BIOCON LIMITED

Analyst / Investor Conference Call
29th April 2010, 3:00 PM

Moderator: Good afternoon, ladies and gentlemen. I am Shirley, the moderator for this conference. Welcome to the conference call of Biocon Limited. At this time, all participants are in a listen-only mode. Later, when 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 that this conference is recorded. I would now like to hand over the conference to Ms. Urvashi Butani of Citigate DeweRogerson.

Urvashi Butani: Thank you. Good afternoon everybody and thank you for joining us on Biocon Limited's Q4 and FY2010 conference call. We have with us on this call Ms. Kiran Mazumdar-Shaw, Biocon's Chairman and Managing Director and also her senior management colleagues. We will begin this call with opening remarks from the Chairman followed by an interactive Q&A session. I would like to add that some of the statements in this conference call maybe forward looking and a note to that effect has been stated 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 period ended 31st March 2010.

Kiran Mazumdar-Shaw: Thank you Urvashi and good afternoon everyone. Welcome to this investor conference call for Biocon's FY10 annual results. I am very pleased to report that Biocon has delivered a very strong set of numbers this fiscal. The Biocon Group, which includes our German subsidiary AxiCorp, has posted a year-on-year income growth of 44% with revenues at Rs 2,405 crores, a little over half-a-billion dollars. EBITDA is at Rs 509 crores, a 31% year-on-year growth and PAT at Rs 293 crores is a 215% YoY growth. EBITDA margins are at 21% and the number of employees in terms of head count is a little over 4,500. Excluding AxiCorp, our total income stood at Rs 1,493 crores, which is a 25% growth year-on-year. EBITDA is at Rs 455 crores, a growth of 22%, and PAT at Rs 270 crores is a 211% year-on-year growth. It is important to note that our EBITDA margins have been maintained at 30%. The high YoY PAT growth is on account of MTM losses posted last fiscal but I am delighted to say that we have recovered from these losses this year.

Our quarter performance has also been very good. At a group level, including AxiCorp, we have posted a robust 37% year-on-year growth in income at Rs 666

crores, EBITDA at Rs 139 crores or a growth of 26% and PAT at Rs 81 crores, up 225%. EBITDA margins were at 21% largely because of the AxiCorp contribution, which is remains a top line contributor. We have registered an income of Rs 415 crores, which is a 36% year-on-year growth this quarter. EBITDA was at Rs 127 crores, which is again a growth of 25% and PAT was a strong Rs 77 crores, which was again a 280% growth on a year-on-year basis this quarter. Again, our EBITDA margin is very strong at 31% which shows you that the Biocon India business is very robust.

In terms of segment-wise performance, you can see that we have begun to share this in a very detailed way. Our insulins and immunosuppressants businesses together have grown 20%. In insulins, we have grown 11% year-on-year and we have been able to enter into several new markets like Brazil and Chile and we have also secured registration approvals in five countries during the year and we are in the process of registering in 21 other countries over the next few years. Immunosuppressants have registered a strong 28% growth and we believe that both these segments are going to be very important in terms of contributing to growth this coming fiscal. Statins have posted a very strong 26% year-on-year growth and we have begun to make very strong inroads into the emerging markets. AxiCorp has posted a 93% year-on-year growth but this is not strictly comparable because last year reflected only three quarters of AxiCorp's financials and this year reflects the full year's revenues. Branded formulations have grown 35% and I think this is a very good indicator of how we have focused on building our branded formulations business. All the segments have delivered well in realizing this 35% growth. In terms of research services, we have grown approximately 25% year-on-year. Largely, this contribution has come from Syngene. Clinigene is now poised to leverage some of the investments we have made in building Clinigene's capabilities and infrastructure. At this time, I am pleased to mention that we have brought on board a new COO for Clinigene, Dr. Abhijit Barve, who comes from the US with 15 years of experience in the clinical development space. Dr. Barve headed Global R&D in CNS for Astellas Pharma prior to this. Dr. Arvind Attignal, the current COO, is retiring and we are very confident that the strong foundation that Dr. Arvind built will be taken forward by Dr. Barve. This is a business that is going to be a very important part of our research services offering going forward.

Also on the research services front, we have realized a 33% margin and this business is beginning to gain traction now as Syngene is increasingly becoming the preferred CRO or clinical research partner of choice. We have also seen Syngene entering into a very interesting partnership deal with Endo Pharma and this again indicates the kind of profile that Syngene is building for its research capabilities. Other highlights include a strong balance sheet with zero debt and our research

unlocking some good licensing revenues for us this year. We have realized Rs 51 crores of licensing income as opposed to Rs 12 crores the previous year and we expect licensing income will be a very important contributor in the coming years. In terms of our research program development, the Mylan partnership in the area of biosimilars continues to make good progress. We expect to enter the clinic later this fiscal. We also expect to advance our novel programs, oral insulin and the Anti-CD 6 antibody, both of which are in Phase III development in India. On our Oral Insulin program, we expect to initiate a Phase I clinical trial under the US IND very shortly. In terms of other programs, our Anti-CD20 program is also likely to enter the clinic later this year.

Overall we are very pleased with the progress we are making on the R&D front. Again, I think it is important for me to point out that our R&D gross spend has increased from Rs 80 crores to Rs 125 crores this fiscal and we expect this to increase to even higher levels in the coming fiscal. R&D is a very integral part of our business but it is also unlocking high value for us. There has been a lot of interest from various global pharma majors for both our leading novel programs, oral insulin and Anti CD6 and we expect to commence some kind of licensing discussions later this year.

With that I would like to start the Q&A session and hand it back to Urvashi. Thank you.

Question and Answer Session

Moderator: Thank you ma'am. 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 the # key.

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

Nimesh Mehta: Hi, thanks for taking my questions and congratulations for a great set of numbers.

Kiran Mazumdar-Shaw: Thank you.

Nimesh Mehta: I have a few questions. First of all, you had given the growth numbers for all the segments. Is it possible for us to get the sales breakup also?

Kiran Mazumdar-Shaw: We are already beginning to share certain segment-wise data. We would prefer not to disclose more details at this point of time to maintain business confidentiality.

Nimesh Mehta: Fine. My other question is - what do you expect out of Atorvastatin? You mentioned in the press release that you are expecting a significant growth. But given that it is a product that does not require fermentation…

Rakesh Bamzai: Nimesh, this is Rakesh. We mentioned in the last conference call in January that we had early entry in Europe through Spain with a different strategy and we are marketing it in Spain and in a few other countries in Europe. Atorvastatin is going to be very important product for Biocon.

Nimesh Mehta: Okay. Any take on Tacrolimus?

Rakesh Bamzai: Sandoz is the only company that has approval for Tacrolimus. There are six other applications under review and all of you are aware that the review period is 24 to 26 months. So, we don't know when the other companies will get approved. As soon as companies get approval, we will be there.

Nimesh Mehta: Okay. You have a supply agreement with two or three customers, if I am not wrong.

Rakesh Bamzai: We have more than 10 customers.

Nimesh Mehta: Okay. Thank you.

Moderator: Thank you sir. Next question comes from Mr. Girish Bakhru of JM Financials.

Girish Bakhru: Can you give us an update on the registration development for your insulin business in the European market?

Kiran Mazumdar-Shaw: In the European market, we have completed the Phase I trials and we are expecting to commence the pivotal Phase 3 trials for registration later this year.

Girish Bakhru: Right. And you talked about the gross R&D being about Rs 125 crores. Does that include CAPEX or is it the revenue expenditure?

Murali Krishnan: It is predominantly revenue expenditure including clinical trials and such other R&D costs.

Girish Bakhru: Okay. And in the accounts I see Rs 78 crores is in the financials…

Murali Krishnan: The reason why we said that the gross is Rs 125 crores is because some of the costs that we are incurring on our R & D programs are being shared by our partners. The total spend is Rs 125 crores and the net charge is Rs. 78 crores.

Girish Bakhru: Okay. The third and last question from my side would be on your raw materials cost. If I look at your accounts, including AxiCorp, for the fourth quarter, we find that the raw material cost, as a percentage to sales has gone up quite a bit, even while your revenue would be consisting of higher value added items like immunosuppressants and other things. So, can you help us understand the factors driving it and what we should expect going forward?

Murali Krishnan: When you say fourth quarter – is it the sequential quarter you are looking at or the FY09 and FY10 quarters?

Girish Bakhru: YOY, FY10 and FY09.

Murali Krishnan: Yes, it has gone up from 43% to 49%.

Girish Bakhru: That's right.

Murali Krishnan: It is a combination of two factors. All these percentages are derived from the revenue number. The first reason is on account of currency fluctuation. Whenever the rupee gets stronger or weaker against the dollar, the revenue numbers go up or down and that has a bearing on the costs expressed as a percentage. Secondly, as indicated in the past, the product mix also plays a role.

Girish Bakhru: Okay, thank you so much.

Moderator: Thank you sir. Next question comes from Mr. Ranjit Kapadia of HDFC Securities.

Ranjit Kapadia: Good afternoon and hearty congratulations. My question relates to the domestic market. You have reported an overall growth of 36% with a strong growth in all the segments diabetology 24%, oncology 59%, cardiology 26% and nephrology 57%. These numbers are good, but ORG March 2010 reports the growth rate as Nil and the MAT ORG from March 2010 reports sales of Rs 70 crores with a growth rate of 3.4%. I presume that the approximate sales formulations are

about Rs 125 crores to Rs 130 crores for the year. Why there is a vast difference in the growth rates given by the company and ORG?

Kiran Mazumdar-Shaw: ORG does not capture the complete market data. They don't record institutional sales and also few segments such as Oncology, etc. I can tell you that the number that you spoke about Rs 125 crores plus is more like what we have realized.

Ranjit Kapadia: And my second question relates to AxiCorp. We have done sales of Rs 251 crores for the fourth quarter and the full year sales was Rs 912 crores. This means that the fourth quarter sales are about 28% approximately for the year. However, the EBITDA margin for the fourth quarter was just 4.8% against the full year margin of 5.9%. Even the net margin was 1.6% for the fourth quarter against the net margin of 2.5% for the full year. Are the margins likely to shrink going forward?

Murali Krishnan: This particular quarter, they have taken a one-time charge very similar to the charge taken by Biocon consequent to the purchase of the 49% stake held by CIMAB in BBPL. Axicorp had purchased a 15% stake held by minority shareholders in one of their subsidiaries. As a prudent measure, they have taken it as a charge instead of accounting it as goodwill.

Ranjit Kapadia: So, can we assume that the future will be in the range of 6% EBITDA margin and 2.5% net margin?

Murali Krishnan: Yes, it should be around that level.

Ranjit Kapadia: Okay. Thank you and wish you all the best, sir.

Murali Krishnan: Thank you.

Moderator: Thank you sir. Next question comes from Mr. Alok Dalal from MF Global.

Alok Dalal: Thank you for taking my questions. Madam, can you throw some light on the services business going forward? Do you think you will be able to maintain this 25% growth rate?

Kiran Mazumdar-Shaw: Well, that is certainly the aim. I think we do have some good opportunities on the horizon. So, I think we will aim for this goal.

Alok Dalal: Okay. Out of the Rs 281 crores from contract services, how much did Syngene contribute?

Kiran Mazumdar-Shaw: Syngene did about 90% of this sum.

Alok Dalal: Okay. And any progress on the listing of Syngene?

Kiran Mazumdar-Shaw: Yes, the plan is to list Syngene and hopefully we will do it this coming fiscal.

Alok Dalal: Okay. And sir, what will be the CAPEX guidance for FY11?

Murali Krishnan: It is likely to be in the region of Rs 250 crores plus. This is going to be largely driven by the projects that we have taken up in the recent past like the additional biosimilar manufacturing capabilities that we need to create.

Alok Dalal: Okay. Specifically for the biosimilars - could you throw some light on the CAPEX number?

Murali Krishnan: Well, it is going to be a substantial part of the Rs 250 crores.

Alok Dalal: Okay. Thank you.

Moderator: Thank you sir. Next question comes from Mr. Bino Patiparambil of IIFL Capital.

Bino Patiparambil: Congratulations on a good set of numbers. There seems to be a significant pickup in the quarter in biopharmaceuticals. Do you think a part of this is related to inventory buildup in Tacrolimus by some customer; is it likely to come off in the next couple of quarters?

Rakesh Bamzai: This is a combination of a lot of products like Simvastatin, immunosuppressants, etc. It is not only Tacrolimus inventory building.

Binu Patiparambil: Okay. And the licensing fee also seems to be pretty high compared to earlier quarters so is there any contribution from any particular customer that is a large component?

Murali Krishnan: No, it has been more or less the same as previous quarters. It has not changed significantly.

Binu Patiparambil: Okay. Does the Mylan deal include the license fee payment? Is it recognized under this?

Murali Krishnan: Yes, it does.

Kiran Mazumdar-Shaw: In this last quarter, there was a licensing income of approximately Rs 12 crores, a large part of which came from Mylan.

Binu Patiparambil: Okay. And what was the CAPEX for FY10?

Murali Krishnan: It was about Rs 80 crores for Biocon in FY10. We had planned for Rs 100 - 125 crores in Biocon but we were able to contain it at about Rs 80 crores. For the entire group, the number is Rs 135 crores.

Binu Patiparambil: Does that include the IDL and BBPL buyouts?

Murali Krishnan: It includes the IDL buyout but not BBPL.

Binu Patiparambil: Okay. The contract research revenue over the last three quarters seems to be pretty stagnant. Have we seen the full ramp up in BMS revenues?

Kiran Mazumdar-Shaw: Let me correct that. It has not been stagnant at all. We have seen a steady growth in the contract research levels. It has increased from Rs 64 crores in the first quarter to Rs 73 crores in the second quarter and now it is Rs 74 crores in this quarter.

Binu Patiparambil: Okay. We can expect some ramp up then?

Kiran Mazumdar-Shaw: Yes.

Binu Patiparambil: Okay, great. Thanks.

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

Bhavin Shah: Good afternoon and congratulations on the numbers. Madam if you could share some more insight into your emerging markets operations - how do we go about distributing there, etc? I know that you are pushing insulin and immunosuppressants specifically, but anything you can share on the distribution side of it?

Rakesh Bamzai: Insulin is going to be one of the major products for us in the emerging markets. Also, we are going into the emerging markets with more products in small molecules and in monoclonal antibodies.

Bhavin Shah: Do we intend to do any partnerships there or are we going alone?

Rakesh Bamzai: We are looking at a few markets ourselves and a few partnerships in some markets.

Bhavin Shah: Okay, great. And could you give us some more insight into the IDL facility that was acquired. What kind of ramp up do we expect in the next fiscal?

Murali Krishnan: We are commencing operations there and we should be getting contribution from this facility during this fiscal.

Bhavin Shah: Okay. Lastly, any data expected from IN 105 in the second half of this year?

Kiran Mazumdar-Shaw: Yes, we should have some data by the second half of this fiscal.

Bhavin Shah: Thank you so much.

Moderator: Thank you sir. I request the participants to press * and 1 for your questions. Next question comes from Ms. Monica Joshi of Avendus Capital.

Monica Joshi: Congratulations on a good set of numbers. Just a couple of questions - one is on the statins front. You have put out a growth which is quite strong. Can you just give us some color on what is driving this growth and do you see some bit of smaller or inefficient players actually moving out of the market? That's one and secondly on the research services if you could give a breakdown of the Syngene and Clinigene for Q4.

Rakesh Bamzai: I can take the first question on statins. The growth is because of two new statins in the market. Also, on the existing statins that we are already marketing, the growth has been quite good and the prices are stabilizing. And we see that happening in this year as well.

Monica Joshi: Also, a breakdown between Syngene and Clinigene.

Kiran Mazumdar-Shaw: Syngene is about Rs 252 crores and the balance is Clinigene.

Monica Joshi: That's for the quarter?

Kiran Mazumdar-Shaw: That was for the whole year.

Chinappa: Syngene's contribution is 90% and 10% is from Clinigene.

Monica Joshi: Thanks.

Moderator: Thank you ma'am. Next question comes from Mr. Surya Patra of Systematix Shares.

Surya Patra: Congratulations on a good set of numbers. What was the performance of BBPL during the year? Was it loss making or has it turned around?

Murali Krishnan: BBPL has delivered a small profit this year. We will be using this facility not only for BIOMAb manufacturing but also for developing other molecules which are in the clinical stage.

Surya Patra: Okay. But can you share some numbers at the top line?

Murali Krishnan: BBPL does only manufacturing and the marketing is done by Biocon. During consolidation, the inter-company sales get eliminated.

Kiran Mazumdar-Shaw: We charged Rs 3 crores as losses on account of BBPL when we acquired the business. Going forward, we do not expect any losses in this business.

Surya Patra: Okay. You indicated that CAPEX for this year would be Rs 250 crores. Would that would be for the FY11 or it would be for next two years?

Kiran Mazumdar-Shaw: This estimate is for FY11.

Surya Patra: Okay. And on the statins, once Atorvastatin comes to the market, what would be its impact on Simvastatin? Would the market of Simvastatin shrink to some extent?

Rakesh Bamzai: It's a good question. In my view, Simvastatin will come down and Atorvastatin will go up. We are lucky because we use the same manufacturing facility for both and we have extended manufacturing facilities for other statins.

Surya Patra: Okay. Thanks.

Moderator: Thank you, Sir. The next question comes from Mr. Binu Patiparambil from IIFL Capital.

Binu Patiparambil: Hi, I had a question on the insulin biosimilars for Europe and the US. You said some time ago that the European Phase III pivotal trials are expected to begin later this year but I think we have been planning it for quite some time. Are there some unexpected delays happening there?

Kiran Mazumdar-Shaw: Yes, the whole regulatory process was more complex than we had earlier anticipated, so we have had some delays in terms of reaching this Phase III but we are now clear about what the regulators want.

Binu Patiparambil: Okay. Would you need another small trial before you start the pivotal trial?

Kiran Mazumdar-Shaw: No, we don't. Initially we had to do the Phase I trials and now we have to do a trial for registration purposes.

Binu Patiparambil: Okay, do you have a design or …

Kiran Mazumdar-Shaw: Yes, we have actually consulted with the regulators and then arrived at this pathway.

Binu Patiparambil: Right. So how big a trial would that be and what is the duration?

Kiran Mazumdar-Shaw: This is sensitive information we cannot share.

Binu Patiparambil: Okay. And what is happening with the US partner?

Kiran Mazumdar-Shaw: The Phase I trials are over and we are looking at the Phase III trials.

Binu Patiparambil: Okay, thank you very much.

Moderator: Thank you, Sir. The next follow-up question comes from Mr. Girish Bakhru from JM Financials.

Girish Bakhru: Thanks for taking my question again. Could you give me some idea about the planned R&D expenditure for the next year given that you have several projects for both novel biologics and bio generics?

Murali Krishnan: It would be double of what we have done this year.

Kiran Mazumdar-Shaw: Yes, at the gross level it may be close to Rs 200 crores.

Girish Bakhru: And do you expect to bear all of that? For instance, this year the gross was Rs 125 crores but the net that you had to spend was only about Rs 78 crores. Do you expect a similar situation?

Kiran Mazumdar-Shaw: Yes, some of it will be shared, but there will certainly be some increase in the net spend.

Murali Krishnan: However, for our exclusive programs like the insulins, we will bear the entire cost.

Girish Bakhru: Right. And with regard to your project with Mylan, you mentioned that some monies were spent and that is the difference between gross and net R&D for this year so the amount is about Rs 50 odd crores which would then mean that a lot of progress would have been made on these products. Could you share some information on this?

Kiran Mazumdar-Shaw: Not all of it came from Mylan. Well, we have already shared that we expect some of these programs to go into the clinic later this year.

Girish Bakhru: For the Mylan programs?

Kiran Mazumdar-Shaw: It includes Mylan.

Girish Bakhru: I see, okay. And on the insulin business, in your opening remarks you referred to getting approvals for insulin for several export markets including Brazil and Chile. Can you give us a sense of what we should expect in the next few years from these markets?

Rakesh Bamzai: Yes, today we have approval over 30 countries and we are expecting another 25 countries over the next two years.

Girish Bakhru: Right. What should we expect in terms of the revenues because I don't know how big these markets are and what is the competition in these markets?

Rakesh Bamzai: There will be good growth in these markets. We do not disclose the numbers for competitive reasons, but the growth will be there. Insulin is a very important franchise for Biocon.

Girish Bakhru: Right. And any thoughts on what kind of growth we should expect for the overall company in the following year given your 25% growth this year?

Kiran Mazumdar-Shaw: The aim is always to get at least 20% growth every year, but as you know we are bound by a lot of regulatory approvals. Therefore it is very difficult to give accurate guidance and that is why we don't give guidance.

Girish Bakhru: Right. Given your expenditures on R&D, do you think you will be able to maintain margins for the following year?

Kiran Mazumdar-Shaw: Well, we have done very well this year. You can see that despite the high costs of R&D, we have managed to deliver a very strong set of numbers so the aim is of course to better that and we think that we should be able to do that next year.

Murali Krishnan: We will certainly be able to maintain the operating margins but we can do better if we can attract more licensing opportunities.

Girish Bakhru: Okay, thank you so much.

Moderator: Thank you, sir. Next question comes from Mr. Ritesh Shah of IDFC Securities.

Ritesh Shah: Hello. Murali I listened to you on the working capital front that there has been a very sharp improvement during the year. Are these working capital levels sustainable?

Murali Krishnan: We want to better this actually.

Ritesh Shah: But what really drove this kind of sharp improvement in working capital this year - anything particular happened?

Kiran Mazumdar-Shaw: Well, better collections certainly.

Ritesh Shah: Even the inventory levels are down pretty much.

Kiran Mazumdar-Shaw: Yes, there has been a lot of work in this area to reduce inventory and to improve some of the debtors' positions.

Ritesh Shah: Perfect. And on CAPEX, when you are saying Rs 250 crores, what are we looking to spend all this money on? In other words, what are the major initiatives there?

Murali Krishnan: As mentioned earlier, a part of this will go towards our biological facilities that we need to get ready and operational for our MAbs program.

Kiran Mazumdar-Shaw: And our Biocon Research Center. These are the two main spends.

Ritesh Shah: But, this biological facility is different from the BBPL facility that we have acquired?

Kiran Mazumdar-Shaw: We will be expanding it.

Ritesh Shah: Okay. And what is this IDL business that you have bought, is it an FDA approved facility and is this going to help you with rest of the sales…how is it going to work?

Kiran Mazumdar-Shaw: Well we are getting it ready for US-Europe regulatory standards, but right now it is not an FDA approved facility and it is being used for either intermediate production or for the emerging markets.

Ritesh Shah: Okay. And lastly with this bit of hurdle encountered for the European trials of insulin, are there any new timelines when you see yourself getting into the markets now?

Kiran Mazumdar-Shaw: Well, we expect to launch our insulin in the next two years.

Ritesh Shah: So, this would be more like calendar 2013 now?

Kiran Mazumdar-Shaw: Yes, 2013-14.

Ritesh Shah: Okay. And with the launch of the insulin pens in the second half of this year - how is it going to really change things? Does it really increase the market that is available to you in India and some other markets?

Kiran Mazumdar-Shaw: Absolutely. Not having the pen excluded us from the pen market up until now and I think that it was a big handicap so going forward getting the pen is going to be very useful for us.

Ritesh Shah: Okay. Thanks very much.

Moderator: Thank you, sir. I request the participants to press * and 1 for your questions. Next question comes from Mr. Purushothaman from Enam Securities.

Purushothaman: Hi, Kiran. There was a release by Oramed couple of months ago in early March saying that they have completed phase 2-B on their insulin capsules and recently, of course, we also had Novo beginning trials on the GLP-1 oral version using the Emisphere technology. From your information, what sort of timelines do you see for these?

Kiran Mazumdar-Shaw: I will ask Harish to answer this question.

Harish Iyer: You are asking about timelines for Oramed and Novo?

Purushothaman: Yes. Would it be possible for Oramed especially because they claim that they have finished Phase II-B?

Harish Iyer: No, I think that this is going to be difficult for even companies like Oramed. One of the key challenges for any technology based company is that they need to access manufacturing and if you want to make any commercial success of it, you certainly need lot of manufacturing. The second point is that I believe there has been no real good data that has come out till date so we expect that they will take several years, somewhere in the range of 4 to 5 years at least to get to a stage where they can get approvals. From our own timelines we believe we are still ahead of them in the race.

Purushothaman: And on NN9924 that Novo is trying to do with the Emisphere technology?

Harish Iyer: This is the insulin analogue you are talking about?

Purushothaman: Yes, the oral diabetic pill they are making?

Harish Iyer: GLP-1 has got a completely different method of action. First of all, it cannot be given to people who have no insulin. For example it won't work in Type 1 and the GLP-1 analogues have to contend with week-long injections, once a week injections, the LAR. It is not clear to me that there is an advantage to delivery of oral tablet for GLP-1. I am not very clear about the compelling advantage there is clinically except of course the tablet, but then talking about a

tablet versus the once-a-week injection again it is hard for me to see the compelling rational.

Purushothaman: Okay, thanks.

Moderator: Thank you sir. Next question comes from Mr. Harish Swaminathan, a private investor.

Harish Swaminathan: Good afternoon and thank you very much for taking my question. I am really happy to see our numbers. I just have three questions; first one is - what is the existing capacity utilization of Syngene?

Goutam Das: The existing capacity utilization of Syngene is somewhere between 75 - 80%.

Harish Swaminathan: Okay. The second question is on the Syngene listing sometime this year. Is there an option that we are considering of demerging Biocon and issuing shares in the Syngene entity free of cost to Biocon shareholders?

Kiran Mazumdar-Shaw: It is too early to contemplate on this but closer to the time, we will definitely share all this information with you.

Harish Swaminathan: Okay and my last question is to understand whether there is a likelihood of the US regulatory mechanism accepting the Indian data to some extent on our IN-105. Let me explain the background to my question. If things go as scheduled, it is likely that an Indian would be able to use the oral insulin pill much earlier than the developed world which I find it a little difficult to visualize. This means that there might be some cooperation between the regulatory authorities so that the entire humanity benefits from this remarkable drug. I wanted to know your take on this. Thank you.

Kiran Mazumdar-Shaw: Well, let me put it this way. We filed an IND with the US FDA which was based on Indian data. So to that extent, they have accepted Indian data but to expect the US FDA to approve a drug done completely in India is not possible. On the other hand, even your understanding is correct that Indian patients may be in a position to benefit from oral insulin earlier than the US patients but having said that, what we will need to do is to first partner for the program because we will need to be aligned with the partner's marketing strategy so all these are questions we will have to answer at that stage and therefore we will not be able to very convincingly say that yes we will launch it in India ahead of

the US or if we do so when that will be. All these questions have to be answered after discussions with a potential partner.

Harish Swaminathan: Thank you very much.

Moderator: Thank you, sir. Next question comes from Mr. Abhay Shanbhag from Deutsche Bank.

Abhay Shanbhag: Just a couple of questions on insulins. You did talk about getting approvals from quite a few markets in the recent past but the growth in insulins has only been at 11%. So other than the fact that we don't have pens, is there anything else which is constraining growth in insulins?

Kiran Mazumdar-Shaw: Yes, I think the main reason why you are not seeing the kind of growth in insulin in many markets is because of the lack of a pen. But in the area of vials I can tell you that we are garnering a lot of market share in most of the markets that we operate in.

Abhay Shanbhag: And in terms of pens, do you have to get approval in every market separately or would a common approval be enough to launch in those 30 markets where you already have approvals?

Kiran Mazumdar-Shaw: I think we may devise this on a country by country basis. In some of the countries, CE rated pens are good enough but our cartridges are under approval in many markets. We should be able to market pens after we launch in India somewhere around September this year.

Abhay Shanbhag: So what you are indicating is that most of the 30 markets where your cartridges are allowed, you should be able to take your pens?

Kiran Mazumdar-Shaw: Yes.

Abhay Shaan Bhag: Okay. The other one was on statins. You did indicate that you are seeing growth in Atorvastatin because of a non-infringing process patent. How does it benefit you because if the product is still under patent protection, will the end users take supplies before patent expiry?

Rakesh Bamzai: We have a small window of opportunity in Spain and that is with the new salt of Atorvastatin. Our IP is very strong around that salt so we entered much before the market opened up and that gave us a big upside.

Abhay Shanbhag: Will the formulation manufacturer also be able to enter earlier than the patent expiry or they will all be stocking it for the formulation patent to expire?

Rakesh Bamzai: This salt was not covered by the innovator and we had a process that was not infringing the innovator's process so we could enter earlier.

Abhay Shanbhag: The stocking up - do we see it continuing in the future?

Rakesh Bamzai: Yes, the business is growing. We are gearing up to meet the demands and it is going to be very good for the next four quarters.

Abhay Shabhag: Okay, so we will build up such a large position in the API before the patent expiration happens?

Rakesh Bamzai: I didn't get the last question, Abhay.

Abhay Shanbhag: The formulator in the market - will he build such a big position in your API before the market opens for the formulation?

Rakesh Bamzai: Sure, there are formulators marketing their own product and also selling it to many other companies, so it is going to be a good upside for us.

Abhay Shanbhag: Okay. So you are saying that after four quarters, when the patent expires in this market you are also able to target other markets through similar routes?

Rakesh Bamzai: Absolutely.

Abhay Shanbhag: Fine. The other question was on immunosuppressants - you have not really supplied Tacrolimus because nobody else has the approval other than Sandoz. Is that correct?

Rakesh Bamzai: We have supplied it but we have not launched it with a partner in the US. We have supplied materials.

Abhay Shanbhag: Okay. So some part of that sale has already come into the current quarter?

Rakesh Bamzai: Yes.

Abhay Shaan Bhag: Okay. Thank you.

Moderator: Thank you, sir. Next question comes from Mr. Rajesh Ranganathan from Doric Capital.

Rajesh Ranganathan: Hello, thanks for taking the call. If you look at Lonza from Europe or Celtreon from South Korea, they are also now diversifying into the biosimilars space and Celtreon, for instance, has a plan to launch a product as early as the second half of next calendar year and they are going into trials this quarter. So why is it that somebody like Celtreon is able to do it or at least claim that they can do it in a period of 18 months while for us we are targeting the first launch with Mylan only in FY14?

Kiran Mazumdar-Shaw: Well, first and foremost I don't think Celtreon can launch it in global markets next year. If Celtreon has said this, I have not heard this particular announcement but I think we must all recognize that there is an IP issue that does not allow you to get into many markets till a certain date. So how they are going to get into those markets in 18 months is beyond us. If they are just talking only about Korea, that is possible.

Rajesh Ranganathan: Okay, but there may be smaller countries which have earlier patent expiries?
Kiran Mazumdar-Shaw: We have a global strategy so we have to go by what Mylan wants to do; we will not go piecemeal and chop up all our opportunities just to take advantage of small markets.

Rajesh Ranganathan: Okay. And can you please give us an update on what is the status with the GCSF that you have been working on?

Rakesh Bamzai: We have launched NUFILsafe in the market. We have grown our ranking from brand number 20 to brand number 8. We are further building up the brand in the next two years. We are also doing a global development of GCSF and PEG-GCSF. I will ask Harish to tell us how that program is progressing.

Harish Iyer: The GCSF program for Europe and the US is being run by our partner.

Rajesh Ranganathan: And what is the status of the approvals, development etc?

Harish Iyer: The partner is driving it independently.

Rajesh Ranganathan: Even the regulatory process?

Harish Iyer: Yes.

Rajesh Ranganathan: Okay and the last question - when you do scale up your MAb manufacturing processes as there is a lot of technology change that continues to go on, today we are looking at yields of 3 to 5 gm a liter but people want to target maybe 4X or 5X that ten years from now. Is there a certain process improvement that you can effect but at the same time you have an issue that approvals may be more difficult if you tweak the process. So how are you thinking about your manufacturing strategy with respect to biosimilars and in general what impact do you think it will have on pricing as well, because if yields improve as much, say 3 to 5 times in the next 5 to 6 years, then pricing may also be totally different from what it is today. Can you give me come color on how you are thinking about these issues?

Harish Iyer: Well, I think that we have modeled the business case for it; we know we can make the product very competitively with our current technology. There have been several takeaways from this. I think Kiran has mentioned in the past that we were one of the first companies to start monoclonal antibody manufacturing so we have several years of experience in doing monoclonal antibody manufacturing and we believe we will be able to manufacture this effectively and competitively from a commercial standpoint.

Rajesh Ranganathan: Could you give me more color on this?

Harish Iyer: I think it is not just titer that matters in MAb manufacturing, you also need to show biosimilarities and sometimes these two don't go together. You can push up yields but you might not get biosimilarity so I think there are some regulatory risks to go to 30 mg per liter for example. 30 gm per liter may not be required and it depends on where the COGS component comes from. It comes from different aspects of manufacturing and I don't want to go too much into the technology and give you a long winded explanation but I think we will be very competitive commercially.

Rajesh Ranganathan: Thank you.

Moderator: Thank you, sir. Next question comes from Mr. Vinit Bolinjkar from Ventura Securities Ltd. Mr. Vinit. There is no response. Next question comes from Mr. Ajith Kumar, an individual investor.

Ajith Kumar: Madam, can you throw some light on starting the trial on Type I diabetics under the USFDA IND whereas you are currently doing a trial on Type II diabetics in India?

Harish Iyer: Yes, we are doing studies on Type II and the reason we want to start with Type I as well is because they are a slightly different population even though they come broadly under diabetics. They tend to be younger patients, patients who do not have any insulin of their own unlike Type II diabetics who actually have some insulin left in their pancreas. So, I think there is a different population and it is important that for any insulin that gets approved you need to do studies in both Type I and Type II.

Ajith Kumar: Okay, thank you.

Moderator: Thank you, sir. The next follow-up question comes from Mr. Nimish Mehta from MP advisors.

Nimish Mehta: I missed the point about the timeframe within which you will be publishing data on IN105 oral insulin.

Harish Iyer: We have recently published a review article in a journal. Some of our data has been published as part of a general oral insulin landscape by another German physician whom we worked with in Germany. There is one more publication in the works - a manuscript that has been accepted which discusses the PKPD data we presented at EASD in the last couple of years so there are two or three publications which contain some of our data.

Nimish Mehta: I see, okay. And we have already filed the IND in the US. What are the next milestones in the US?

Harish Iyer: I think we will complete the Type I study in India. We will complete the long-term study in India as well and we will initiate additional studies in India. That is our thinking right now and after that we will look at longer term studies in diabetics in the US.

Nimish Mehta: Okay. So when are we likely to complete Type I in the longer term studies in India this year?

Harish Iyer: Hopefully by the end of this year.

Nimish Mehta: This will be in Phase III, right?

Harish Iyer: Yes, the long-term study is essentially something like a Indian phase III.

Nimish Mehta: So, is it possible then to launch the product in India after these studies or will it require some more formalities?

***Harish Iyer*:** It depends on our partner and whether they want a global launch. I mean how they think in terms of launching it and what data they want to launch.

Nimish Mehta: I see, so the decision of launch will only be taken once it is licensed?

Harish Iyer: Yes.

Nimish Mehta: Okay and any timeline that you can think of for licensing this product?

Harish Iyer: I think probably over the next financial year.

Nimish Mehta: Okay. Thank you very much.

Moderator: Thank you, sir. I request the participants to press * and 1 for your questions. Next follow-up question comes from Mr. Vihari Purushothaman from Enam Securities.

Purushothaman: Harish, there was a review by Lutz Heinemann on oral and buccal insulin over a year ago in May 2009 in the Journal of Diabetes Science and Technology. Has there been a subsequent update on this?

Harish Iyer: Yes, some of our data was published by Lutz in his article. There is a newer review that Biocon R&D published in January of this year.

Purushothaman: In the same Journal?

Harish Iyer: No, that was in Diabetics, obesity and metabolism. Our review was more clinical oriented and Lutz's review was more technology oriented as you can see from the journal license.

Purushothaman: Okay, thanks.

Moderator: Thank you, sir. I request the participants to press * and 1 for your questions. There are no further questions, now I hand over the floor to Ms. Kiran Mazumdar-Shaw, Chairman and Managing Director of Biocon Limited for closing comments.

Kiran Mazumdar-Shaw: Thank you very much for participating in this conference call and I would ask any of you who need further clarifications to contact my colleagues Murali Krishnan and Chinnappa for any financial details. Thank you very much.

Moderator: Thank you ma'am. 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.

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