin front?

*Kiran M. Shaw:* Our lead markets are Mexico, Brazil, Latin America, Africa, Middle East, North Africa, Southeast Asia, and Ukraine.

*Surya Patra:* What is the cumulative size of the markets that we are addressing at the current moment?

Rakesh Bamzai: It is a sizeable opportunity.



*Surya Patra*: So, going ahead, the insulin pie would possibly be much bigger than the immunosuppressant pie than what it currently is?

**Kiran M. Shaw:** You are absolutely right. The insulin pie will become much bigger than Immunosuppressants in the next two years.

**Surya Patra:** On the power cost side, there is a report that plants around Hosur are getting power from the grid for around 10-12 hours a day. Is that a concern for Biocon?

*Kiran M. Shaw:* I think being a Biotech company we cannot rely solely on the grid, hence Biocon generates captive power as well. I do not think that if Hosur or Bengaluru does not generate enough power, it would impact us but if they did generate power at the lowest cost it would help us.

*Moderator:* Thank you. The next question is from the line of Vivek Agarwal from MP Advisors. Please go ahead.

*Vivek Agarwal:* Can you give me some updates on the ramp up of Fidaxomicin that you have partnered with Optimer?

Rakesh Bamzai: The information is publically available. In Q2 CY12 they launched in UK, Australia and certain parts of Nordic. In Q3, they did an extended launch in UK and added few more countries like Canada, Greece, and Netherlands. At the end of the last quarter, they were present in as many as 15 countries including Hungary, Slovakia, Czech Republic, France, Netherlands, Greece, Canada, Nordic, and Australia. So they have continued ramping up and we continue to supply them.

Vivek Agarwal: Can you give me the constant currency growth of the Biopharmaceuticals?

**Kiran Kumar:** Biopharma (excluding branded formulations) has seen a 12% growth for the nine months in constant currency terms. Compared to the previous quarter where the exchange rate has been largely flat, there is negligible growth on account of FOREX.

Vivek Agarwal: What is the net impact of FOREX on your bottom line?

**Kiran Kumar:** Low single digit gain in the current quarter.

**Moderator:** Thank you. The next question is from the line of Hitesh Mahida from Fortune Equity Brokers. Please go ahead.

**Hitesh Mahida:** When can we expect the listing of Syngene? And secondly, what are our plans as far as Itolizumab is concerned? What sort of estimates do we have in terms of top-line from this particular product?

*Kiran M. Shaw:* As you know we have been wavering about taking Syngene to the market. This was because we felt that the true value of Syngene was not being captured. The first step was to



make sure that we get a proper baseline valuation of Syngene. This was done through the investment that GE has made where they picked up about 8% equity stake at a post money valuation of \$325 million. We will be advised by our financial advisors on the IPO timing. In the meantime, we are getting into a state of readiness so that we can get to the market at a very short notice. Just to emphasize, we would not like to take Syngene to the market to realize cash, but to unlock value. Your second question was about Itolizumab. We plan to launch this product under the brand name Alzumab later this year and this could be a 100 Crores product within four years of its launch.

**Moderator**: Thank you. The next question is from the Krishna Prasad from Kotak Securities. Please go ahead.

Krishna Prasad: How are we placed on the hedges front currently?

Satish Arunachalam: We take a hedge on the net exposure, evaluated on a quarterly basis.

Krishna Prasad: So what is the current outstanding hedge that we have?

**Kiran Kumar:** All our contracts are plain puts or range forward at this point in time; except for the one in Syngene where we have a forward contract taken about four years ago at the initiation of the BMS contract.

Krishna Prasad: Could you quantify the amount of hedges that you have?

Satish Arunachalam: We can take it offline.

*Krishna Prasad:* I think you had mentioned that the tax rate would hover around 20-21%. Is that correct going forward?

Satish Arunachalam: That is right.

*Krishna Prasad:* Is there any specific reason why we have seen this tax rate go up? Or should Malaysia help in bringing that down over a period?

**Satish Arunachalam:** We had indicated 18-20% tax rate at the beginning of the year. Once Malaysia comes up, we will definitely see the tax rate going down.

*Moderator:* Thank you. The next question is from Hardik Vora from Motilal Oswal. Please go ahead.

*Hardik Vora:* I think it was mentioned that the Biopharma sales for the nine months on constant currency basis is 12%. Is that right?

*Kiran Kumar:* On a constant currency basis, biopharma sales excluding branded formulations grew at 12%.

Hardik Vora: Can I get the similar number for Contract Research on total sales for nine months?



Chinappa: There is about a 10% benefit of exchange in the Contract Research numbers.

Hardik Vora: Have you added more MRs in this quarter?

Rakesh Bamzai: We are below 1700 currently.

Hardik Vora: The plan is to increase this going forward to achieve the growth target...

Rakesh Bamzai: Yes.

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

**Nitin Agarwal:** A question on the Immuno suppressants and the statin business. In these two segments, do you still see growth coming through for the next two to three years, what are the drivers for these two businesses?

*Rakesh Bamzai:* The growth will continue because there will be new statins coming in the market along with the existing statins which are also growing. For example, the share of Pravastatin in the total statin space has grown from 11% to 14%. So, statins continue to have a positive and bright future in the US.

**Nitin Agarwal:** What would be the primary drivers in Immuno suppressants: would that be genericization of some of the newer Immunosuppressants or do you still see market share gains in the current ones?

**Rakesh Bamzai:** There are a few Immuno suppressants in the pipeline, so there will be new launches in the markets where it is possible. In the existing Immuno suppressants, we are gaining more market share.

Nitin Agarwal: In the US, what is the market share that you hold in Immunosuppressants?

Rakesh Bamzai: It is close to 30%, including all the molecules that we have launched in US so far.

**Nitin Agarwal:** On the contract manufacturing business, are there any other products like Fidaxomicin that you see coming through the commercialization phase over the next couple of years?

**Kiram M. Shaw:** As a strategy we look for partnerships in building up the molecules via codevelopment. They are a number of them in different phases.

**Nitin Agarwal:** But is there a late Phase-III product, which has a reasonably higher probability of coming through?

**Peter Bains:** There are opportunities on the contract research side to extend the service platform into manufacturing as well. We have a number of these programs moving forward.



**Nitin Agarwal:** Peter, earlier we were looking at expansion of the Syngene model in terms of a contract manufacturing framework. Where do we stand on that?

**Peter Bains:** You are right, there is a framework for doing that and it will be a natural evolution of the business that we already undertake for many of our customers. We will be looking to expand the manufacturing component of our contract service.

**Moderator:** Thank you. The next question is from the line of Anand Rawani from Horizon Research.

*Anand Rawani:* Let us say Biocon is to launch Itolizumab in July-September 2013 and you expect around INR 1 billion revenue between FY14 to FY17. I want to understand what kind of an EBITDA margin you would be looking at.

*Kiran M. Shaw:* We are looking at healthy EBITDA margin on this kind of product; it has to be a minimum of 30%.

Anand Rawani: What is the EBITDA margin of Syngene for this quarter?

Chinappa: Above 30%.

**Anand Rawani:** And how much of the INR 5.392 billion of deferred revenue has been realized or taken to the income statement in the last nine months?

**Satish Arunachalam:** The deferred revenue from Pfizer stood at Rs. 4.929 Billion at the beginning of the year. None of the deferred revenues actually gets reflected in the P&L. We adjust the expenses on account of the insulin program against this amount. A sum of about 28 Crores was adjusted in the last 9 months.

Moderator: Thank you. The next question is from the line of Kaushik Poddar from KB Capital.

*Kaushik Poddar*: Madam, you had said in your opening address that you have spent Rs. 121 Crores towards your R&D. Is this Rs. 121 Crores completely charged in these nine months itself or has something been capitalized of this R&D expense?

Kiran Kumar: The entire amount is passed through the P&L account.

*Kaushik Poddar:* How is the income that you received from Pfizer being accounted for across the years?

**Satish Arunachalam:** Until last year the income was recognized as part of licensing revenues, but since the beginning of this year we are adjusting it against the R&D spends on insulin program. So it is not reflecting as a licensing income but in a way, it is reducing the R&D spends.

Kaushik Poddar: So how much income have you taken which has been charged off against R&D?

Kiran Kumar: 28 Crores for the first nine months of this year.



Kaushik Poddar: How much income is yet to be recognized?

*Kiran kumar:* That is reflected as part of deferred revenue.

*Moderator:* Thank you. The next question is from the line of an individual investor, Vipul Shah. Please go ahead.

**Vipul Shah:** I had a question regarding the deal with BMS for oral insulin. Is there any clause in the contract which allows either party to back away from this arrangement?

Kiran M. Shaw: Every contract will have such a provision.

Vipul Shah: Can you elaborate under which circumstances...?

*Kiran M. Shaw:* This is a small option agreement and I do not think it is in the interest of either party to back away. Like every legal agreement, we have provided for a termination clause. And if the data does not go well in the trial, then either side has the option of terminating.

**Vipul Shah:** If the data is satisfactory on the completion of phase II, is it contractual on your part to enter into an agreement with BMS only?

Kiran M. Shaw: Yes, if they opt for it we have to go with them.

*Moderator:* Thank you. The next question is from the line of Ravi Agarwal from Standard Chartered Equities. Please go ahead.

**Ravi Agarwal**: Just one question on Contract Services business. How much is our gross block in the research services business today?

Chinappa: Gross block is \$120 million + for Syngene & Clinigene

Ravi Agarwal: What is our CAPEX expected in the next two to three years?

**Peter Bains:** We will not be able to share that at present.

**Ravi Agarwal**: The next question was on margins. We have been clocking around 23% after netting off the Pfizer income. On a 1-2 year timeframe, what is the margin outlook for our company? Can we expect it to remain around these levels or do we expect some expansion or compression of these margins going forward?

**Chinappa:** The drag on margins in the last 2 years is on account of the increasing R&D cost without commensurate licensing income. Over the next two years we should see licensing income counter the increased R&D spend and margins will revert to the levels that we have enjoyed prior to the spike in R&D spend.

*Ravi Agarwal:* So we can actually expect a scenario where margins should go up to maybe 25%, 26% levels in the next two to three years?



Kiran M. Shaw: Yes.

Ravi Agarwal: What do you think would drive that, the domestic business or Syngene?

**Kiran M. Shaw:** Mr. Chinappa just mentioned that as we get into partnering deals, the licensing income will offset some of the R&D spends and increase the margin. In addition to that we are getting into a better product mix for our small molecules which should improve margins as well. Our Biosimilar business certainly expects to generate much higher margins. Research Services is already delivering margins in the mid-30s. So we expect to see some healthy margins going forward.

Ravi Agarwal: Can I have the CAPEX program for this year?

**Kiran M. Shaw:** The key CAPEX for us is the Malaysia project which is roughly \$200 million investment. It is a very important capacity expansion project for insulin, which is expected to come on stream by FY15.

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

**Nitin Agarwal:** Kiran, on the licensing front, are we waiting for some milestones to come through before we start approaching partners or are the discussions already underway? I am referring to Itolizumab and rh-insulin, how do we see the partnering for these programs playing out?

**Kiran M. Shaw:** We believe that we can unlock greater value once we file IND for Itolizumab. We would like to ramp up the licensing discussions after that, so that we can unlock maximum value for this novel biologic. If you are hasty and prematurely license it, you may not unlock the true value. It is an opportunity for us to carefully position this product in the market. So we will take some time to find the right licensing partner at the right valuation.

**Nitin Agarwal:** When do we see the IND filing? Are there any specific process steps that lead to it because we have already done the trials in India? Do you need to do some additional trials before you file the IND?

*Kiran M. Shaw:* No, we do not need to do that. We need to basically compile all the data that we have generated in India.

**Abhijit Barve:** The plan is to file the IND for this particular molecule over the next 3-4 months. We have a pre-IND meeting on Itolizumab scheduled with the FDA. Post that meeting we will compile the documents and then file the IND.

*Nitin Agarwal:* On the recombinant insulin in Europe, how do you see that playing out? Are we waiting for certain milestones to come through before we engage in discussions?

**Abhijit Barve:** We are in advanced discussions with a couple of probable candidates and the milestones will only come up after signing the contract.



*Moderator:* Thank you. The next question is from the line of Bhagwan Choudhary from India Nivesh Securities. Please go ahead.

**B.** Choudhary: How much of the licensing income have we recognized at the EBITDA and PAT level?

**Kiran M. Shaw:** This quarter, we have seen very little licensing income and therefore it tells you that we have seen a very strong performance from all our core businesses. The 660 Crores that you are seeing at the topline is representative of our core businesses with very insignificant amount of licensing income reflected in those numbers.

B. Choudhary: So the same is at the EBITDA and PAT level ...?

*Kiran M. Shaw:* Yes. Last year there was a much higher licensing income. PAT level was better because our taxation level was a little lower.

**B.** Choudhary: Out of the 31 Crores that we received in that quarter, how much was realized at EBITDA level?

Kiran Kumar: It was 11 Crores at the EBITDA level.

**B. Chaudhary:** And at PAT level, same accordingly?

Kiran Kumar: Yes.

*Moderator:* Thank you. As there are no further questions I would now like to hand over the floor back to the management for closing comments.

**Kiran M. Shaw:** Thank you for participating in this Q3 Conference Call. If you have any further clarifications or questions, please do not hesitate to contact us and we will be happy to provide you with answers. Thank you.

*Moderator:* Thank you. On behalf of Biocon Limited that concludes this conference. Thank you for joining us and you may now disconnect your lines.

\_\_\_\_\_

Note: This document has been edited to improve readability.