



## BIOCON LIMITED

### Q2 – FY 2010 Analyst / Investor Conference Call

22<sup>nd</sup> October 2009, 03:00 PM IST

**Mansi Parekh:** Good afternoon all and thanks for joining us on Biocon Limited's Q2 and H1FY2010 results conference call. We have with us on this call Ms. Kiran Mazumdar-Shaw, Biocon Chairman and Managing Director and also her colleagues who are part of the senior management team. We will begin the call with the opening remarks from the Biocon management, followed by a Q&A session with all of you. I trust you all have received a detailed release on the results announcement along with the fact sheet, which has been e-mailed to you earlier and is also available on Biocon's website. Before we begin I would like to state that some of the statements made in today's discussion may be forward looking. Now I would like to invite Ms. Kiran Mazumdar-Shaw to briefly discuss the company's performance for the quarter ended September 30<sup>th</sup>, 2009.

**Kiran Mazumdar-Shaw.** Good afternoon, everyone. It is a great pleasure to hold this conference call with all of you. At the outset, I hope that you have all had a very good Diwali and I hope we can really look at the year ahead with a lot of confidence and I hope that every one of us will have a bright future as we look to build not only our own companies, but also our country's future.

I would like to start by saying that we are very pleased and hope that we have met your expectations in terms of our performance for this half of the year. As you can see from the announcements that we have made today, Biocon has delivered a very strong set of numbers. At the group level we have seen a rise in the revenue level by 50% to roughly Rs.1,100 crores and about Rs. 700 crores without the AxiCorp numbers. What is also very important is that, at the PAT level, we have seen a 30% growth without factoring the MTM, and of course if you factor in the MTM, then it's a huge difference of 230%. So, overall, we are very pleased with the performance in this quarter and I think there are a few things that I would like to point out. We have seen good growth being delivered across all segments of our businesses. Our Research Services business has delivered good growth. Our Branded Formulations has also been a very good performer this quarter and we see this as a very important growth driver going forward. Our API business has done extremely well and here our margins have been pretty good because we have seen that the stable prices we are seeing in our APIs, combined with some of the small FOREX advantages, have helped drive some growth in this segment. We have also seen good numbers coming in from our insulin and biopharma businesses, not just in India, but also globally. We have also seen good numbers coming from licensing income. Whilst at a group level, excluding AxiCorp, the revenue growth is only 17%, you can see that at a PAT level and at an EBITDA level, we are witnessing good year-on-year growth of 24% and 30%. This is really coming from very improved margins in our businesses, thanks to the kind of product mix in this quarter's sales.

Another important point I would like to touch upon is that Biocon has been building its biopharmaceuticals strategy by investing in creating global scale. This is the beginning

of that pay off time and what you are now seeing is Biocon getting to become recognized as a very strong player in the biopharma space. Here, I would like to highlight some of our partnerships and the areas we are focusing on. One, as you know, is our partnership with Mylan. The biosimilar space is certainly a very important space for us. USD 25 billion worth of biologics are going off patent by 2016. This opens up some very attractive opportunities which Mylan and Biocon are jointly going to address. We see ourselves as being a key player in this segment as these markets open up. The emerging markets obviously are going to open up and be accessible to us much earlier than the regulated markets, but even US and Europe are seriously looking at getting approvals for biosimilars. I think one can gauge the importance of biosimilar opportunities by looking at the numerous, large pharma companies that have expressed interest in this segment. It is inevitable and is really going to happen sooner than later. We believe that the Biocon-Mylan combination is really a unique partnership with definite advantages over other competitors given the cost and capability base which will be synergized by the two of us.

Our recent announcement of our acquisition of the facilities of IDL Specialty Chemicals is another very important step in the right direction. This deal is about addressing an emerging opportunity for some newer generic APIs because certain patent protections are going to start opening up some new opportunities for us. In this case, it was really a question of whether we opted for a green-field expansion avenue or whether we do it through an inorganic route. The inorganic route through IDL became the preferred option finally because it really gave us a cost-effective solution in terms of expanding our API manufacturing capabilities. It was not just about cost but I think it was also about speed. It allows us to hit the ground running as well as start earning revenues from this expansion starting this fiscal. So I think this is a very important acquisition and a very cost-effective one. I would like to add that this is not about acquiring the business but about acquiring the physical assets of this firm.

The next thing I want to touch upon is our research partnership with Amylin. Amylin is a very important research partner for us in diabetes. As you know, Biocon is very committed to its innovation and novel program and here we believe that the Amylin partnership is going to be very valuable because Amylin is known and recognized as a leader in diabetes research. Also, the Biocon-Amylin partnership brings together some very synergistic capabilities and the program that we are looking at is a very interesting, first-in-class kind of program based on Amylin's proprietary hybrid technology.

And now I would like to quickly shift gears and touch upon some of Biocon's own novel programs. I think Biocon's oral insulin is being watched very carefully and with great interest from people all across the world. We are hoping that this will become a blockbuster global opportunity for Biocon because we will look at partnerships to gain that global access. Having said this, I must also be very realistic. This is a program that will have to wait until the clinical data emerges, which will only happen by around June 2010. Patient enrolment is nearing completion but the unblinding of the data will happen only by around June next year. So that is the time we feel that we may be able to make a big announcement on this.

We have a second program which also looks promising and that is the Anti-CD6 - the T1h program. Again the data that we have generated from Phase 2 trials in Psoriasis and Rheumatoid Arthritis look very promising. We have seen very good outcomes in

Psoriasis and Rheumatoid Arthritis patients who have been administered this drug. The Psoriasis trial report is complete and we are now hoping to commence Phase 3 trials shortly. Rheumatoid Arthritis trials will also commence soon after.

Therefore, overall, I think, we are very gung-ho about our innovation pipeline. We believe that for a company of our size, we have a very respectable and enviable, if I may say so, pipeline of innovative products.

We also have our IATRICa program, which is again about a new class of antibodies and we hope that, if we go by the animal data that we are seeing, we hope to be able to file an IND late next year. This means that we can start clinical trials for these conjugated antibodies. BVX-20 is also making progress in the preclinical stage. As far as our Branded Formulations are concerned, today they account for about 12% of our overall revenues but going forward I think you will see this becoming a larger part of our business. We expect Branded Formulations to account for almost 25% of our business in 7 to 10 years.

To sum up, everything is on track and I think this is really about Biocon getting out of its gestational mode and getting into its growth mode. Therefore, I am hoping we can provide you with the confidence that we are on the right track and that we are confident of repeating the H1 performance in the second half of the year. I think we will be able to end the year on a very good and positive note.

With that, I will bring my opening comments to a conclusion and I now invite question and answers from all of you. Let me introduce my colleagues - I have my colleague from R&D, Dr. Harish Iyer, our COO, Dr. Arun Chandavarkar, our President Marketing, Rakesh Bamzai, our President Finance from Syngene, MB Chinappa, we have our Vice President Finance, Indranil Das, and of course our CFO, Mr. Murali Krishnan, and the Vice Chairman John Shaw, and myself. We would be very happy to take on your questions now. Thank you.

### **Question and Answer Session**

**Moderator:** The first question comes from Mr. Nimesh Mehta of MP Advisors.

**Nimesh Mehta:** Good afternoon and congrats for a great set of numbers. First of all I would like to know that we have reported about Rs.106 million of licensing income, whereas we were not expecting this income as per your guidance, so can you throw some light on how sustainable this could be and what is the outlook going forward on that?

**Kiran Mazumdar-Shaw:** I think we had indicated in our last call that we are expecting some licensing income from the Mylan co-development deal coming over two fiscals and this is the first time the licensing income is reflected in our books of accounts. We can expect more licensing income as we make progress in these various biosimilar programs that we are co-developing, and you are likely to see a steady stream of licensing income for the next five or six quarters.

**Nimesh Mehta:** So this licensing income is towards R&D expenses that Biocon is likely to spend?

**Kiran Mazumdar-Shaw:** No, this is about milestone achievements. We are supposed to reach certain milestones and at each one, we recognize the income. Now that we have met a milestone, we have recognized the first milestone payment. We expect to be able to meet the other milestones also as these are biosimilars and we are quite familiar with this segment having developed quite a few ourselves in the past.

**Nimesh Mehta:** Right. So we will see similar kind of things happening almost every year or how frequently will it happen?

**Kiran Mazumdar-Shaw:** Well we can expect them over the next five to six quarters.

**Nimesh Mehta:** Okay. Secondly, in spite of this licensing income, which is kind of a flow through to the profitability, we have seen that between the last quarter, that is Q1 and Q2, the EBITDA margin has actually come down a little bit. So, if we exclude the licensing income, then the EBITDA margin has been substantially down. Can you give any reasons for this?

**Murali Krishnan:** The primary reason for that is the R&D expenses have increased on account of various programmes. Our R&D expense, which was about Rs. 60 crores last year, is likely to be around Rs. 80 -100 crores this year. The cost of these programs is being charged to the P&L account and therefore you cannot exclude the licensing income and compute the EBITDA.

**Nimesh Mehta:** Okay. Also, we have seen some robust performance in AxiCorp. On a year-on-year basis, the profit has shot up from about Rs. 2 crores to almost Rs.10 or 11 crores. Any specific reasons and how sustainable this can be so that we understand it better?

**Murali Krishnan:** This should also be sustainable. They have been able to source materials at better pricing and accordingly their gross margin levels have been increasing quarter-on-quarter. The indications are that these margin levels are sustainable.

**Nimesh Mehta:** Has this anything to do with the tender that they have got from the German market?

**Murali Krishnan:** That is one of the reasons.

**Kiran Mazumdar-Shaw:** Yes, I think Biocon has also played quite an important role in helping them bring down costs.

**Nimesh Mehta:** Okay. Finally, how much sales have you been able to generate from generic Tacrolimus and Mycophenolate Mofetil and if you can throw some light on that?

**Rakesh Bamzai:** The product patent on Mycophenolate Mofetil expired on 9<sup>th</sup> May and we have participation in the US through three customers. On Tacrolimus, in phase 1 it was only Sandoz that got an approval. In phase II, Biocon's customers are likely to participate. People are buying material from us and building up stocks.

**Nimesh Mehta:** Are there any sales you have booked for Mycophenolate Mofetil this quarter?

**Rakesh Bamzai:** Part of the bigger picture.

**Nimesh Mehta:** It is there, okay. And you expect any kind of rapid ramp up now or it will be kind of the same. If you can share the number, that will be great.

**Rakesh Bamzai:** We cannot share the numbers because we have signed CDAs with these customers but we will see Tacrolimus sales in this year.

**Nimesh Mehta:** Thanks very much and that's all, sir.

**Moderator:** Next question comes from Mr. Ranjit Kapadia of HDFC Securities.

**Ranjit Kapadia:** Good afternoon and hearty congratulations for a good set of numbers. My first question refers to the raw material cost. We have seen that the raw material cost has increased substantially during the quarter by 380 basis points from 53.2% to 57% whereas the same in the half year has also gone up substantially by 660 basis points, from 49.5% to 56.1%, so I want to know the steps that the management is taking to control this cost. And my second question pertains to IDL Specialty Chemical. Can you quantify how much sales, how much have we paid, what is the breakeven and when is the company expecting to achieve breakeven?

**Kiran Mazumdar-Shaw:** To answer your first question, I think, I will start by saying that the reason why the material cost is higher is largely because of the fuel prices that were very high at a time when we have actually booked some of the products and these purchases are being consumed in our current production programs.

**MB Chinappa:** Let me add that there is also a play of the mix of sales. The overall business is doing well and the product-wise margins are similar to those in the previous quarters. The numbers that you are seeing is the consolidated mix and to that extent there is always a variability of 2-3% between different quarters.

**Ranjit Kapadia:** But sir, because of this, if you see the first half, your margins have shrunk by almost 80 basis points, from 21% to 20.2% and that is mainly because of the material cost. This quarter we have performed well - we have improved our margins by almost 200 basis points from 17.6% to 19.6%. So the main reason appears to be the material cost that is pulling down the margins. Do you have any thoughts on that?

**MB Chinappa:** Primarily, as I said, it is the mix of sales. The business of AxiCorp is completely different from the rest of the businesses and then within biopharmaceuticals, again, different products have different gross margins. So there is a play to the extent of the mix of the business that is represented in the sales. But what we wanted to assure you all is that by product groups, we are not seeing a decline in margins.

**Ranjit Kapadia:** Okay and sir, the second question is regarding the IDL Specialty Chemical?

**Kiran Mazumdar-Shaw:** IDL Specialty Chemicals is not just about acquisition of a business. It is about the acquisition of a facility. So we have only acquired the production facilities of IDL Specialty and, of course, that has been done in a very cost-effective way. Unfortunately, we are unable to share the actual amount paid for these facilities at this point in time because we still have to go through some formalities and we are bound by confidentiality not to reveal this number. But I can tell you that when we had to make the choice between a green-field project versus an acquisition, this has certainly proven to be a much more cost-effective way of expanding our facilities.

**Ranjit Kapadia:** And madam, will the clients of IDL be our clients? Is that possible in the future?

**Kiran Mazumdar-Shaw:** Probably yes or no. Difficult to predict at this point of time, since our production plans & product mix can be different.

**Ranjit Kapadia:** Okay, thank you very much and all the best.

**Kiran Mazumdar-Shaw:** Thank you.

**Moderator:** Next question comes from Mr. Bino Pathiparampil of IIFL Capital.

**Bino Pathiparampil:** Hi. Congrats on a good performance. I need a couple of clarifications from the earlier questions. The IDL Specialty Pharma business - I know you can't share details of the transaction - but just from a projection perspective, from this quarter onwards how much might it add to the top line? Would you be able to give some kind of guidance?

**Kiran Mazumdar-Shaw:** I don't think we will be able to add anything this quarter, but I think that in the next quarter, we might be able to start earning some kind of revenues from that facility. But the real, full impact will be only in the next fiscal.

**Murali Krishnan:** The transaction will close this quarter and there will be some amount of investment made in getting this facility up to Biocon standards which will happen in the next quarter, followed by trial production. So April 2010 onwards is when we will see revenue coming from this facility.

**Bino Pathiparampil:** Okay, so it is not like having ongoing revenues...?

**Murali Krishnan:** As I mentioned earlier, having taken over this facility, we would like to get it up to Biocon's standards and after that we will start operations. Otherwise, it is an operable facility.

**Bino Pathiparampil:** So the current business, what is happening there?

**Murali Krishnan:** We may not continue with those products.

**Kiran Mazumdar-Shaw:** Let me explain. We have bought this facility for some of our products and we may lose our market if we don't start with those products ASAP.



**Bino Pathiparampil:** Okay right. And on AxiCorp, they must have launched Metformin, or rather started supplying Metformin on June 1<sup>st</sup> when the AOK contract took effect. So one month of Metformin sales could be included in this?

**Murali Krishnan:** Yes.

**Bino Pathiparampil:** Okay. So can we expect, when it becomes three months in the next quarter reporting, that kind of a growth coming up?

**Murali Krishnan:** You will certainly see this growth.

**Bino Pathiparampil:** Okay. And also on this depreciation and interest cost, has it started fully coming in to the P&L?

**Murali Krishnan:** It is more or less fully coming into the P & L.

**Kiran Mazumdar-Shaw:** I think this is the first time you are seeing the full impact of the capitalization of all the projects that we have engaged in up to now.

**Murali Krishnan:** Next quarter, you may see the additional depreciation element coming from acquisition of IDL's facility.

**Bino Pathiparampil:** Okay, right. But the interest cost has actually come down from the previous quarter.

**Indranil Das:** Precisely. If you see the secured loans, Biocon has repaid the foreign exchange denominated loans of nearly about Rs.100 crores and that is why interest is coming down and there is a sustainable sort of decline in the interest rate.

**Murali Krishnan:** Biocon does not have borrowing today. Most of the borrowings are only in Syngene and BBPL.

**Bino Pathiparampil:** Okay. And a last question - the expenses incurred on the trials of Oral Insulin, T1h, etc., what is the accounting treatment for that?

**Murali Krishnan:** They are charged to the P&L.

**Bino Pathiparampil:** On the biosimilar trial in Europe

**Murali Krishnan:** The expenses incurred in the Insulin trials in Europe are getting accumulated and will be amortized when we go commercial.

**Bino Pathiparampil:** Okay, great. Thank you very much.

**Moderator:** Next question is from Mr. Krishna Kumar of Capital Market.

**Krishna Kumar:** Madam, congrats for a good set of numbers.

**Kiran Mazumdar-Shaw:** Thank you.

**Krishna Kumar:** Madam, my question relates to FOREX hedging. If I remember correctly, the last time you informed us that 25% of the future earnings have been hedged with zero cost call option and 75% with some put option of paying back some premium. Is the same thing happening or any changes in policy?

**Murali Krishnan:** Yes, the same policy continues and there is no change.

**Krishna Kumar:** How much is the hedged amount?

**Murali Krishnan:** Today in Biocon we have about Rs.80 - 90 million.

**Krishna Kumar:** At the group level?

**MB Chinappa:** We maintain a hedge of 18 months net earnings, FOREX earnings, across the group.

**Krishna Kumar:** Is it possible to share Syngene and Clinigene numbers?

**MB Chinappa:** That's represented in the fact sheet. The contract research revenues represent Syngene and Clinigene.

**Krishna Kumar:** Is it possible to give the breakup?

**Kiran Mazumdar-Shaw:** Yes, I think you can see that it's about Rs. 137 crores from contract research, which is Syngene and Clinigene and biopharmaceuticals is actually Biocon, which is Rs. 539 crores, and then there is other income of Rs. 20 crores, so you get to Rs. 696 crores.

**Krishna Kumar:** Okay thank you Madam.

**Moderator:** Next question comes from Ms. Cheenu Gupta of Tata AIG Life Insurance.

**Cheenu Gupta:** Hello. Congratulations madam on a good set of numbers. We have seen actually good traction in the contract research business, but is it primarily on the back of the BMS contract scale-up or has there been an improvement in the non-BMS contracts as well?

**MB Chinappa:** BMS is the main component. The highest growth comes from BMS. We have seen growth with other clients too and more importantly we are well positioned in the biology segment where we are seeing positive growth.

**Cheenu Gupta:** Okay sir. How would you rate the overall current environment for contract research? We were seeing inventory cleanup, which was happening in the system for innovators, has that been completed?

**Kiran Mazumdar-Shaw:** We are not in the typical CRAMS business as you know. What we really offer is end-to-end services, research services, and there we are seeing a much greater interest now and Syngene is very well positioned because it doesn't offer just chemistry services, but also biology services and today as Chinappa said, the need



for biology services is really escalating and I think Syngene is very uniquely placed to take advantage of that opportunity.

**Cheenu Gupta:** Okay, so in the coming quarters we should expect this kind of ramp up to continue?

**Kiran Mazumdar-Shaw:** Yes.

**Cheenu Gupta:** Okay, and on our revenue front, what percentage of revenues will be exports?

**Murali Krishnan:** About 50% plus. Somewhere between 50%-60%.

**Cheenu Gupta:** Okay, so 50%-60% of our revenues is exports. And the 18 months hedging is on this kind of revenues?

**MB Chinappa:** Net of import, about 18 months revenue is hedged.

**Cheenu Gupta:** Okay, thank you.

**Moderator:** Next question is from Mr. Manoj Garg of Emkay Global.

**Manoj Garg:** Yes, good evening to all of you. Just one question - if we see the FOREX loss and gain over EBITDA, this quarter we had a gain of Rs. 56 million vis-à-vis last year's same quarter where there was a loss of Rs.122 million, so if I adjust these two items, despite higher revenue from the contract research business, there was a contraction in the operating margin, does it indicate that the Biopharmaceutical business is still under pressure?

**MB Chinappa:** As I mentioned earlier, when you go by individual product groups we have seen similar margins, and the play is in the overall margin, because of the mix of our various business segments. The gain of Rs.56 million v/s loss of Rs. 122 million last year is mainly because exports are booked at one rate and realized at another rate and that amount of play will always be there where there is a large export component. It is difficult to control that part, but overall we have hedged our exposure to ensure that we get a net realization with a floor price.

**Manoj Garg:** So, normally when we book the revenue, do we book the revenue at the contract rate or the actual prevailing rate?

**MB Chinappa:** At the prevailing custom rates.

**Manoj Garg:** Okay, thank you.

**Moderator:** Next question comes from Mr. Bhavin Shah of Dolat Capital Market Ltd.

**Bhavin Shah:** Hi and congrats on the good set of numbers. Wanted to know on IDL - are there any investments planned, if any, in that manufacturing leg of Biocon now?

**Kiran Mazumdar-Shaw:** Yes, I think we will have to invest some money to upgrade the facilities to our standards and to also make some of our products, because this plant makes many products that we may not want to pursue. Therefore to make some of our products, we will have to install some balancing equipment and also since we sort of obviously will look at registering many of these products with the US FDA and European authorities, we believe that we will have to upgrade some of the facilities, so to that extent, we will have to invest some money in IDL.

**Bhavin Shah:** Okay, but would it be substantially big?

**Kiran Mazumdar-Shaw:** No, it won't be. The reason we went and acquired IDL is because the cost of a green-field operation was going to be much larger than doing this up-gradation and buying out IDL.

**Bhavin Shah:** All right, thank you Madam. My other question was - if you could guide us on the BMS contribution in Syngene for this quarter - a rough number.

**MB Chinappa:** We do not reveal customer break-up.

**Bhavin Shah:** Okay. And when would we reach the peak potential of this deal?

**Kiran Mazumdar-Shaw:** I think one has to remember that Syngene is also pursuing other big customers so while BMS is certainly ramping up and is still at about 75% of its overall projected requirement, we are also in discussions with a few other large pharma players.

**Bhavin Shah:** Okay. One last question - I wanted to know, let's say next year what are the growth levers in the business given that most of the deals that would really significantly contribute to the top line will be latent or may be after 2012? Is it going to be more or less the Bio-pharma traction that we are currently seeing?

**Kiran Mazumdar-Shaw:** I think you are going to see a lot more traction in Biopharma because we are making a lot of progress globally with many of our Biopharma, insulin and immunosuppressant products. These are going to be important growth drivers in the next few years and licensing is also expected to see some good interesting upsides.

**Bhavin Shah:** Okay, wish you all the best, Madam. Thank you so much.

**Moderator:** Our next question comes from Mr. Sameer Baisiwala of Morgan Stanley.

**Sameer Baisiwala:** Hi, good afternoon everyone. First question is about the USD 10 million licensing income that you have received from Mylan. You mentioned that we should expect this to continue over the next five to six quarters?

**MB Chinappa:** It is Rs.100 million.

**Sameer Baisiwala:** And that will continue for next five to six quarters?

**Kiran Mazumdar-Shaw:** Yes, at roughly those levels.

**Sameer Basiwala:** Okay and the second question is about IDL. I am just trying to understand that the manufacturing that they do, how is this synergistic to Biocon, I mean, which part of your business is it about - is it fermentation?

**Kiran Mazumdar-Shaw:** It is really a chemical synthesis facility so what we expect to do is to utilize all the equipment obviously. It can cater to any sort of synthesis needs so what we will do is look at this facility for some of our advanced intermediates that we plan to make and probably finish them off at our own end.

**Sameer Basiwala:** Right. You also mentioned some product opportunity at IDL for a brand going off patent, if I understood you correctly?

**Kiran Mazumdar-Shaw:** No, I said there are a number of generics going off patent over the next two, three years and I think we will look at all those products in terms of APIs and use the IDL facility to ramp up our needs because otherwise we would have had to set up a new facility.

**Sameer Basiwala:** Okay and the markets you have got in mind are the US and Europe?

**Kiran Mazumdar-Shaw:** Yes.

**Sameer Basiwala:** Okay and the final question is on the biosimilar opportunity in the US and Europe.

**Kiran Mazumdar-Shaw:** Yes.

**Sameer Basiwala:** You mentioned about the upcoming legislation, any thoughts on this? The way the legislation is shaping up, if I am not wrong, 12 years of data exclusivity and stuff like that?

**Kiran Mazumdar-Shaw:** Well, it is still up for debate because there is a lot of lobbying going on and I think having a partner like Mylan actually puts us in a good position because they are the ones who will also be at the forefront of the lobbying and we will get to know from them what finally pans out when the final legislation is rolled out, so we will have to wait and watch. The day before yesterday you saw an announcement made by President Obama that he is actually going to do away with malpractice in the law courts and he wants to take it to an expert panel, so these are kind of signs and indications that they are very serious about bringing down the cost of health care and I think bio-generics is certainly a very important part of that cost-reduction effort.

**Sameer Basiwala:** Okay, thank you very much.

**Moderator:** Next question comes from Mr. Nitin Agarwal of IDFC SSKI Securities Pvt Ltd.

**Nitin Agarwal:** Good afternoon, Madam. I just wanted to check with you on the status of Insulin for Europe. How are we progressing on that and what are the kind of timelines are we looking at?

**Kiran Mazumdar-Shaw:** Well, I think we are just on track. As I mentioned last time, it will take us about 18 months to start the market registration process.

**Nitin Agarwal:** So is it calendar 2012 that you are looking at?

**Kiran Mazumdar-Shaw:** Yes, that's right.

**Nitin Agarwal:** Okay, thank you.

**Moderator:** Next question comes from Mr. Ranjit Kapadia of HDFC Securities.

**Ranjit Kapadia:** Madam I just want to know what is the CAPEX plan for this year and what is the R&D budget estimate for this year?

**Kiran Mazumdar-Shaw:** I think you must have heard earlier on the call that the R&D budget this year will be anything between Rs. 80 to Rs. 100 crores.

**Murali Krishnan:** As far as the CAPEX is concerned, it is going to be in line with what we have said in the past. It is about Rs.125 to Rs. 150 crores.

**Ranjit Kapadia:** Okay, thank you so much.

**Moderator:** Next follow up question comes from Mr. Nimesh Mehta of MP Advisors.

**Nimesh Mehta:** Yes, I wanted to clarify - did you mention that you are expecting Rs.10 crores of licensing income almost every quarter from Mylan?

**Kiran Mazumdar-Shaw:** Roughly, yes.

**Nimesh Mehta:** I see. And one more clarification - the oral insulin program that is underway, it is right now still in the regulatory phases of the Indian regulation, right?

**Kiran Mazumdar-Shaw:** Yes.

**Nimesh Mehta:** Any timeline from when are we likely to take it for the US FDA standard referral.

**Kiran Mazumdar-Shaw:** No, it will be done to US FDA standards and we are expecting to file an IND fairly soon. But the phase 3 trials are being done in India so we have a plan to use the India strategy with which to really prove a point through the proof of concept and the moment we get that data out, we will get into the US with phase 3 clinical trials.

**Nimesh Mehta:** Okay, thank you. That's all from my side.

**Moderator:** Next follow up question comes from Mr. Bino Pathiparampil of IIFL Capitals.

**Bino Pathiparampil:** Hi, just quickly on Glargine - anything working out regarding partnering that out for the developed markets?

**Kiran Mazumdar-Shaw:** Well, we are in discussions with a number of players.

**Bino Pathiparampil:** Okay, so do you have any timeline in mind, six months, one year?

**Kiran Mazumdar-Shaw:** Difficult to put a time factor. We will do it when we get the right partner and the right offer.

**Bino Pathiparampil:** Okay and the recombinant insulin partner in the US, have they already started some clinical work or are they still in preclinical work?

**Kiran Mazumdar-Shaw:** No, they have started clinical work.

**Bino Pathiparampil:** Right and the European trial, would you be able to share more details about whether patient recruitment has commenced?

**Kiran Mazumdar-Shaw:** Yes. We have started clinical trials in Europe and that is where we hope to start the market registration process in about 18 months.

**Bino Pathiparampil:** So the trial that you have started now - will that be the pivotal trial - the final one?

**Kiran Mazumdar-Shaw:** Well, the pivotal trials are going to start very shortly.

**Bino Pathiparampil:** Okay, thank you very much.

**Moderator:** Next question comes from Mr. Sriram Rathi of Centrum Broking Pvt Ltd.

**Sriram Rathi:** Yes, congratulations on good set of numbers. I want the breakup of contract research revenue into Syngene and Clinigene. Can you provide?

**Kiran Mazumdar-Shaw:** It is about Rs.14 crores in Clinigene and the balance is Syngene - around Rs 123 crores.

**Sriram Rathi:** Okay. The second question - we have seen a lot of fluctuations in your effective tax rate. So can you provide any indication as to what could be the full year effective tax rate for FY2010?

**Murali Krishnan:** It will be around 15%. It all depends on our products being shipped to which market, from which plant (DTA / EOU / SEZ) etc.

**Sriram Rathi:** Okay, thank you.

**Moderator:** Next question comes from Mr. Girish Bakhru of JM Financial Institutional Securities Pvt. Ltd.

**Jesal Shah:** Yes, just a question on oral insulin. You have completed your Phase 2 trials and you are moving into Phase 3 for India, so I wanted to hear your thoughts on what do you think about out-licensing opportunities for the developed market for oral insulin given that you want to launch it in the Indian market. Wondering if you have already spoken to some potential partners, based on the data that you have collected?

**Kiran Mazumdar-Shaw:** There has been a lot of expression of interest in looking at licensing oral insulin by several companies, but we don't want to enter into any licensing discussions till we really get the data out. It is important to make sure that the data looks good and then you can unlock a very large value so we have not really advanced in any of kind of discussions or entertained any serious discussions on this, apart from just sort of sharing with them data on what is available right now. We have made it very clear to every potential interested party that we will really get into serious discussions as soon as the data is available and I think there are a number of people who are interested in licensing this program.

**Jesal Shah:** Right. So when you complete Phase 3 studies, you said sometime by June of next year, at that time, do you think that you would have enough data to be able to talk to some of these partners?

**Kiran Mazumdar-Shaw:** Absolutely, that is the time we will start.

**Jesal Shah:** Okay and the second question is on the insulin and the immunosuppressants businesses. You said these are the two major growth drivers for the next one or two years. So overall, in terms of contribution, I understand you do not really give a breakup of sales, but you did mention somewhere around 12% is the contribution of the domestic formulation business. Is that right?

**Kiran Mazumdar-Shaw:** Yes.

**Jesal Shah:** Right and you also mentioned that 50% of your Biopharmaceutical business is exports, is that right?

**Kiran Mazumdar-Shaw:** Yes.

**Jesal Shah:** Okay, so would you be able to tell roughly – in this export business in Biopharmaceuticals, how much would be the current proportion of immunosuppressants and insulin be?

**Kiran Mazumdar-Shaw:** Sorry, we cannot share that.

**Jesal Shah:** All right, but the overall breakup that you have normally given in the past of 30% to 40% of sales from Statins - does that still hold or has that changed?

**Murali Krishnan:** It is about 30%.

**Jesal Shah:** That is 30% of total sales?

**Murali Krishnan:** Yes, the sales coming from Biocon, Syngene and Clinigene.

**Jesal Shah:** Okay, thank you.

**Moderator:** Next question comes from Mr. Ravi Agarwal of Edelweiss Securities Limited.



**Ravi Agarwal:** Yes, good evening and thanks for taking my call. Congrats on a great set of numbers. Just one question - interested in understanding ex-Mylan the licensing income which we used to actually book very strongly at least until FY08 and then last year we had a very tough year. I do remember you mentioning that post markets normalizing internationally, you could actually start to see some revenues come out of that. Can you share any thoughts on this?

**Kiran Mazumdar-Shaw:** It is happening.

**Murali Krishnan:** Mylan income is one of them.

**Ravi Agarwal:** No, ex-Mylan. Earlier we used to book some licensing income from our insulin contracts?

**Kiran Mazumdar-Shaw:** Yes, we are getting the same, but I think you will see more in the future.

**Ravi Agarwal:** Is it fair to expect some kind of a number which we used to get in FY08, some - Rs.40-50 crores kind of numbers coming from those kind of markets?

**Kiran Mazumdar-Shaw:** On an annualized basis, you will get this kind of number.

**Ravi Agarwal:** I am talking ex-Mylan here.

**Kiran Mazumdar-Shaw:** We can't really say - it is all dependent on when we close these deals. It is not easy to predict but certainly the potential is there and we will have to see how we can get it every year.

**Ravi Agarwal:** Okay, thank you.

**Moderator:** Next is a follow up question from Mr. Sameer Baisiwala of Morgan Stanley.

**Sameer Baisiwala:** Yes, thanks for taking my question again. Just two questions, first is on Tacro. Rakesh, what is your assessment, when do you think your customers will get the approval in the second wave of launch?

**Rakesh Bamzai:** Everybody is guessing on it but people are expecting approval from next month onwards. There were queries, replies have been sent and questions have been answered. If you are following the FDA process right now, they are taking more time than they normally do, so we are expecting approvals to come in from next month onwards.

**Sameer Baisiwala:** Okay and what is your current market share in the Mycophenolate Mofetil market - if you can share?

**Rakesh Bamzai:** In Mycophenolate Mofetil, 57% of the market has converted into generics in the first six months of being there, so in that total five we have close to 20% market share.

**Sameer Baisiwala:** 20% out of 100%.

**Rakesh Bamzai:** Yes.

**Sameer Baisiwala:** Okay. Just one question on oral insulin - assuming all goes well and we get favorable Phase 3 data by the middle of next year, what would be the timelines for the clinical trials and regulatory process for the US and European market?

**Kiran Mazumdar-Shaw:** I think Harish will answer these questions.

**Harish Iyer:** So, I think that the plan is to file an IND hopefully later this year or at worst early next year and do some short bridging studies and then with hopefully good data coming in from our Indian studies go into longer term studies, but of course we have a global clinical development plan already in place based on which we expect global approval to happen in, let's say, 2015 or so, but really those plans will be driven in conjunction with the partner who will probably have a bigger say in all the products developed globally.

**Sameer Baisiwala:** Okay. But your best guess is that it will be 2015 by the time you get approval for the US and European markets.

**Harish Iyer:** Yes.

**Sameer Baisiwala:** Okay, thank you very much.

**Moderator:** Next question comes from Mr. Amit Hiremath of Enam AMC.

**Amit Hiremath:** Thanks for taking my question. It relates to the contract research segment, especially with the profitability, because in the first half, our contract research segment had a formidable EBITDA of 36%, which seems to have dropped sharply to 26% this quarter. Can you give any reasons for this?

**MB Chinappa:** You are talking about the numbers excluding AxiCorp and including Biocon standalone? Is that how you have arrived at that?

**Amit Hiremath:** No, I am looking at the numbers which are given in the press release, where the contract research revenue for this quarter is Rs. 78 crores and PBIT is Rs.20 crores, while in the last quarter it was Rs.67 crores in total sales and around Rs.25 crores as EBITDA.

**MB Chinappa:** Could I get back to you offline? I need to reconcile these numbers.

**Amit Hiremath:** Sure, thanks.

**Moderator:** Next question comes from Mr. Debanshu Patra of VCK Share & Stock Broking Services Ltd.

**Debanshu Patra:** Good afternoon everybody. Most of my questions have been answered. I have just one question regarding the Amylin and Biocon agreement. According to the agreement with Amylin, Biocon with own commercialization rights for

the “phybrid” in South Africa and most of East Asia and Middle East. So what sort of opportunity you are seeing from these regions?

**Arun Chandavarkar:** Although we have not discussed the specifics, we have rights everywhere except North America, so that includes Europe and many other countries.

**Debanshu Patra:** It includes only South Asia and most of the Middle East.

**Arun Chandavarkar:** No, those are exclusive rights, but we have co exclusive rights everywhere else.

**Debanshu Patra:** And Amylin has commercialization rights for the phybrid in North America.

**Arun Chandavarkar:** Amylin has exclusive commercialization rights in North America, we have exclusive commercialization rights in some countries that you mentioned in South Asia and South East Asia and the Middle East and the rest of the countries are co exclusive. So our opportunities are not limited only to our exclusive territory, an opportunity comes from also the co exclusive territory and also from royalty from Amylin’s territory.

**Debanshu Patra:** Can you give us some kind of numbers?

**Arun Chandavarkar:** No, because this is at a very early stage of development and we can probably talk of numbers only when we reach a Phase 3 kind of a stage, when we have a target product profile established.

**Debanshu Patra:** Okay, thank you.

**Moderator:** Next question comes from Mr. Nimesh Mehta of MP Advisors.

**Nimesh Mehta:** Yes, thanks for this follow up question again. Just wanted to know if you have any idea of how much is the generalization in the generic Tacrolimus program happening. I understand there is only one player right now - Sandoz?

**Rakesh Bamzai:** On Tacrolimus, the data has not come in, but industry experts say 30% with one customer, so the potential is huge in Tacrolimus.

**Nimesh Mehta:** Okay, thank you.

**Moderator:** Next is a follow up question from Mr. Girish Bakhru of JM Financial Institutional Securities.

**Girish Bakhru:** Yes, just a question on the foreign exchange loss that you have booked. If you can help us understand the components of the foreign exchange loss, you said something to do with transaction, so wanted to understand how much is the loss or gain on the debtors, creditors and also on the hedge position?

**MB Chinappa:** There is too much of detail to get into and explain the individual breakup. During this period, we have paid a premium on all our covers, and there is a small loss

on account of the difference between the premium we paid and the gain on the forward contracts, where both were netted off in that line item. In addition to that, there is re-translation of loans, creditors, debtors, etc.

**Girish Bakhru:** So just one small thing.. all the losses or gains on the hedges, would it be fair to assume that you would have booked them in the quarter, or is it something you followed AS11 and therefore something has not been booked?

**Murali Krishnan:** The FOREX gains and losses have been booked.

**Girish Bakhru:** Okay, thank you so much.

**Moderator:** Next question comes from Mr. Balaprabhala Subramanyam of PCS Securities Ltd.

**Balaprabhala Subramanyam:** Yes, good evening. Thanks for taking my call and congratulations on a very good set of numbers. My question was regarding ABRAXANE, especially after the recent recall of the drug by DCGI from the markets of Natco, how is ABRAXANE doing?

**Rakesh Bamzai:** I think we have priced our product approximately 30%-35% in comparison to the United States prices. There was a news article, which was misleading that our product is expensive, whereas our product is actually priced very humane in comparison to other prices prevailing in other parts of the world. That has been one of the strategies that we have always had in oncology. So coming to the product, it is doing very well; there is a 600 patient exposure and increasing.

**Balaprabhala Subramanyam:** Okay. Approximate size of the market...?

**Rakesh Bamzai:** The total Paclitaxel market is around Rs. 55 crores and if you add other Taxanes, the total market size would be very close to Rs. 100 crores. So we are right now looking at a market pie of Rs. 100 crores. We want to participate in that Rs. 100 crore market.

**Balaprabhala Subramanyam:** Okay, thank you very much.

**Moderator:** Last question comes from Mr. Debanshu Patra of VCK Share & Stock Broking Services Ltd.

**Debanshu Patra:** My last question is on the Amylin-Biocon agreement. Amylin and Biocon share some sort of development cost, so what will be the basis of sharing this development cost?

**Arun Chandavarkar:** We will not disclose the percentage of sharing, but yes, we share development costs. We have the lesser share.

**Debanshu Patra:** Actually Amylin will bring in expertise in Peptide or hormone development, particularly in the area of "phybrid" technology and Biocon will, for its part, offer expertise in recombinant microbiology expressions. So what is the basis?

**Arun Chandavarkar:** Amylin as you know has a great deal of expertise in diabetes because they have two products in the market, which are Exenatide or Byetta and Symlin, which is Pramlintide, and both are peptides hormones. So they are trying to expand their portfolio of peptide products and one such platform technology they have is called hybrids. They were looking to collaborate with somebody like Biocon who can bring in process skills, manufacturing skills as well as a strong knowledge of diabetes, in terms of both peptides and proteins. Adding to this is our own programs in Insulin, Glargine and other analogs - we have the right skills. We both bring complementary skills to the table and we share costs. And obviously since the markets in the US and North America are the more lucrative markets, Amylin takes the bigger share of the cost and we take a smaller share of the cost.

**Debanshu Patra:** Okay, thank you.

**Moderator:** There are no further questions. Now I hand over the floor to Ms. Kiran Mazumdar-Shaw for closing comments.

**Kiran Mazumdar-Shaw:** I would just like to thank all the participants and if there are any other queries or questions, please feel free to have offline conversations with any of my colleagues. Thank you very much and we look forward to meeting with you again on the next quarterly call.

### **Disclaimer**

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