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 of Citigate Dewe Rogerson. Over to you ma'am.

Urvashi Butani: Thank you so much. Good afternoon everybody and thank you for joining us on Biocon Limited's Q2 and H1FY11 conference call. We have with us on this call today Ms. Kiran Mazumdar-Shaw, Biocon Chairman and Managing Director and also her colleagues who are part of the senior management team. We will begin this call with opening remarks from the Biocon management followed by interactive Q&A session. I would like to add that some of the statements in this conference call maybe forward looking statements and a note to that effect is in the release sent out to you earlier. I would now like to invite Ms. Kiran Mazumdar-Shaw to briefly discuss the company's performance for the quarter ended 30th September 2010. Over to you ma'am.

Kiran Mazumdar-Shaw: Thank you Urvashi and good afternoon all. This is indeed a very important earnings call for us at Biocon. We are extremely pleased to report a very strong set of numbers this quarter and for the first half of this fiscal. For the first half of FY11, we have delivered revenues of Rs 1360 crores, a 24% increase over the previous year, an EBITDA of Rs 293 crores and a PAT of Rs 166 crores, a 26% increase over last year's number. Importantly, the EBITDA margin has increased from 21% to 22% at a consolidated level and maintained at 30% excluding AxiCorp. We have seen traction across all business segments. I would like to make a special mention of the branded formulations business which grew a robust 30% and our research services business which grew 20%. However, the margins and the bottom lines for the research services do not show much growth because we are recalibrating our business

offerings in these segments. We have seen that the global landscape is changing quite extensively in these businesses and customers are now demanding value-added services, differentiated speciality services, and this is something that we are now revamping and gearing up for. We see a number of our fee-for-service offerings threatened by commoditization and extensive competition, and it is for this very reason that a few quarters ago we have actually put into place infrastructure and skills that can actually take us into this value-added services space.

AxiCorp also has had a stellar quarter. It has delivered a 30% growth in the first half with good traction in the generics business. This has grown 117% YoY and we have won several important tenders like Metformin, Simvastatin, Metoprolol, Amoxicillin, and Fluconazole.

But as all of you know one of the biggest events that we have to report this quarter is our global commercialization agreement with Pfizer for our biosimilar insulins portfolio that comprises recombinant human insulins, Glargine, Lispro, and Aspart. I think that this is a transformational phase in our business. This particular agreement is an important partnership for us with a deal size of $350 million in the form of upfront and milestone payments.

I would like to highlight that these upfront and milestone payments will be received by Biocon as follows - An immediate $100 million upfront payment will be received by Biocon this quarter and this will be reflected in our balance sheet. We will recognize income against this upfront fee over a period of three to five years, linked to certain specific development activities. We will be receiving an additional $100 million upfront into an escrow account that will be drawn down based on certain specific activities largely pertaining to capacity expansion over the next three to five years. In addition, we will also see milestone payments of $150 million upon reaching certain development and commercialization milestones. In addition, Biocon will also receive payments linked to sales in the global markets starting next year onwards because Pfizer does expect to get into certain emerging markets immediately. Although these numbers will not be large, the real numbers will start from 2015 onwards when the insulins are expected to enter the regulated markets. Biocon will be co-marketing these insulins with Pfizer in certain markets such as India and Germany. Besides these, Pfizer will also have co-exclusive commercialization rights in certain other markets where we currently have certain licensees marketing our insulin products. With this overview, I would like to move to the Q&A session. I

request people to kindly state their names and identify themselves when asking these questions. And if there are any questions that we are not able to answer at this conf call, please do get in touch with our Investor Relations department and they will certainly answer all your queries. Thank you very much.

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. Bino Pathiparampil from IIFL.

Bino Pathiparampil: Hi, good afternoon and congratulations on the great quarter that also saw a lot of news flow. Can you tell me what was the licensing fee income recorded in the quarter?

Kiran Mazumdar-Shaw: Rs 23 crores.

Bino Pathiparampil: Ok. Also, I noticed that your R&D expense was lower than last quarter and originally I thought it would be much higher given that you are starting the Phase 3 trial. So what has happened there?

Kiran Mazumdar-Shaw: Well, I think you should look at this on an annual basis as R&D expenses are lumpy because of the timing of payments pertaining to certain clinical trials. Please, don't look at it quarter-wise but on an annual basis.

Bino Pathiparampil: If your original guidance is to be met then the second half would see double the research and development expense of the first…?

Kiran Mazumdar-Shaw: Yes, that is correct.

Bino Pathiparampil: And the other expenses were much higher as well. Was there any one-off item in there?

Murali Krishnan: Are you comparing with the Q1 sequential quarter?

Bino Pathiparampil: Yes, sequential as well as YOY.

Murali Krishnan: I will ask my colleague, Kiran Kumar, to answer this.

Bino Pathiparampil: Okay. And lastly on AxiCorp, could you give some color on the tender business margins and price points compared to say Indian price points - how below are the market prices in the tender business in Germany and what margins do you make there?

Kiran Mazumdar-Shaw: We cannot share any information on this.

Bino Pathiparampil: Okay. I will get back in the queue. Thank you.

Kiran Kumar: On your previous question on the other expenses, we have seen some increase in the promotional expenditure for our formulations business and some maintenance expenses for plant operations.

Bino Pathiparampil: Okay. Thank you very much.

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

Ranjit Kapadia: Good afternoon and congratulations on the Pfizer deal. My first question refers to AxiCorp which has done sales of about Rs 335 crores during the quarter but the net profit is only Rs 1.9 crores so the net margin is 0.5% and the EBITDA margin is approximately 9%. So going further with a five year deal what is the management thought on AxiCorp?

Kiran Mazumdar-Shaw: Let me answer your second question on AxiCorp. This was an acquisition we made specifically to launch our biosimilar insulin in Germany as the first market for a European global footprint. Now, with the Pfizer deal in place, this is an exciting opportunity for us to really do a co-marketing exercise with Pfizer in Germany, and as per the deal, the rest of Europe will be taken by Pfizer. We remain committed to the plan of using and leveraging AxiCorp's good understanding of the insulins business and this is a very exciting time for us to build a good marketing base for us in Europe through Germany.

Ranjit Kapadia: Can you comment on the profitability of this company because it is eating into the overall margin of the Group.

Murali Krishnan: Axicorp is a marketing / distribution company and therefore has a much lower margin than the manufacturing business. Having said that, on a quarterly basis, it has been delivering about Rs 7-10 crores for the Biocon Group. For H1 FY11, it has recorded Rs 19.5 crores against last year's Rs 10 crores.

Kiran Mazumdar-Shaw: I am not sure where you got your number from but in the first half of the fiscal, AxiCorp has delivered Rs 19.5 crores in profits.

Ranjit Kapadia: The number came from the difference between consolidated and standalone.

Murali Krishnan: Consolidated numbers have all the subsidiaries numbers within it and just not Axicorp. Therefore, computation of Axicorp's number this way will not give the correct numbers. The profit for Axicorp is Rs 19.5 crores in the first half against last year's Rs 10.4 crores.

Kiran Mazumdar-Shaw: We have always maintained that AxiCorp is going to be a top line business for sometime until the insulins kick in. And therefore, I don't think you have to start looking at AxiCorp any differently now. Having a marketing footprint in Europe involves a brand-building exercise and we cannot do it without having a company like AxiCorp in place.

Ranjit Kapadia: And can you give a flavor of the tender business - you have won five tenders for Metformin, Simvastatin, etc. Can you throw some light on what is the competition like in Germany and how you were able to garner these tenders with steep competition?

Kiran Mazumdar-Shaw: Well, we support Axicorp with a strong supply chain from India and that is how we are able to win these tenders.

Rakesh Bamzai: I would like to add to what our Managing Director just said. Most of the generics business in Germany is going the tender way. And besides other trading businesses, AxiCorp has created a good presence in the tender business there. We have won some major tenders and some minor tenders.

Ranjit Kapadia: And how are the margins likely to improve over a period of time for AxiCorp?

Kiran Mazumdar-Shaw: I don't think we should expect any margin improvement. On the contrary, there is likely to be a slight margin erosion as the German government has mandated an additional 10% rebate to be given by all drug companies. Fortunately, AxiCorp has taken some steps to minimize the impact on its earnings.

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

Kiran Mazumdar-Shaw: Thank you.

Moderator: Next question comes from Mr. Krishna Prasad from JM Financial.

Jesal: Hi, this is Jesal. Can you tell us something about the trials, in Germany? On which forms are they really on, and what will be the implication of that for the other forms. Do you think you can use these trials for filing even the other forms of insulin?

Kiran Mazumdar-Shaw: No, this is for recombinant human insulin. Each analog is a distinct product so you cannot use the data of one product for another.

Jesal: Right. In terms of the market size in Germany between the various insulins and the various devices, I don't know whether the trials are for pen or for cartridges, but when do think you will be able to have a portfolio addressing the German markets fully?

Kiran Mazumdar-Shaw: We are addressing this in a holistic way. We are trying to make sure we will be present in the market with everything required starting 2013 onwards.

Jesal: Right. So do you already have the pen devices for that market?

Kiran Mazumdar-Shaw: Well, yes, we have these pens under development.

Jesal: Okay. And just one question on oral insulin - Given that you have such a big deal with Pfizer for generic insulin, I was wondering if there was ever any discussion on the oral insulin part of the business?

Kiran Mazumdar-Shaw: The deal with Pfizer is confined to the biosimilar insulins portfolio. Oral insulin is a novel asset and we will license it separately. It is not part of the deal with Pfizer.

Jesal: Right. So, there is no right given to Pfizer on any kind of first right of refusal or any such thing?

Kiran Mazumdar-Shaw: We have not given any such right.

Jesal: Right. Can you tell us the status of the oral insulin trials in the US?

Kiran Mazumdar-Shaw: We are doing multiple trials to create global asset value for oral insulin. The original thinking was to have a two-pronged strategy for oral insulin – one for India and the other global - but the thinking has changed since then and we now believe that it is important to focus on a global asset creation model and therefore we have dropped our

plans to register in India first. We realized that there is a potential of devaluing this asset if we do that so we will now stick to a global development plan that will engage and involve a number of clinical trials under the US IND. And we have already commenced the first of these trials and we expect to start a few more trials starting next quarter onwards.

Jesal: Okay, thank you.

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

Bhavin Shah: Good afternoon and congratulations on the path breaking deal. A couple of questions – when does the recombinant insulin get registered in the US?

Kiran Mazumdar-Shaw: As you are aware, the US still does not have guidelines for biosimilars but we are evaluating a 505 b(2) route for this particular registration and we expect that it could happen any time around 2015.

Bhavin Shah: And the increase in MMF and Tacrolimus supplies - how many partners are you supplying to currently?

Rakesh Bamzai: For Tacrolimus, in the US, we have four approvals. Out of those four approvals, we have two customers presently. And in Mycophenolate Mofetil, we have three customers. In both cases, we have three customers each in the pipeline. Once the approval comes through, we expect to garner a good market share.

Bhavin Shah: If you could share the outlook on the research services segment - when does the inflection point really come?

Kiran Mazumdar-Shaw: As I mentioned earlier, in terms of top line, the research services business has grown about 20% YoY so we have no doubt that this is a business that is doing well. However, we are concerned about shrinking bottom lines because we find that the fee-for-service business based on FTEs is becoming very competitive and unless there is differentiation and specialization, we will not be able to sustain growth and margins. Based on this, we are revamping our business offerings to provide value-added services. We will see some improved performance going forward and we will see the efforts paying off possibly about three quarters to four quarters from now.

Bhavin Shah: Okay, thank you so much.

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

Sameer Baisiwala: Hi, good afternoon everyone and big congratulations on this Pfizer deal. My first question - Kiran, in your opening remarks you spoke about percentage of sales coming from this deal, fiscal '12 onwards from emerging markets probably not so significant, and then did you say 2015 onwards significant swing?

Kiran Mazumdar-Shaw: Yes.

Sameer Baisiwala: Okay. But I am just wondering because 2013 is when you are expected to launch it in Europe.

Kiran Mazumdar-Shaw: Yes but that will be only recombinant human insulin. The real big ticket items are going to come later.

Sameer Baisiwala: Which are the analog versions?

Kiran Mazumdar-Shaw: Yes.

Sameer Baisiwala: Okay. But I would have imagined this alone is a billion dollar opportunity in Europe so…

Kiran Mazumdar-Shaw: Well, I guess we are being conservative in our estimates.

Moderator: Next question comes from Mr. Vivek Kumar from SBI Capital Securities.

Vivek Kumar: Hi. On your tender business - you were expecting some big tenders for quarter 3 or quarter 4. Is it something that you have got in this particular quarter and is that the reason the tender business has grown 117% or is it that that the big orders are going to be there in Q3 and Q4?

Kiran Mazumdar-Shaw: We won some tenders in the last few quarters and that is what is reflected in these numbers but while we continue to win tenders, you cannot have large numbers coming through by way of tenders. You will see some good top line contribution, but again, the tender business is not a high margin business.

Vivek Kumar: Okay. And is it possible share some color on the research services business - how have they performed in terms of margins?

Chinnappa: We have yet to ramp up to full capacity. We are at about 70% of our capacity utilization and that is telling on the margin, which is currently at about 25%. As we ramp up, there won't be a commensurate increase in the fixed costs

and we should see margins improve as we go towards the end of the year and into the next year.

Vivek Kumar: Okay. The last one is on the CD6 MAb for Psoriasis and Rheumatoid Arthritis. I guess July 2011 is what you are looking at in terms of outcome of the data for Psoriasis. Is it possible then to share some of your assessment as to what is the kind of target market you will be looking at in India for this particular indication?

Kiran Mazumdar-Shaw: Again, I think we should look at the T1h asset as a global partnership opportunity. So we will be looking at this particular asset in terms of unlocking good value for this.

Vivek Kumar: Okay. And on Rheumatoid Arthritis - is it same strategy?

Kiran Mazumdar-Shaw: Yes. We are going to commence RA studies shortly.

Vivek Kumar: Currently in Phase 2b in India?

Kiran Mazumdar-Shaw: It will enter Phase 3 shortly.

Vivek Kumar: Okay, thanks.

Moderator: Next question comes from Mr. Manoj Garg from Emkay Global Financial Services.

Manoj Garg: Yeah, thanks for taking my question. Just want to understand, how big is this biosimilar insulin market in the rest of the world?

Rakesh Bamzai: The global opportunity is $20 billion overall put together and the emerging market is close to 10 to 15% of this market. 85% of this opportunity is in the US, Europe, and Japan.

Manoj Garg: And in the emerging markets where we have 27 registrations, are we expecting to launch them starting next year onwards.

Rakesh Bamzai: That is correct.

Manoj Garg: And who are the other large players in the biosimilars insulin market?

Rakesh Bamzai: There are very few manufacturers because production of insulin is not easy. It involves a lot of technology, background, and a lot of research. In India we are a big manufacturer and there are a couple more - one in China and one in Poland.

Manoj Garg: What is our current capacity and what could be the peak potential in terms of revenue that we can attain from that facility?

Kiran Mazumdar-Shaw: Well, we don't share capacity details but suffice to say that we will be able to support Pfizer's needs from this particular facility for the next three to five years.

Manoj Garg: Okay. And what was the CAPEX we mentioned for putting up another insulin facility? Was it USD 300 million?

Kiran Mazumdar-Shaw: We did not specify that number.

Manoj Garg: Okay, the understanding was that we need to put up an incremental capacity close to around $300 million.

Kiran Mazumdar-Shaw: No, the capacity expansion is not for USD $300 million. That is not a correct number. But there is a capacity expansion required and we will be putting it up.

Manoj Garg: But any numbers of that capacity like how much CAPEX we need for that?

Kiran Mazumdar-Shaw: It will be a fairly large expansion from the existing facility's capacity, and that will come on stream in the next three to five years.

Manoj Garg: Okay. Any numbers on that?

Kiran Mazumdar-Shaw: I don't think we will be able to share any numbers.

Manoj Garg: Okay, thank you very much. Wish you all the best.

Moderator: Next question comes from Mr. Abhay Shanbhag from Deutsche Bank.

Abhay Shanbhag: Hi, congratulations on the deal. Have a couple of questions. On the cash flow front, you are getting about USD 100 million upfront, USD 100 million over next three to five years, so in terms of the cost of development and the CAPEX, would you be cash flow positive from this deal immediately or would you have to spend some money before the escrow and the milestones start coming in?

Kiran Mazumdar-Shaw: Can you repeat that question?

Abhay Shanbhag: If I look at the deal, it is USD 100 million upfront, USD 100 million in an escrow which will come in anywhere from three to five years and there is a milestone of another USD 150 million. You would also be spending a lot of money on both product development and CAPEX. So would it remain

cash flow positive for long or would you have to spend money from your pocket before you start getting money from Pfizer?

Kiran Mazumdar-Shaw: We will be cash flow positive.

Abhay Shanbhag: So your cost of development and CAPEX would be entirely be covered by the Pfizer deal.

Kiran Mazumdar-Shaw: Yes.

Abhay Shanbhag: And what sort of potential can the emerging markets go to?, Probably in say by 2014, 2015, can we expect a revenue of around $40 mn, $50 mn from insulins or can it go to about $200 mn to $300 mn in next three, four years in the emerging markets itself?

Kiran Mazumdar-Shaw: We can't share this data with you but there are good opportunities in these markets and we will do our best in exploiting them.

Abhay Shanbhag: Lastly, in terms of current revenues, will they be transferred to Pfizer because technically now Pfizer would be the front end partner or how would that happen?

Kiran Mazumdar-Shaw: Well, when we have a co-marketing arrangement, we will recognize our own revenues and Pfizer will recognize its revenues from the partnership. There will be some additional income we can get from Pfizer because of payments linked to their sales and supplies of products. But other than that, there is no transfer to Pfizer.

Moderator: The line got disconnected, madam.

Kiran Mazumdar-Shaw: Ok.

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

Nimish Mehta: Hi. Thanks for taking my question and congratulations on a good set of numbers as well as the deal. My first question is related to the R&D expense that we have incurred this quarter. It has been much below the guided expense of Rs 180 to Rs 200 crores so what can we expect in the next coming quarter for this?

Kiran Mazumdar-Shaw: Nimish, R&D expenses are lumpy because they are linked to clinical trials and when we spend that money and when we make those payments. Although you haven't seen such a huge spend this quarter, you are likely to see increased spends for the next two quarters.

Nimish Mehta: Okay. My second question is related to the research services. You mentioned that you have registered a 20% growth on the top line but in the press release we see 7% for Q2 and 9% for the first half, so am I missing something?

Chinappa: Let me explain that - When Kiran referred to 20%, she had read it from our MIS which includes the internal sales. The external sales have grown by 7%.

Nimish Mehta: And at what stage are we with the Bristol Myers contract? Are we likely to see a ramp up or we are servicing them at the full capacity?

Kiran Mazumdar-Shaw: There is still ramp up taking place at the BMS facility.

Nimish Mehta: I see, okay fine. Finally on the deal side - can you share the cost advantage or the price advantage Biocon's insulin offering has in comparison to multinationals in all the markets that you are present in, including India?

Kiran Mazumdar-Shaw: In most emerging markets, it is a very competitive bidding process. I don't think it is offering a discount or a cost advantage in that sense but I think that the biosimilar insulin business opportunity is really about producing high quality insulin and then being able to compete in a very cost effective way. And if you combine that with a very strong brand that Pfizer brings to the table, I think it translates into a very huge value proposition in the biosimilars space.

Nimish Mehta: Right. Finally, what would be the kind of clinical trial expenses that you will be spending on the insulin for the deal with Pfizer?

Kiran Mazumdar-Shaw: Well, we cannot share it at this time.

Nimish Mehta: Okay fine. Thanks very much and best of luck.

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

Monica Joshi: Hi. Thank you for taking my question. Madam, on the R&D cost side, on your P&L account, do we stick to our earlier target of Rs 150-180 crores especially given that your oral insulin and your other molecules are going to be on a global scale, much larger than what you had earlier projected?

Kiran Mazumdar-Shaw: Yes, it will be in that range.

Monica Joshi: Okay. Is it fair for us to assume that not a significant portion of this was earmarked for the biosimilars studies, so that…

Kiran Mazumdar-Shaw: No, this figure includes everything. We have done an exhaustive exercise to include all our research programs and evaluate the kind of spends these will entail during this fiscal to take them to the next level.

Monica Joshi: So we maintain Rs 150-180 crores for this year and the next. Could you give us some guidance on the tax rate?

Murali Krishnan: It will be about 15%. Next year, it will probably be between 15% and 20%.

Monica Joshi: Okay, thank you so much.

Moderator: Next question comes from Mr. Nimish Desai from Motilal Oswal.

Nimish Desai: On the Pfizer deal - is Pfizer giving you any minimum guarantee of market share or is it an open ended kind of a deal?

Kiran Mazumdar-Shaw: We cannot discuss such details of the agreement.

Nimish Desai: Okay, my second question is also related. Nevertheless, I will ask it. You are going to supply insulin to Pfizer when they launch it so should we see that the supplies as a decent opportunity or is there some sharing on the revenue front in the form of royalty you may not be able to make big margins on supplies?

Kiran Mazumdar-Shaw: We have already mentioned that we will be getting payments linked to sales and therefore as soon as we start supplies, those payments will be coming in.

Nimish Desai: The payments are in the form of royalty?

Kiran Mazumdar-Shaw: It is not exactly royalties.

Nimish Desai: So the payment you receive will cover your supplies - the cost as well as your margins. Is that the way we should see it?

Kiran Mazumdar-Shaw: Yes.

Nimish Desai: Okay. My second question is - the balance sheet item, intangibles, have gone up significantly. Could you give some clarification on what has caused this?

Chinappa: This happened in the previous quarter and it reflects additional rights that we had purchased from our Cuban partners in the T1h program.

Nimish Desai: Okay. Lastly, we see a significant reduction in debt but a corresponding reduction in the interest cost is not visible.

Murali Krishnan: We have Rs 246 crores of secured loans in the current year and it is mostly foreign currency denominated loans. The hedging cost in the current year has increased to about 6-7% as against 2-3%. This is reflected in higher interest rates.

Nimish Desai: Okay. Thanks a lot.

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

Krishnandu Saha: Thanks for taking my questions. In Germany will you be solo or will you be with Pfizer?

Kiran Mazumdar-Shaw: With Pfizer.

Krishnandu Saha: And on the financial side, this time the minority interest was Rs 2 crores compared to Rs 3 crores. I would like some clarification on that? In the P&L - it is Rs 22 million.

Kiran Kumar: The minority interest predominantly reflects the share of profits from AxiCorp.

Krishnandu Saha: On the deal side, we have already tied up for Biosimilars with Mylan and we have the insulins with Pfizer so which are the products for out-licensing?

Kiran Mazumdar-Shaw: We have a number of assets in our research pipeline.

Krishnandu Saha: Okay, thank you.

Moderator: Next question comes from Mr. Chirag Talati from Execution Nobel.

Chirag Talati: Good afternoon and thanks for taking my question. Few questions on the Pfizer deal, firstly the deal - does it cover different forms of insulin delivery in the sense of cartridges, vials and injections as well as pens or does it just cover vials and injections for all the four products?

Kiran Mazumdar-Shaw: It covers everything. It covers all the presentations that are required.

Chirag Talati: Secondly, you mentioned that you moved into clinical trials. if you can help me understand - are these glucose clamp trials or have you even begun the immunogenicity trials that are required by EMA?

Kiran Mazumdar-Shaw: We are doing trials in accordance with EMA guidelines and that is all I can share with you right now.

Chirag Talati: Yeah, I mean, what I wanted to understand was that will you be going the process sequentially or will you be running the trials…

Kiran Mazumdar-Shaw: Yes but I am not able to share that information with you at this time.

Chirag Talati: Ok. And in terms of the products, is this only for the recombinant insulin that you started trials or you are also starting it for premix?

Kiran Mazumdar-Shaw: This trial is for recombinant human insulin which is also a premix.

Chirag Talati: Ok. Thank you.

Moderator: Next question comes from Mr. Bino Pathiparampil from IIFL.

Bino Pathiparampil: Hi, just a followup question on the Pfizer payments, the USD 100 million that is coming right away which you will recognize over the 3-5 year period, would that be more back ended or more or less uniform?

Kiran Mazumdar-Shaw: It will be phased.

Bino Pathiparampil: Okay and the $100 million that goes with the escrow and accrues as the capacity expansion happens, will that also be recognized as revenue as it comes?

Murali Krishnan: Yes, over a 4 - 5 year period.

Bino Pathiparampil: Okay, so the question I asked was if it is a more or less uniform payment then it turns out to something like USD 40 million a year which compared to the current rate of licensing fee will be almost three times, so is that something a right way to look at it or is it going to be more back ended?

Kiran Mazumdar-Shaw: It is linked to certain activities and events and therefore it may not be uniform.

Bino Pathiparampil: Okay. Thanks very much.

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

Sameer Baisiwala: On the pen device for India - I guess you will be launching it by the middle of next year or thereabouts so what is the additional clinical work that you are required to do for the India launch, is it too different from the earlier clinical trials or do you build up on that?

Rakesh Bamzai: There are no additional clinical trials needed for launch of a pen device in India but there is a regulatory approval requirement as per DCGI norms for the devices, so we are in the process of getting approval for that.

Sameer Baisiwala: Okay. Are there any meaningful patents surrounding pen devices for Europe and US markets?

Kiran Mazumdar-Shaw: Yes.

Sameer Baisiwala: And for Europe when could the expiration be?

Kiran Mazumdar-Shaw: There are devices that are protected by patents. Our device development partners are aware of the patent scenarios around devices.

Sameer Baisiwala: Okay. And from a capacity point, in three years time I guess once our phase I is ready, what does it do to the current capacity, it doubles, triples, anything that you can help us over here?

Kiran Mazumdar-Shaw: No, we cannot share that information but suffice to say that it will be a multifold expansion of our existing facility.

Sameer Baisiwala: Okay, excellent and just as there is a case in India with DCGI that you are not required to conduct any clinical trials for the pen device, would the same hold true for the European market as well?

Kiran Mazumdar-Shaw: We cannot really share this information with you, but we are doing it as per EMA requirements?

Sameer Baisiwala: Okay, that is perfect and just one last question on Glargine - when will you begin the clinical trials for that?

Kiran Mazumdar-Shaw: We are trying to do it in a timely way so that we can be there on the date of market formation.

Sameer Baisiwala: Okay, could this begin in the next calendar? Would that be a fair guideline?

Kiran Mazumdar-Shaw: Yes.

Sameer Baisiwala: Okay, good luck to you.

Kiran Mazumdar-Shaw: Thank you.

Moderator: Next question comes from Mr. Harish Swaminathan a private investor.

Harish Swaminathan: Good afternoon and first of all thank you very much for this great news on the Pfizer deal just as we had on the enzyme sale deal, so I am very happy on that front. I just have two questions, which are more accounting related questions, if I may. My first - is there any tax implication on the Pfizer deal?

Murali Krishnan: Yes, there will be a tax implication. We will also be spending on the clinical trials and other development activities. The net of this amount will get taxed and the tax rate is expected to be around 10%.

Harish Swaminathan: Okay and my second and last question is on our debt position - on a gross basis we are a zero debt company but we are not so on a net basis right as of now because we have a debt of roughly about Rs 400 crores whereas we have investments of similar amount as of now so I wanted to know the logic behind keeping investments on the one hand and keeping debt on the other hand particularly since we end up paying about Rs 30 crores per year as interest. I just wanted your take on when we might become a zero debt company on a gross basis? Thank you.

Murali Krishnan: The debts were taken by different entities within the group and it is not tax effective for Biocon to fund the subsidiaries. Syngene has about Rs 200 crores and Clinigene about Rs 10 crores. This is reflected on their respective balance sheets. The cash is in Biocon and the same is invested in liquid funds. This position is expected to continue till the respective companies start pay off their debts.

Harish Swaminathan: Okay, what I was just thinking is that on a group basis, on a consolidated basis we end up losing money to the banks whereas if Biocon lends money to the subsidiaries to payout those loans then as a group, because as an investor we just look at the consolidated numbers, so that was the thought process behind this question.

Murali Krishnan: Yes even when we do that, we will have to charge a notional rent on which we would need to pay tax on it. We

have done that in the past and found that it is not tax efficient.

Harish Swaminathan: Okay, thank you very much.

Moderator: Next question comes from Mr. Girish Bhakru of HSBC.

Girish: Hi, thanks for taking my question. A question on the Pfizer deal - there was a case of withdrawal of the marketing authorization application by Marvel in EMA and they were quoted that their PK/PD data somehow did not meet the desired specifications, after that do we have any clear sense on what are the specific guidelines related to the filing of the biosimilar insulin and is our strategy any different?

Kiran Mazumdar-Shaw: The fact that we have started Phase 3 trials means that we have gone beyond that phase.

Girish: Right, so per se it would be fair to assume that it would be meeting in all those parameters?

Kiran Mazumdar-Shaw: Yes.

Girish: Okay. I know this has been raised before - on the global competition front we have not seen big players like Teva or Sandoz going into biosimilar insulins, though they are targeting MAbs and other biologics. What do you think is the key criteria that a player is present in an insulin market and not in the other biologics?

Kiran Mazumdar-Shaw: Well, we must understand that biosimilars are very different from generics. In the case of biosimilars, you need physician's prescriptions because there is no substitutability allowed. So when you look at a product like insulin, you will need a company like Pfizer as a partner who has the marketing infrastructure to get physicians to prescribe our products. Most of the MAbs need lesser efforts to address the kind of prescribers. That is probably why people have not taken to the insulin portfolio as generic companies.

Girish: Okay, alright. Thanks a lot.

Moderator: Next question comes from Mr. Peter Verdult from Morgan Stanley.

Peter Verdult: Yes, good afternoon, this is Peter Verdult here from Morgan Stanley. I have a few strategic questions maybe we could take one each individually. Just firstly, could you remind me what caused the delay with regards to your pen

device? Will you deliver a device longer term that will compete with the FlexPen because I know you made a big deal about the importance of the device earlier in the call?

Rakesh Bamzai: We have two pen devices under development - one is disposable pen and the other is a reusable pen. There are no delays and both pens will be ready at the time of market formation and we will be there in the market.

Peter Verdult: Okay. This is my understanding from work up done, I am not expecting you to either confirm or deny, but if you do choose to do so that will be helpful, but it is my understanding that production capacity for insulin globally stands around 40 tons with Biocon accounting for anything about 2 tons of the capacity which is likely to may be triple over the next seven years, so given that you are going after human insulin, Lispro, Aspart, and Glargine, you have to be thinking about how you are going to spread your capacity, are you going to prioritize products, prioritize geographies, so some sort of comment there would be helpful?

Kiran Mazumdar-Shaw: We have plans to expand capacity in the next few years.

Peter Verdult: I am just trying to get a better understanding of how you are going to prioritize, there are a lot of products, you are going after geographies and it seems to me that you are going to be capacity constrained to supply everything at the same time, so just trying to get a sense as to what are your priorities?

Kiran Mazumdar-Shaw: The capacities we have are adequate to cater to our market projections for the next three to five years and beyond that we have firmed up plans to expand capacity significantly.

Peter Verdult: Okay, it seems to me that with respect to biosimilar insulins the three real challenges are the cost of production given the order copy that is currently present, the device requirements and sales force capabilities and it seems that we have finally got a long way to addressing that side of the equation but in terms of the proposition that you are going to go with hopefully in Europe and the US, are you going to be just essentially trying to win share on price or there is something else you think you are going to be able to do to differentiate yourself versus the incumbent and then could you may be just give us some sense as to your market shares currently outside of India in the emerging markets you are trying to sell recombinant human insulin just to get a sense of how you are approaching there once the market shares are treated?

Kiran Mazumdar-Shaw: The global commercialization strategy will be led by Pfizer so they are the ones who will decide the strategies to gain market share globally.

Peter Verdult: But do you think you know the product, do you think it is going to have much over and above price to differentiate yourself versus the incumbents?

Kiran Mazumdar-Shaw: We recognize that we need to be cost competitive as well. We recognize the fact that biosimilar products will be sold at a discount to the innovator product. How much of a discount and what strategies will be used other than price to enter the market will be decided by Pfizer.

Peter Verdult: So, you are trying to cover the emerging markets outside of India that you are in, I am assuming that you are probably getting in at a 20% discount, what everyone is thinking that your market shares are still below 10% or are you achieving market shares similar to the 15% in India?

Kiran Mazumdar-Shaw: Yes but we have a pretty high market share in certain markets and in certain markets even as high as 30%.

Peter Verdult: Okay, thank you very much.

Moderator: Next question comes from Mr. Adi Narayan from Bloomberg Data Services.

Adi Narayan: Hi, thanks for taking my question. You mentioned earlier in the call that you are realigning the strategies for the oral insulin; you are not focusing on India anymore and focusing instead on getting the US approvals. Just to understand does that mean that you are going to end the India trial and then halt it prematurely?

Kiran Mazumdar-Shaw: No, the India trials continue. In addition, we will have to do many more trials if we have a global approach rather than just an India-first approach.

Adi Narayan: So, India will continue, there is no de-prioritizing of that one?

Kiran Mazumdar-Shaw: Yes, the India trials will continue but we have to put it into a form that converts into a good global package.

Adi Narayan: Does that mean that if the India trial succeeds it will not be launched right away?

Kiran Mazumdar-Shaw: Yes, that is what we are saying. We are not going to launch it in India immediately.

Adi Narayan: Okay.

Moderator: Next question comes from Mr. Priyesh Joshi from NVS Brokerage PVT LTD.

Priyesh Joshi: Hello, yeah sir my question is that how the company is going to deploy the funds that it will be raising from the Pfizer deal?

Kiran Mazumdar-Shaw: We have already stated that we will be using a large part of this fund to program develop and expand our capacity.

Priyesh Joshi: Okay, thanks a lot, ma'am.

Moderator: Next question comes from Ms. Amrita Kasthuri Rangan from Franklin Templeton.

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Amrita Kasturirangan: Thank you for taking my question and congratulations on a very significant deal, just a couple of questions. The first is, was there any discussion around cost sharing for the clinical trials?

Kiran Mazumdar-Shaw: No.

Amrita Kasthuri Rangan: Okay and secondly, Kiran, I know that the pathway has not been defined as yet; it is difficult to do so when we are talking about biosimilars, but…

Kiran Mazumdar-Shaw: Only the US pathway is unclear...

Amrita Kasthuri Rangan: Yes, so I am referring specifically to the United States market here, nonetheless looking at competitors, do you have a sense as to what the scale of the trial could potentially be, what order of magnitude of patients are we talking about and over what timeframe?

Kiran Mazumdar-Shaw: Well, I think one of the approaches for this market for our insulin is the 505 b(2) route. It will all depend on what the US FDA is willing to accept.

Amrita Kasthuri Rangan: Okay, but I mean, just looking at competitors do you think it will be 1000s of patients and may be over a year timeframe mostly in the United States?

Kiran Mazumdar-Shaw: I am unable to comment on this at this point in time. I will be able to share more information a year down the line.

Amrita Kasthuri Rangan: Sure, thank you very much.

Moderator: Next question comes from Ms. Priti Arora of Kotak Securities.

Priti Arora: Thanks, just a question on the R&D costs of Rs 150 to Rs 180 crores; are we to understand this is the gross number or the net of reimbursements from Mylan?

Kiran Mazumdar-Shaw: Net.

Priti Arora: Okay and the second question on oral insulin, you always maintain that the start of out-licensing discussions will happen post phase 3 trials in India so now with the additional discussions are we to understand that the start of the out-licensing discussions will get pushed further may be to…

Kiran Mazumdar-Shaw: Well, you know we are new to this whole innovation game and our original thought process was that we would be able to very easily start engaging in licensing discussions as soon as we finish the Phase 3 clinical proof-of-concept studies in India but it is apparent to us that we need to do some studies under the US IND in order to really build good value for this asset and therefore it is very important that we conduct a few clinical trials under the US IND to add to what we have already done in India. This will make it a much more attractive asset.

Priti Arora: And the first set of these trials have already commenced?

Kiran Mazumdar-Shaw: Yes.

Priti Arora: Okay, that's all, thank you very much.

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

Sameer Baisiwala: Yes, just a question on oral insulin, Kiran. I am just wondering, how would our global approach for oral insulin be disadvantaged if you were to launch it here in India as well?

Kiran Mazumdar-Shaw: Well any potential global licensee will be concerned with the price at which we launch in India and we would run the risk of devaluing the asset.

Sameer Baisiwala: I am sorry, why do you say by India launch it may get devalued, I mean, would this not be validating?

Kiran Mazumdar-Shaw: We have been advised that a global partner might opt for a different product positioning than what we might choose in India and this would not be in the best interest of the product. A combination of price and product positioning that are not aligned with the global partner can certainly reduce our value proposition.

Sameer Baisiwala: Fair enough. But I am just wondering whether the overriding factor would be validation of technology and that would get established if it were to get launched in the market.

Kiran Mazumdar-Shaw: Not really. You will anyway validate the product through clinical trials. So I think being hasty and launching it in India is not going to add value to the program. I think we were in some sense naïve in thinking that an India first strategy would play to our advantage. This thinking has since changed.

Sameer Baisiwala: Okay and any timelines on a potential deal, I mean, it could be middle of next year, end of next year or any such thing?

Kiran Mazumdar-Shaw: Well, let's see how soon we can do it.

Sameer Baisiwala: Okay, thank you.

Moderator: I request the participants to press * and 1 for your questions. Next question comes from Mr. Ravi Agarwal from Edelweiss Capital.

Ravi Agarwal: Yes, thanks for taking my question. Actually a couple of questions, the first is again on the Pfizer deal, when we say we have a net R&D expenditure of around Rs 150-180 crores for this year, this at some level, would also include some of the Phase 3 trials for our insulin project in Germany, that's correct?

Kiran Mazumdar-Shaw: Yes.

Ravi Agarwal: So, are we going to get reimbursed for part of this from the Pfizer deal from the USD 100 million dollars?

Kiran Mazumdar-Shaw: No.

Ravi Agarwal: Okay, the second question is again on Glargine - when we say emerging markets, could Pfizer launch it in India next year?

Kiran Mazumdar-Shaw: Yes. Glargine is already in the Indian market and certainly Glargine will be available to Pfizer for marketing as well.

Ravi Agarwal: Ma'am, but can you also tell me how much of, is there any of the emerging markets where Glargine can also be sold out for the current agreement with Pfizer?

Kiran Mazumdar-Shaw: Yes, there are several markets available to us…

Ravi Agarwal: So, what could be that addressable opportunity in terms of the Glargine markets in emerging markets?

Rakesh Bamzai: The market potential is USD 400 million.

Kiran Mazumdar-Shaw: But the market potential in these emerging markets is USD 400 million.

Ravi Agarwal: The third question is actually if I look at the business this quarter, I mean, taking away AxiCorp and the tech fees, really the quarter seems to suggest that the top end has grown by between 9% to 10% and AxiCorp, the quarterly run rate which we have of around Rs 250 to Rs 260 crores is basically a run rate of the last four quarters, I mean, the question is that if that is really the run rate for AxiCorp going forward then is there something where the case that the base business outside AxiCorp is actually going to do between 9% to 10% only?

Kiran Mazumdar-Shaw: I think we are going to see much higher growth because many of these products that we are currently seeing traction in are going to grow much faster.

Ravi Agarwal: But Biopharma has actually been flat sequentially, so I was actually wondering if there are any issues there outside AxiCorp?

Rakesh Bamzai: Well, the first quarter had the impact from the Atorvastatin launch in Europe for the first time. This was absent in this quarter but the growth has been good in comparison with the last quarter.

Ravi Agarwal: Okay, thank you so much.

Moderator: Next question comes from Mr. Vipul Shah, an individual investor.

Vipul Shah: Yes what is the expense on the clinical trials for the oral insulin program until you reach a deal with any company for this product?

Kiran Mazumdar-Shaw: It is captured within the Rs 150-180 crores that we have guided.

Vipul Shah: Okay, that will include the clinical trial expenses, ma'am?

Kiran Mazumdar-Shaw: Yes.

Vipul Shah: Thank you and all the best.

Kiran Mazumdar-Shaw: Thank you.

Moderator: There are no further questions. I would like to 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 earnings call of Biocon's Q2 fiscal 2011. If you have any further questions, please contact Mr. Murali Krishnan, our CFO or Ms. Jill Deviprasad, our Investor Relations contact. Thank you very much.

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 evening.

Note:
1. This document has been edited to improve readability.
2. Blanks in this transcript represent inaudible or incomprehensible words.