Transcript

Conference Call of Biocon Limited

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Moderator: Good afternoon ladies and gentlemen. I am Shirley, moderator for this conference. Welcome to the Biocon Limited conference call. At this moment all participants are in listen only mode. Later, we will conduct a question and answer session, at that time if you have a question, please press * and 1 on your telephone key pad. Please note this conference is recorded. I would now like to hand over the conference to Ms. Urvashi Butani of Citigate Dewe Rogerson. Over to you ma'am.

Urvashi Butani: Thank you. Good afternoon everybody and thank you for joining us on Biocon Limited's Q3FY11 conference call. We have with us on this call today Ms. Kiran Mazumdar-Shaw, Biocon Chairman and Managing Director, and her senior management team. We will begin this call with opening remarks on the Biocon management followed by an interactive Q&A session. I would like to add that some statements in this call may be forward looking statements 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 quarter ended 31st December 2010. Over to you ma'am.

Kiran Mazumdar-Shaw: Thank you Urvashi and a very happy new year to all the listeners. I am delighted to say that we have reported a very strong set of numbers for the first nine months and this the third quarter of FY11. On a group consolidated basis, we have reported a 21% year-on-year growth in top line and a 25% growth in PAT to Rs 267 crores. On a standalone basis (excluding contract research and AxiCorp), Biocon has delivered a very strong growth of 30% in revenues to Rs 1,102 crores from Rs 845 crores last fiscal, and an operational PAT, excluding one-time licensing income of Rs 250 crores against Rs 176 crores last fiscal. (A PAT of Rs 250 crores is after excluding the IP transfer to Biocon SA. If this is included, PAT is Rs 371 crores). Our research services business Syngene has delivered Rs 10 crores of PAT this quarter, which is a significant improvement from the previous few quarters. This also demonstrated the re-jigged Syngene business

model from a fee-for-service business to a more integrated offering where we are positioning both Syngene and Clinigene as preferred development partners to the global pharma and biotech companies, and this certainly seems to be paying dividends.

One of the concerns this quarter has been the impact of the 16% rebate imposed by the German government on AxiCorp's numbers. AxiCorp's revenues have declined this quarter and although there is a 12% growth over the last year in the top line and a 16% PAT growth, a decline in the top line will impact the margins going forward. Having said this, this is not a matter of grave concern for the company because our rationale for acquiring AxiCorp has always been to roll out our biosimilar insulins in Europe which we hope to do starting with the German market some time in 2013. With that, we do expect to see good growth in both margins and profitability. Meanwhile, we will look at how to improve the quality of the AxiCorp business going forward. We are looking at products that will be more adversely impacted than others and we will discard products with wafer-thin margins from our portfolio.

I would now like to make a few quick comments on some of the other aspects of our businesses. Licensing income has been strong for the first nine months at Rs 122 crores. All our programs are advancing well. We have recently shared data pertaining to our oral insulin program where a high placebo effect has marked the primary endpoint but it is important to say that we have met some of the very key secondary endpoints, which have clearly demonstrated efficacy. It has also demonstrated what we expect of the drug in terms of reduction of postprandial glucose levels, which has been statistically significant when compared to the placebo arm. The learning and the data generated from this particular study will be put to good use as we proceed with further studies and this is something we would like to do ideally after we identify an appropriate global partner. We will start partnering discussions immediately and we hope that over the next six months we will be able to identify a suitable global partner with whom we will design and discuss the way forward in terms of further studies under the US IND. In all, I think we have had a very good quarter and we are very confident that we will end the year on a very strong note. Finally, a number of people have asked me questions on Syngene's IPO - we remain committed to listing Syngene as we go forward, but it is very important for us to ensure that we have four quarters of sustainable growth and it is after this point that we will really look at taking Syngene to the market. This we expect to happen some time over the course of the

next 18 months or so. With that, I would like to conclude by saying that we are very optimistic about the year ahead and we can now move to the Q&A session.

Question and Answer Session

Moderator: Thank you madam. Ladies and gentlemen, we will now begin the question and answer session. If you have a question, please press * and 1 on your telephone key pad and wait for your turn to ask the question. If your question has been answered before your turn, and you wish to withdraw your request, you may do so by pressing # key.

First question comes from Mr. Ranjit Kapadia from HDFC Securities.

Ranjit Kapadia: Good afternoon ma'am and hearty congratulations for a good set of numbers. I just wanted to reconfirm the licensing number – Is it Rs 122 crores?

Kiran Mazumdar-Shaw: Yes, Rs 122 crores over the last nine months.

Ranjit Kapadia: Ok, thanks. On their conference call, Pfizer said that they are talking to Biocon for marketing a range of insulin products in India. Could you throw some light on that?

Kiran Mazumdar-Shaw: Yes, as you are aware, we have got our Recombinant Human Insulin and Glargine approved in India and these are products that we will co market with Pfizer and this business is likely to kick in over the next fiscal.

Ranjit Kapadia: FY12?

Kiran Mazumdar-Shaw: Yes.

Ranjit Kapadia: Thank you very much and wish you all the best.

Moderator: Thank you sir. Next question comes from Mr. Krishnendu Saha from Quantum AMC.

Krishnendu Saha: Hi, thanks for taking my question. There is one question on the R&D front. Am I correct in understanding it is Rs 550 mn compared to Rs 197 mn last quarter, a huge jump. Could you throw some light on that please?

Murali Krishnan: If you remember, last quarter we indicated that upon signing the commercialization agreement with Pfizer, we may have to expense all the development costs incurred for the biosimilar insulins till date, which were getting capitalized. About Rs 35 crores was capitalized in the books of our 100% subsidiary Biocon SA for the EU clinical

trials and this amount of has now been expensed fully by taking it through this quarter's P&L a/c.

Krishnendu Saha: Okay, this is non cash expenditure, is it?

Murali Krishnan: Yes, it is non-cash expenditure, to the extent that it was not incurred during this quarter.

Krishnendu Saha: Right. So this is the run rate we could expect from next quarter or three, four quarters?

Murali Krishnan: R&D spend will increase over the next few years until we take all these products to the market. However, we will not be able to comment on the run rate because these costs will be incurred as and when we get the regulatory approvals for carrying out the clinical trials in different countries, which are not completely predictable in terms of timelines.

Krishnendu Saha: Right. And another question sir, when I look at your balance sheet, there is a huge jump in your current liabilities, so just wondering, it is Rs 947 crores versus Rs 564 crores last quarter.

Murali Krishnan: This is also on account of the money that we have received from Pfizer.

Krishnendu Saha: Okay, I get it. And one last question on the tax rate, so the effective tax rate is 22% as of now?

Kiran Kumar: This is on account of a licensing of IP from Biocon to its wholly owned subsidiary, Biocon SA Switzerland for the same Pfizer transaction. As they are in two different tax entities, we have provided for the tax from Biocon Limited's standalone books with a one-time impact. Going forward, we will revert back to the previous quarter's tax rate level.

Krishnendu Saha: And if you could just let me know the breakup of the technical fees, how much was the Pfizer, how much for Mylan for this quarter?

Murali Krishnan: The Mylan number would be similar to previous run rate and the additional licensing fees for this past quarter has largely come from the Pfizer partnership.

Krishnendu Saha: Okay, thank you very much.

Moderator: Next question comes from Mr. Binu Patiparambil from IIFL.

Binu Patiparambil: Hi. Congrats for a great set of numbers. Just I wanted to know what has contributed to the growth in biopharma;

your note says Tacrolimus and MMF has seen good traction in the quarter. Is there any particular reason for that?

Rakesh Bamzai: There are a couple of reasons - one is the growth in branded sales as Kiran mentioned in her opening remarks. The other is our launch of Tacrolimus in the United States and Europe with our partners. In other products, which are traditionally strong products for us, like Atorvastatin or the other Statins, we have done well.

Binu Patiparambil: Right. Just a followup question, as we all know, later this year and early part of next year, atorvastatin is going generic, do you think it will have a step down impact on your biopharma revenues?

Rakesh Bamzai: I don't think it will impact our biopharma revenue negatively and if at all it will have an impact, it will be a positive one.

Binu Patiparambil: Right. Just one more question on the recognition of licensing revenue from Pfizer, if we do the rough calculation, it turns out that about Rs 50 crores has been recognized in the quarter versus R&D that has been about Rs 35 crores. So that means roughly 30% margin of profit you make over and above your development cost. Is that the right way to look at it?

Murali Krishnan: Not really. This will vary over time based on actual spends and estimated future costs.

Binu Patiparambil: Right. And finally, given your CAPEX target of USD 160 million in Malaysia, could you give a revised CAPEX guidance for FY11, '12, and '13?

Murali Krishnan: We are working on that. We will be able to share the indicative number in our next call during April.

Binu Patiparambil: Okay, right. But apart from this 160, which may come over three to four years, what is the base…

Murali Krishnan: The normal run rate has been around Rs 150 crores for the group. It is likely to be around that number.

Binu Patiparambil: Okay, perfect. Thank you very much and congrats again.

Moderator: Next question comes from Ms. Monica Joshi from Avendus Capital.

Monica Joshi: Hi, thank you for taking my question. If you could just clarify this capitalized R&D, what was this regarding, that is

one, and just wanted to confirm whether nothing else is remaining on the balance sheet?

Murali Krishnan: All the costs incurred towards conducting the clinical trials to obtain marketing approval in the EU for our Rh insulin, were being capitalized in the books of Biocon SA. IGAAP permits such capitalization, since this product is already in the Indian market and several other emerging markets after establishing the proof of concept & getting marketing approvals. Under this scenario, all such costs (past & future) would have got capitalized and upon getting the marketing approval from EU Authorities, the entire cost would have got amortized over a 10-year period. But now that we have entered into a contract with Pfizer for commercialization of the products including this product, it is prudent to charge it to the P & L account and hence we have taken this cost to thru our P & L a/c. Post this, there is no other costs sitting in the Balance Sheet pertaining to the bio-similar Insulins.

Monica Joshi: Okay. So if I understand it correctly, over a year ago you had started clinical trials of insulin in Europe, is that right?

Murali Krishnan: Yes, that is correct.

Monica Joshi: And just to take this further, you must have received the Pfizer income the first 100 million dollars, clearly the trial process in Europe is not completely crystallized yet, so how is it that you are going to incur a similar amount of 55 crores every quarter?

Murali Krishnan: We have never said that Rs 55 crores is going to be incurred every quarter. All costs related to the Rh Insulin trial will be recorded through P&L.

Monica Joshi: Okay. And licensing income would be written down, what, in eight to 10 quarters…

Murali Krishnan: Corresponding licensing income will be recorded over 4 – 5 years, as we progress with the clinical trials for Insulins, for global commercialization, based on “percentage of completion” method.

Monica Joshi: Okay. Just one question on the biopharmaceutical sales other than licensing income, have you seen any one-off, any tender businesses in this quarter?

Murali Krishnan: No.

Monica Joshi: So that’s the normalized run rate that you are having?

Murali Krishnan: Yes, it is the normal run rate.

Monica Joshi: Also ma'am I just wanted to get your views on Mankind's inhaled insulin, which was rejected by the FDA yesterday, so what is your take on that and how would that impact IN-105?

Kiran Mazumdar-Shaw: The US FDA has demanded more safety studies because inhaled insulin has always had safety concerns. The one thing we have shown in our studies of IN-105 is that it is a very safe drug. In fact, we have seen no clinically relevant hypoglycemia, it was shown to be non immunogenic as well as weight neutral. These are very positive factors for safety.

Monica Joshi: Thank you so much and wish you the best.

Moderator: Next question comes from Mr. Manoj Garg from Edelweiss Securities.

Manoj Garg: Hi. Good afternoon to all of you. Sir, like if I step down the income from the biopharmaceutical business, I think the growth for the quarter in biopharma is around 5% and even, like on quarter-on-quarter basis also I see the growth is more or less muted, despite that you have launched the Tacrolimus and you said that there is a good growth in the branded formulation business. So can you put some more light on that?

Murali Krishnan: We sent out one more update in the morning after the one that was sent with our press release, wherein we bifurcated the total bio-pharma sales into two line items (i.e: Biocon and AxiCorp). This up-date would show that the biopharma business, excluding licensing income and Axicorp, has grown by about 22% in this quarter over the same quarter last year.

Manoj Garg: Okay, fair enough. I will correct myself. And the second thing, like, you say that this quarter there was exceptional case because of transferring of IP and that resulted in your 22% kind of tax rate, but going forward do we model around 15, 16% kind of tax rate, on consol business?

Murali Krishnan: Yes, it is likely to be around that level.

Manoj Garg: And thirdly, though you have indicated about safety aspects of IN-105, I would like to understand little more in terms of the efficacy of the drug, because as you say that the effect has been marked by placebo, can you put some more light particularly about the trials, which has recently been released.

Vivek Shenoy: While our primary endpoint was not met because there was a high placebo response, as Kiran mentioned earlier in the call, we have seen efficacy in the drug from a secondary endpoint perspective. We have seen that the drug clearly reduces the postprandial glucose level and that is essentially what Insulin is supposed to do. It is supposed to reduce your glucose levels, and this drug does this unambiguously.

Manoj Garg: Do you need to conduct little more trials in order to establish further efficacy of that drug or you feel that these data are sufficient enough for you to convince the FDA or maybe the Indian Government to approve the efficacy.

Kiran Mazumdar-Shaw: We mentioned clearly that we will still need to conduct a number of studies. This was the first set of trials that were designed to show that there is safety and efficacy of the drug and that has been demonstrated. The high placebo effect was obtained because of a lifestyle modification that we saw in the placebo arm. And that also resulted because as a part of the protocol, we had requested the patients to monitor their blood glucose levels on a periodic basis, say an hour after a meal, and obviously what we believe is that the placebo arm, basically did not see the post-prandial glucose drops that the drug arm saw, and so they have actually changed their lifestyle in the form of more exercise and better diet. And this is what has caused the placebo effect. And this is to be expected in an early type 2 diabetic kind of stage of the disease.

Vivek Shenoy: And if I may add on to that, diabetes is an asymptomatic disease. You don't have physical symptoms, but when a patient who monitors their blood sugar regularly sees that the blood sugar is not getting controlled, he will suddenly make it into a symptomatic disease. Any lifestyle modification will obviously then impact the disease, which is great for the patient, unfortunately for the drug, it wasn't so helpful.

Moderator: Next question comes from Mr. Ranvir Singh from Brics Securities.

Ranvir Singh: Yeah, hi. My question was relating to AxiCorp. Whether that de growth is due to only price impact or there has been a decline in volume also?

Kiran Mazumdar-Shaw: This is largely the price impact. In their objective of bringing down the spiraling health care cost, the German government has introduced a flat 16% rebate on all drug

makers. All products have this 16% rebate and therefore this impacts the top line and the margins.

Ranvir Singh: So, do we take it this run rate?

Kiran Mazumdar-Shaw: Yes, it will continue at these levels as the rebate is for 3 years.

Ranvir Singh: Okay, thanks. I will go back in queue.

Moderator: Next question comes from Mr. Krishna Kiran from ICICI Securities.

Krishna Kiran: Hello. Ma'am during the quarter raw material cost has decreased sharply; can you just throw some light on it?

Murali Krishnan: It has not decreased in absolute terms. It has decreased sharply as a percentage because of the increased licensing income.

Krishna Kiran: Sir, if I remove licensing income also, it is 150 basis points decline in raw material costs.

Murali Krishnan: This movement depends on the stock levels under "work-in-progress and finished goods". Also, Axicorp contributed to a higher material cost in the earlier quarters.

Krishna Kiran: Okay, thanks sir.

Moderator: Thank you sir. Next question comes from Mr. Nitin Agarwal from IDFC.

Nitin Agarwal: Good afternoon. A couple of questions. One is a) when do you see the marketing of your insulin in emerging markets by Pfizer as far as Pfizer deal, or when Pfizer starts…

Kiran Mazumdar-Shaw: You will start seeing that only next fiscal.

Nitin Agarwal: So it is going to be largely in markets where you already got approvals or, I guess, for them to get approvals in newer markets will take some time I assume.

Kiran Mazumdar-Shaw: No. Obviously it is where we have already got approvals and of course India is one of them and there are other markets, which are also quite attractive markets like Brazil, so you will start seeing some traction next fiscal.

Nitin Agarwal: And in terms of the pen device, where are we in terms of development of pen device per se?

Rakesh Bamzai: We are on track. We will launch our reusable pen by mid 2011; the disposable pen is going to take some more time.

Nitin Agarwal: And on Tacrolimus in US, how many active customers do you have right now, who are already marketing the products and using your API?

Management: There are four customers.

Nitin Agarwal: Okay fine, thanks very much.

Moderator: Next question comes from Mr. Nimish Mehta from MP Advisors.

Nimish Mehta: Yeah hi, thanks for taking my question. Can you let us know why has there been a dip in the other expenses, is it because of the FOREX and what is it otherwise?

Kiran Kumar: The dip in other expenses is largely on account of a recharge of costs to our co-development partners.

Nimish Mehta: Okay, so this is related to the Pfizer deal?

Kiran Kumar: Partly yes, but not entirely.

Nimish Mehta: Okay. And so on a like-to-like basis, what it would have been, if you can just let us know?

Murali Krishnan: Largely around the same and it is likely to be in the same range on YTD basis.

Nimish Mehta: Yes, I am talking about this quarter, which is…

Murali Krishnan: Which is Rs 61 crores to Rs 45 crores?

Nimish Mehta: Yes.

Murali Krishnan: Adjusted to the last year's Forex loss, it is all largely based on that.

Nimish Mehta: Okay. Q3FY10 I see that there was a foreign exchange loss that you had booked in, I assume that this Rs 61 crores of last year represents that loss, so do we have any gain this year from foreign exchange?

Kiran Kumar: There is a gain but it is not very significant.

Nimish Mehta: Right. So what is the real difference, because both of these things don't seem to be small or insignificant in quantum…?

Murali Krishnan: Adjusted to the last year's Forex loss, the forex gain for the current quarter is insignificant.

Nimish Mehta: Thanks. Also what I am trying to understand is that because of the Pfizer deal I see impact on three headline numbers, one is the licensing income, second is this recharge that you just talked about and third is the liability side and also the R&D expense as you mentioned earlier, so if you can just help us go through this once again so that we are able to understand how will it pan out in coming quarters, that would help us?

Kiran Kumar: As mentioned earlier, the R&D expenses in the current quarter has been higher because of charge down of the capitalized costs in the past quarters.

Nimish Mehta: And that will not recur again.

Kiran Kumar: It will not recur again, on account of re-charge from the capitalized R & D costs.

Nimish Mehta: So, we will see a taper down in R&D expenses, right.

Murali Krishnan: No, that will keep increasing upward as we proceed to the global clinical trials. That will also have an impact on the income recognition - essentially on the licensing fee. Based upon our progress in the clinical trials we will keep recognizing the income also.

Nimish Mehta: I understand. So as and when we see R&D expense going up it is in the same lines that we will see the licensing income coming in.

Kiran Mazumdar-Shaw: Yes.

Nimish Mehta: Okay and what about the recharge of the costs that we have booked in the other expenses, will it recur again or it has kind of…

Murali Krishnan: Yes, that will keep recurring to the extent we do work within Biocon. As we begin the clinical trials outside India, etc, this will start coming down. Today some of the developments are happening in-house for which there is a recharge. When the expenses are incurred with a third party, the recharge will not come to Biocon.

Nimish Mehta: I see okay, so how long do you think that you will be doing trials roughly?

Murali Krishnan: There are few products and these products go off patent between 2014 and 2018. For these products, currently a

large part of work is happening within India, but very soon it will also start happening from outside India. It will be an on-going process till we get the marketing approvals globally.

Nimish Mehta: I see, okay.

Nimish Mehta: Okay, fine and is any of this recharge or the licensing income tied up with a CAPEX that you have to do, so as and when you incur any CAPEX you would…

Murali Krishnan: No, this has nothing to do with CAPEX. It is R&D.

Nimish Mehta: Okay, fine. Thank you very much.

Moderator: Thank you sir. Next question comes from Mr. H. R. Gala from Quest Advisors.

H. R. Gala: Hi, I just wanted to know what are the major reasons for the loss in the subsidiaries. If we subtract the standalone from consolidated, we just wanted to understand that is it mainly because of these AxiCorp what you said?

Murali Krishnan: Most of the subsidiaries too have generated profits. However, on account of transfer of IP from Biocon Limited to Biocon SA (a wholly owned subsidiary), the standalone financials show a higher income & PAT, but gets eliminated in consolidation.

H. R. Gala: So, how much is that amount?

Murali Krishnan: We have a PAT of Rs 381 crores in the standalone financials and as mentioned earlier we have a PAT Rs 250 crores net of IP licensing to Biocon SA, so the difference is actually that number.

H. R. Gala: That is the transfer of IP?

Murali Krishnan: Yes, it gets eliminated in the consolidation.

H. R. Gala: But if you really look at it the material cost to sales in a subtracted amount in subsidiary, that percentage looks very high at 87%.

Murali Krishnan: No, it will not be 87%; it is high only in AxiCorp because it is a pure trading business.

H. R. Gala: So, in the standalone turnover you mean to say this sale of IP is included?

Murali Krishnan: Yes.

H. R. Gala: Okay, and in consolidated it is not.

Murali Krishnan: In consolidation, it gets negated because it is transferred to our 100% subsidiary, Biocon SA.

H. R. Gala: Okay. Thanks, bye.

Moderator: Next question comes from Mr. Sriram Rathi from Anand Rathi Securities.

Sriram Rathi: Yeah hi, congratulations on a good set of numbers. Sir, my main question was like in the first three quarters we have incurred around 96 crores of R&D expenditure and our guidance was around 150-180 crores of R&D for the full year, so do we still stick to the guidance of 150-180 crores or…

Murali Krishnan: Yes.

Sriram Rathi: Okay and can you give any guidance for the next year in terms of R&D expenditure.

Kiran Mazumdar-Shaw: Even this year although we have provided for Rs 150-160 crores, we may not spend all that much but going forward also we expect to spend around that kind of number or even little more than Rs 150 crores.

Sriram Rathi: Okay and my last question is about the tax rate, I mean, hopefully this year we will have around 15-16% kind of tax rate so can we expect some more tax rate next year basically because of the expiry of the EU exemption and all those things.

Kiran Mazumdar-Shaw: Yes.

Sriram Rathi: So, can it be around 20%, 22%?

Murali Krishnan: Yes, roughly 22%.

Sriram Rathi: Okay, thank you.

Moderator: Next question comes from Mr. Surya Patra from Systematic Shares.

Surya Patra: Yeah, in fact congrats for the good set of numbers. Two things I wanted to know, any progress on the Clinigene front now?

Dr. Abhijeet Barve: I think the Clinical CRO business as many of you know is going through a rough patch globally, but at Clinigene we

have been able to differentiate ourselves by offering value added services that would offer more like an integrated platform across different stages of clinical trials versus just offering piece meal work to clients and we are also looking more at partnership based work rather than just one-off work from sponsors.

Surya Patra: Okay so, that means are we expecting any sort of a clinical trial deals for that in the near future or something like that?

Dr. Barve: We won't be able to comment on that, but we are working on different models, one of that would be what you mentioned.

Surya Patra: Okay and the second question is you were relating to Biocon's intention of launching formulations in regulatory markets particularly this US markets, recently you have commented something like filing ANDAs to be specific like ophthalmic front, so…

Rakesh Bamzai: It will not be in the near future, but when we do it we will let you know.

Surya Patra: Okay, but what would be your ANDA filing strategy or planning?

Kiran Mazumdar-Shaw: The plan is to start entering this whole area of dossier development and we will look at some of the high-end products that we haven't developed dossiers around them and then the plan is that probably in the next fiscal we can start looking at a better and clearer strategy in the ANDAs.

Surya Patra: Okay and those would be fully integrated or how would be the…

Kiran Mazumdar-Shaw: Well, the plan is definitely to have a dossier which could be either licensed or partnered at some stage.

Surya Patra: Okay, but you don't think that, that would impact your API business in the regulated market?

Kiran Mazumdar-Shaw: No, we don't think so.

Rakesh Bamzai: It will help the API business because we will be better value providers in terms of reducing the time of development for our customers.

Surya Patra: Okay, that's great and even in the recent quarters you launched various other formulation products in the domestic market and the emerging markets, how many products that you have launched or what is the, definitely you said the growth is quite good, 35…

Rakesh Bamzai: We have launched two new divisions in the third quarter - comprehensive care and immunotherapy divisions. The impact of these businesses will come from next fiscal.

Surya Patra: Sir, last question, what would be the size of this formulation basket?

Rakesh Bamzai: Today we have six divisions, approximately 1000 people across six divisions.

Surya Patra: Okay and basket in the sense, number of products that is there?

Rakesh Bamzai: We have a long list of products and this information is available on our website.

Surya Patra: Okay, fine. Thank you.

Moderator: Next question comes from Mr. Bhavin Shah from Dolat Capital.

Bhavin Shah: Thanks, my question has been answered. Thank you.

Moderator: Next question comes from Mr. Manoj Garg from Edelweiss Securities.

Manoj Garg: Yeah, thanks for taking my question again. See, like you have indicated that about 16% rebate which is being charged by the German Government, is it across the segment for both tender as well non-tender business products or even only for non-tender products?

Kiran Mazumdar-Shaw: It is only non-tender products.

Manoj Garg: Okay, thanks.

Moderator: Next question comes from Mr. Hitesh Mahida from Marwadi Shares.

Hitesh Mahida: Congratulations, ma'am for a good set of numbers.

Kiran Mazumdar-Shaw: Thank you.

Hitesh Mahida: I wanted to know what were the EBITDA margins of AxiCorp during the quarter?

Kiran Mazumdar-Shaw: AxiCorp's EBITDA for the nine months was about Rs 46 crores and for the quarter it was Rs 8 crores.

Hitesh Mahida: Okay, thanks a lot.

Moderator: Next question comes from Mr. Sameer Baisiwala from Morgan Stanley.

Sameer Baisiwala: Hi, good evening. The first question is on Tacrolimus, Rakesh what is your assessment of further approvals for your customers in the US market?

Rakesh Bamzai: We have one more customer awaiting approval but the good news is that we have filed one new product and we are also filing two new products, so we are going to be very strong dominating that field in years to come.

Sameer Baisiwala: Okay and the second question is on the Europe insulin clinical trials, for us to launch the product in 2013 when do you expect to submit the dossier, i.e. fully complete the human trials?

Harish Iyer: We are still recruiting patients in this particular study and we expect to file somewhere half way through next year.

Sameer Baisiwala: So middle of 2012 is when you would file the dossier, right?

Harish Iyer: Yes.

Sameer Baisiwala: So that means you will complete the trials by the end of this calendar year?

Harish Iyer: Yes, the treatment areas.

Sameer Baisiwala: Okay and any timelines on when would you be commencing the human trials for Glargine for the European market?

Harish Iyer: It will happen sometime this year, but really we are having discussions with our partner on coordinating and making sure the strategy is right.

Sameer Baisiwala: Okay, so it is roughly what, should we say 1 to 1-1/2 years behind the human insulin?

Harish: I would think so. The IP expiry anyway will be only in 2014, so we have until then.

Sameer Baisiwala: Okay and just on oral insulin, it is a field which is not too well known to us, but are there instances where companies miss on the primary endpoint, but meet secondary endpoint and take it further for trials and succeed at the end?

Kiran Mazumdar-Shaw: Absolutely all the time. I think this is an area which is not very familiar with people here, because there aren't too many novel programs under development but it is very rare to find a slam-dunk kind of clinical trial on the first go so basically you will expect to have this kind of results when you are conducting these trials. Having said that,we are very pleased that we met the secondary endpoints.

Sameer Baisiwala: Okay and it looks like there was a postprandial lowered glucose levels, but just it is as compared to the placebo it was not good enough and that was…

Kiran Mazumdar-Shaw: No. The difference in terms of postprandial glucose lowering was statistically significant, but that was a secondary endpoint. The primary endpoint was lowering of HbA1c and that got masked by the placebo effect and we know clearly that HbA1c can very easily be affected by a lifestyle modification.

Sameer Baisiwala: Okay and so just to take this point further, for our future trials how do we for the primary endpoint, how do we overcome the placebo affect because the lifestyle change may still be there?

Vivek Shenoy: But there are some learnings obviously that we have from our trial right now and these learnings will educate us for our upcoming trials, one of those as Kiran mentioned earlier was, if you have patients monitoring their blood sugar on a regular basis that is something that could potentially impact the outcome and there are some other parameters also that we have learnt which we can use to mitigate a potential placebo effect.

Sameer Baisiwala: So, if the patients were not testing their glucose levels that frequently they would not have done more exercise and better diet control and so what we were required to do was not to let the patients do too much or too frequent blood test, is that what it is?

Kiran Mazumdar-Shaw: Yes but we wanted people to test their glucose levels because of hypoglycemia. In order to address the safety concerns, we had to get these people to measure their glucose levels because to see whether they would get hypoglycemia. But, now that we know that there was no clinical hypoglycemia it gives us the confidence that future trials need have such frequent blood glucose monitoring.

Sameer Baisiwala: Okay, that's all from my side, thanks.

Moderator: Next question comes from Ms. Ashwini Desai from Bajaj Allianz.

Ashwini Desai: Good afternoon sir. Yes, I have two questions, can you please explain why your interest costs have been up, and if you see YOY nine months compared to nine months FY10 and then second question is why have your intangible assets also gone up December compared to March?

Kiran Kumar: I will take the second question. In the current year, we have purchased some IPs from one of our partners and that has led to an increase in the intangible assets compared to last March.

M.B.Chinnappa: Regarding the first question: The interest cost largely relates to the Syngene loan and at Rs 7 crores per quarter, it has been consistent through Q1, Q2 and Q3. When compared to last year, the increase reflects the higher interest rate, including the hedging cost on foreign currency loans.

Ashwini Desai: Okay, that's all from my side, thank you.

Moderator: Next question comes from Mr. Akshat Vyas from Anvil Shares.

Akshat Vyas: Yeah, congratulations on good set of numbers.

Kiran Mazumdar-Shaw: Thanks.

Akshat Vyas: I just wanted to clarify one thing, after the 16% rebate impact AxiCorp growth is 12%, right?

Murali Krishnan: Right.

Akshat Vyas: So, going ahead should we see that this much growth in AxiCorp coming in or it will be lower than this?

Kiran Mazumdar-Shaw: I think we are trying to be very cautious about this and we would like to feel that we should not look at even 12% growth because one of the things is that we are planning to actually also downsize the portfolio of AxiCorp and you might see just marginal kind of growth.

Akshat Vyas: Single digit growth.

Kiran Mazumdar-Shaw: Yes.

Akshat Vyas: Okay, thank you ma'am.

Moderator: Next question comes from Ms. Arora Priti from Kotak Institutional.

Arora Priti: Yeah, thanks. I just wanted to know is this 55 crores of R&D net expenditure, I thought that you had indicated that the reimbursements on R&D front had been booked in other expenses, is that correct?

Murali Krishnan: There are two levels of recharge. Some of the expenses are books under R & D costs and others are taken to the respective line items & included in other expenses.

Arora Priti: Okay, so what is the gross expenditure?

Murali Krishnan: We will come back to you on that.

Arora Priti: Okay, thanks, that is it from my side.

Moderator: Next question comes from Mr. Krishnendu Saha from Quantum AMC.

Krishnendu Saha: This is a followup question, next financial year Pfizer is going to launch in the non-regulated markets with your help, could you let me know what is the market size for those couple of countries?

Rakesh Bamzai: We are talking about many countries. It will start next fiscal but it will continue for the next 3 to 4 years. We are looking at market potential of around 100 to 200 million dollars.

Krishnendu Saha: Accumulated, right?

Rakesh Bamzai: Yes, these are emerging markets alone.

Krishnendu Saha: And start from next financial year?

Rakesh Bamzai: Yes.

Krishnendu Saha: Okay and Pfizer does not have any presence in those markets as of now, is it?

Rakesh Bamzai: Pfizer does not have an insulin portfolio other than these.

Krishnendu Saha: And one more question on the AxiCorp, would you not be participating anymore in the tender business?

Kiran Mazumdar-Shaw: No, we are participating in the tender business.

Krishnendu Saha: Okay, right because I understood it wrongly probably that you are downsizing the portfolio?

Kiran Mazumdar-Shaw: No, only of their existing business, the non-tender business. Yeah, non-tender business we want to basically see how we can improve the earnings.

Krishnendu Saha: Okay and when is the next tender, any idea, like let us know?

Kiran Mazumdar-Shaw: I think these tenders are quite regular. I think the next one is in a few months time.

Krishnendu Saha: Fine, thank you very much.

Moderator: Next question comes from Ms. Monica Joshi from Avendus Capital.

Monica Joshi: Hi, I just wanted a clarification on the R&D, in the first half you spent about 40 odd crores, so is that what we should assume is your R&D excluding insulin and developmental insulin in European markets, is that right?

Murali Krishnan: The R&D expenses could be lumpy. It depends on several factors such as when we get the approval for starting the, when the trials actually begin, etc., Hence our R & D spends should be evaluated on an annual basis.

Monica Joshi: I understand, so Rs 150 crores as what you were looking at and probably Rs 180-190 crores in FY12, how much of this would be your biosimilar insulin cost?

Murali Krishnan: It will be largely on biosimilars (Insulins and MAbs) and the other novel programs.

Monica Joshi: Okay, thank you so much.

Moderator: Next question comes from Mr. Nitin Agarwal from IDFC.

Nitin Agarwal: Ma'am, just wanted to check on fidaxomicin, now it has got an off on drug status and it is probably looking for an approval sometime next year, how material in opportunity will it be for Syngene business going forward?

Kiran Mazumdar-Shaw: It will be quite material.

Nitin Agarwal: So, what is your sense in terms of the size of where fidaxomicin could be in a couple of years?

Kiran Mazumdar-Shaw: This is an opportunity that will be a Biocon opportunity, not a Syngene opportunity.

Nitin Agarwal: Okay, but how big do you see this opportunity potentially being in 3 to 4 years?

Kiran Mazumdar-Shaw: Well, it depends on the success of the drug, but certainly we expect it to be a very good drug and we expect it to have a big upside for us as well.

Nitin Agarwal: But, I mean, so this is a one off sort of an arrangement that you had with an innovator where you were working with the innovator through the development phase or there are more products which are close to commercialization or like fidaxomicin?

Kiran Mazumdar-Shaw: Fidaxomicin is one such program which has really been very successful for us.

Nitin Agarwal: Okay fine, thanks very much.

Moderator: Next question comes from Mr. Adinarayanan from BloomBerg.

Adinarayanan: Yes, good evening ma'am, do you agree that there was a assertion from Novo that after the tender thing that happened in Brazil that their cost of production for insulin were about 45% lower than yours, is it just sheer production economies of scale or is it some technological difference between the way you produce it and the way the Novo produces it.

Kiran Mazumdar-Shaw: We don't agree with Novo's comments, but having said that I don't think we want to comment on it, because I really don't agree with what they are saying.

Adinarayanan: Okay and what sort of a global market share do you target to achieve now that you are entering this deal with Pfizer and becoming a bigger global player, where do you see Biocon being in about 3 to 4 years' time?

Kiran Mazumdar-Shaw: We have done this deal with Pfizer to be a very significant player in the insulins market and I think this question we will be able to answer in the years to come.

Moderator: Next question comes from Mr. Nimish Mehta from MP Advisors.

Vishal: Hi, this is Vishal from MP Advisors. I have a question on your oral insulin trials; I just wanted to know whether it was an open label or a double blinded trial?

Kiran Mazumdar-Shaw: It was a double blinded placebo controlled trial.

Vishal: Okay and can you also explain, like why we did not see the placebo effects as far as your secondary endpoint is concerned?

Kiran Mazumdar-Shaw: No, because it is a post-prandial insulin, it is doing what it is supposed to do.

Vishal: Does dieting and exercising not affect the insulin sensitivity of the body, so like after continued exercise your insulin sensitivity improves and that can probably also affect the postprandial glucose?

Vivek Shenoy: Well, you see the secondary endpoints were compared and were statistically significant compared to the placebo, so the primary endpoints it has been shown that the HbA1c level does get affected and even if internal insulin secretion was enhanced with exercise, even then the secondary endpoints showed very clearly that IN-105 was superior to placebo.

Vishal: Okay, thank you.

Moderator: Next question comes from Mr. Avinesh Burman from India Infoline.

Avinesh Burman: Yeah, hi, I am sorry for the earlier glitch. I just wanted to have a quick view on the AxiCorp product portfolio, wanted to know whether the products majorly are backward integrated products or are they majorly traded products.

Kiran Mazumdar-Shaw: They are traded products.

Avinesh Burman: Okay, thank you ma'am.

Moderator: Next question comes from Mr. Harish Swaminathan an individual investor.

Harish Swaminathan: Good afternoon, my questions are basically around IN-105, I just wanted to know could the placebo effect, could it have been minimized or foreseen by the design of the clinical trial or is it something that could not have been avoided, that is my first question?

Kiran Mazumdar-Shaw: Well, it could not have been avoided because we had to do certain trials in a certain way as a first trial because you know investigators would be very concerned with hypoglycemia, investigators wanted to make sure that we did the trials in a very responsible way, so I think we could not have avoided what happened in this particular trial in terms of frequent blood glucose monitoring and other aspects of the trial.

Harish Swaminathan: Okay, can you share anything on the Type 1 trials?

Vivek Shenoy: The Type 1 trials are ongoing and should be reading out sometime around the middle of the year.

Harish Swaminathan: Okay, thank you. Thank you very much.

Moderator: There are no further questions, now I handover the floor to Ms. Kiran Mazumdar-Shaw, Chairman and Managing Director of Biocon for closing comments.

Kiran Mazumdar-Shaw: Thank you very much for participating in this call and if you have any queries please do contact my colleagues Murali Krishnan, Kiran Kumar and M.B. Chinnappa. Thank you.

Moderator: Thank you madam. Ladies and gentlemen, this concludes your conference for today. Thank you for your participation and for using Door Sabha's conference call service. You may disconnect your lines now. Thank you and have a pleasant day.