

## **Biocon Limited**

## Investors/Analysts Conference Call January 18, 2006

**Shiv Muttoo:** Good Afternoon everyone and thank you for joining us on Biocon's nine months FY 2006 result conference call. Joining us from Bangalore are Ms. Kiran Mazumdar-Shaw, Biocon's Chairman and Managing Director and her colleagues on the senior management team. Before we begin, I would like to state that some of the statements made in today's discussion maybe forward looking in nature. These are based on the management's current expectations and may involve some risks and uncertainties. A detailed statement in this regard is available in the nine months FY 2006 results announcement release which has been e-mailed to you and which is also posted on Biocon's corporate website. I now invite Ms. Kiran Mazumdar-Shaw to provide a brief overview of the Company's performance for the quarter.

**Kiran Mazumdar-Shaw:** Good Afternoon everyone. Welcome to our conference call for Biocon's Q3 and nine months results. As you can see, we have continued to maintain our performance that we have shared with you in the first half of the year and I believe that in this particular quarter year-on-year performance has been extremely good. Because if you were to factor in the last year's Q3 numbers which actually reflect the Rs. 6.5 crore foreign exchange gain, I think this quarter's results can be tread as being robust. Our performance this quarter actually has helped us to very confidently keep investing in our R&D programs, especially the discovery-led R&D programs, which as you know are fairly investment heavy programs and we do need these kind of healthy profits to sustain the spend.

Now in terms of the various components of our business, the research services business has done extremely well and it has continued to build on its previous growth and new businesses like insulin and other pharmaceutical products have also contributed very well to this quarter's performance. What is also important for me to share with you is that we have just established an oncology division which will look at selling oncology and nephrology products into the Indian market and this is going to be spearheaded by the first of our novel antibody molecules Biomab(R), which we hope to market in India latest by the second quarter of this year.

I would also like to say that the statins business has not seen any further significant deterioration of pricing in Europe, so we are led to believe that the worst pricing pressure times are over. We expect that the US will afford us some respite because as the market opens we do expect to see some premium pricing over the European prices, though we are well aware of the fact that this is only a short window of



opportunity because once the markets do open up we are likely to see some price erosion taking place in US. But this is of course entirely dependent on how many players are there in the US market which is again contingent upon how many people manage to get US FDA approval for their statins.

Having said that, Biocon is very committed to the statins segment and the fact is that we have been able to fend off very-very aggressive competition that we have seen in Europe. We believe that this actually gives us a lot of confidence to establish a very strong hold in the US market.

We would also like to state that our research programs are progressing fairly satisfactorily both in terms of our oncology and diabetes programs. One of the important aspects of these programs is the fact that we strongly believe that discovery-led programs are going to provide Biocon with very attractive growth prospects in the future. Having said that, I think it is important for all of us to understand that these are gestational businesses requiring a lot of investment. They need lot of new skills to be developed and Biocon is focusing on all this to make sure that going ahead we will be a very globally competitive innovator company.

Finally to summarize, I would like to say that even on a sequential basis our performance has been very well sustained. I think we expect no dramatic changes by the end of the year, but we are aware of the fact that going forward we will have higher depreciation costs on account of the new project as well as higher R&D spends. But with increased sales growth our overall margins will continue to remain attractive and more importantly will certainly enable us to afford all these very exciting programs that we are engaged in which we are very confident will deliver very attractive results in the long term.

So with that, I would like to hand this over for Q&A session. Thank you.

**Moderator:** Thank you very much Madam. We will now begin the Q&A interactive session. First in line, we have Ms. C Visalakshi from DSP Merrill Lynch, over to you Madam.

**C Visalakshi:** I would like to start with a question on your oral insulin project, could you please update on the status of this project? My second question is on the recent generic insulin filing which has happened in EMEA, could you give us some more clarity on that, I believe we expect a few more filings in the next couple of weeks? Can the management give us some more clarity on these filings?

**Kiran Mazumdar-Shaw:** As far as the oral insulin program is concerned, we have submitted an application to the Indian regulatory authorities providing them with all the preclinical data that we have collected, for a permission to start phase 1 human clinical trial in healthy volunteers. In terms of our US



INDA filings, we are on track and expect to be able to submit this INDA filing by the end of this year. As far as the biogenerics is concerned, I would rather not call it biogenerics because you know the term is mostly inappropriate for biologics, it is called bio-similars or follow-on biologics. In terms of our insulin filings, EMEA has just announced a set of guidelines and we will have to submit a dossier based on all these requirements. We are basically beginning to compile this particular dossier for submission and in the meantime we are beginning to look at registering and filing these kinds of dossiers in a number of European markets.

C Visalakshi: Okay.

**Ajay Bharadwaj:** If you are referring to the news item which was there in the papers today then what was said there was that Europe would probably be earlier than US in terms of filings. Biocon will also be present through some companies, as they are filing using our material and at the same time we are also preparing our own dossier.

C Visalakshi: Okay, could you also clarify whether the recent filing had anything to do with Biocon at all?

**Kiran Mazumdar-Shaw:** Well unfortunately, I do not think we are allowed to reveal anything because of confidentiality reasons.

C Visalakshi: Okay, and finally just an update on your insulin registrations for the developing markets?

**Kiran Mazumdar-Shaw:** Yes, we have extensively registered our products in several markets in the Middle East, Latin America and South East Asia. That is as much as we can share with you. In fact, all we can say is that we have submitted registrations in more than 25 countries.

C Visalakshi: Thank you so much.

**Moderator:** Thank you very much Madam next in line, we have Mr. Jesal Shah from JPMorgan.

**Jesal Shah:** Good Afternoon everybody. To start off, my first question is on the capital expenditure. The fact sheet which you have sent shows that the total net assets are about Rs. 782 crore. How much of this you think would be for the fermentation, specifically for statins, and how much would be for the MABs and the other biotech projects that you have?



**Murali Krishnan:** Biocon has earmarked about Rs. 450 - 475 crores for fermentation facilities which includes statins and about Rs. 125 crores for the biological facility.

**Jesal Shah:** Okay, so when you say fermentation, would it include immunosuppressants and the other products in the small molecules space besides statins.

Murali Krishnan: Yes that is right.

**Jesal Shah:** When Ms. Shaw referred to some higher depreciation, I guess it would pertain more to the fermentation facilities which will get commissioned as you would start supplying to the US market?

Murali Krishnan: Yes. Depreciation charge on Biological facility will commence early next year.

**Jesal Shah:** Given the way this space is evolving and whatever outlook you have on the pricing along with the quantities that you would be able to supply to the US, what kind of returns do you think you can get out of the Rs. 475 crores of gross block that you have built for fermentation?

**Kiran Mazumdar-Shaw:** Obviously we will try and maximize the returns as much as we can and as I mentioned earlier. Since this is dependent on many factors, it is very difficult for us to very accurately quantify and estimate these kinds of numbers. It will suffice to say that we will absolutely maximize returns on these investments.

**Jesal Shah:** What kind of capacity, what kind of total tonnages can you actually make if you were to operate on 100% capacity utilization?

**Kiran Mazumdar-Shaw:** Well these are the numbers we would never be able to share because of competitive reasons.

**Murali Krishnan:** Since this plant is not in a single product plant, the number depends on the product mix as well.

**Jesal Shah:** Right, in terms of the pricing outlook for the US supplies of Simvastatin, are you getting any sense in terms of how these spaces will evolve and how many ANDAs do you think could get approved?

**Ajay Bharadwaj:** See, we do not expect too many ANDAs, but yes, closer to the date I think the consensus view should be about 6 to 7 ANDAs, one or two more for Simvastatin.



**Jesal Shah:** If there are six to seven ANDA approvals likely on day one, where do you think the bulk pricing or the formulation pricing would settle?

**Kiran Mazumdar-Shaw:** It is very difficult to predict because as we said, it will start definitely higher than Europe, but then, we have to see how fast it will come down to European prices.

**Ajay Bharadwaj:** Yes again what people feel is that there will not be as much of a rapid reduction in price as it was in Europe, so there is a reasonable expectation that the pricing will be better.

**Jesal Shah:** Okay, moving onto the contract research space, which has been a phenomenal driver in the first nine months currently, can you share with us the number of scientists that you have recruited in the first nine months and what is driving this business and where to you see the growth coming from in the next couple of years?

**Goutam Das:** The total right now is about 500 people in the contract research in Syngene, and with Clinigene there are another 50 odd people. So we have about 550 people all together, and about 125 people were added in the nine months.

Jesal Shah: Much of that would be for Syngene, I presume.

Goutam Das: Yes, predominantly.

**Jesal Shah:** Okay, and do you have any plans for the next maybe 12 months or so, what kind of outlook do you have in terms of how many people that you would add in the next 12 months or so?

**Kiran Mazumdar-Shaw:** We do expect a large increase in the number of scientists over the next one year and I think we could expect even close to doubling of this number.

**Jesal Shah:** One of the key drivers for the current quarter has been the insulin supplies and some supplies of immunosuppressants to ROW markets. Can you give us some idea about which markets are actually driving this growth? Also how the penetrations are getting achieved and what's your basic strategy, let's say India over the other markets?



**Kiran Mazumdar-Shaw:** It is mostly the Middle East, Latin America, and South East Asian market that are driving all these businesses.

Jesal Shah: Are you marketing on your own or you are going through partners?

**Kiran Mazumdar-Shaw: Since** we do not have our own marketing setup outside India, as such we are supplying the APIs to generic pharmaceutical companies, in the respective Countries.

Jesal Shah: Right, and what about the Indian market?

Kiran Mazumdar-Shaw: We have our own sales force for the Indian market.

Jesal Shah: What is your share in the Indian insulin space?

**Kiran Mazumdar-Shaw:** In our own markets, we have close to 8%. We are not selling in every state in the country, but for whichever states we are selling we have close to 8% market share.

Jesal Shah: So is there a plan to increase your reach to the other states?

**Kiran Mazumdar-Shaw:** Yes, That would require us to increase our sales force, which we are in the process of doing and setting up the distribution channels.

Ajay Bharadwaj: Our plan is to cover whole country by the end of the next financial year.

Jesal Shah: How do you see the field force ramping up from where it is now to in the next 12 months?

**Ajay Bharadwaj:** We are adding lot more people so that there is adequate number of people who can cover the whole country. We have a plan to add at least 100 more people.

Jesal Shah: Thank you so much.

**Moderator:** Thank you Mr. Jesal Shah. Next in line we have Mr. Ashwin Aggarwal from Akash Ganga investments.



**Ashwin Aggarwal:** I have a question for Syngene. Recently we read that GVK Biosciences had bagged a multiyear deal close to \$40 million with Wyeth and Syngene being a clearly dominant leader in the discovery services, could we expect similar kind of tie ups going forward for Syngene?

**Goutam Das:** Well we have been scouring the market and there is every possibility that we could do something like that, but there is nothing on the anvil right now.

**Ashwin Aggarwal:** My question is more broadly that is there an opportunity so huge visible that with GVK bagging this order, the visibility of India can improve and Syngene being a dominant leader can participate?

Goutam Das: Yes, certainly.

**Ashwin Aggarwal:** My second question was on the oral insulin program. We had announced that we would plan to get the balance IPR of Nobex, the decision on which was expected by March end. So are we continuing to look for alliances to develop this IPR or presently we are not in discussion with any multinational companies for this?

**Kiran Mazumdar-Shaw:** You know we are planning to look for alliances and we believe that the best value will be got for these kinds of alliances after the product is in human trials. At this moment it is still not in the clinic in terms of human data. We are hoping that the Indian regulatory authorities will give us permission to conduct phase 1 trials sometime in the next two months.

**Ashwin Aggarwal:** Lastly if you can comment on what we read about Pfizer having acquired the balance right on Exubera from Aventis by paying \$1.3 billion. What does it suggest for the inhaled insulin program, is Pfizer so positive on the outlook?

**Kiran Mazumdar-Shaw:** Well I think non-injectable insulin's are going to be very-very attractive as a product segment and I think that is why Biocon is also aggressively looking at this segment. In fact one of the other things apart from the oral insulin program is nasal insulin. The nasal spray insulin program that Bentley has partnered with us on, and as you know Biocon has many territorial rights for this product apart from supplying insulin to Bentley. So, again this is how we are covering this whole space to various types of non-injectable insulin. And yes Pfizer I am sure is paving the way to make sure that there is a strong focus on non-injectable insulin's, but we will also be looking at how to gain a good amount of footprint in this particular area.



Ashwin Aggarwal: Okay, thanks a lot and all the best to the management.

Kiran Mazumdar-Shaw: Thank you.

Moderator: Thank you Mr. Aggarwal. Next in line, we have Mr. Prashant Nair from Citigroup.

**Prashant Nair:** I had a couple of questions. The first one was what kind of timeline do you envisage for launch of or your supplies of Pravastatin and Simvastatin to the US market. The second one was that your tax rate this year has been much higher than what it was last year, do you expect it to continue rising in this manner going forward or where do you think your sustainable tax rates will be ultimately settle at?

**Ajay Bharadwaj:** We expect to start supplying Simvastatin this quarter, unless something really surprising happens on the exclusivity front, but as of now nobody is expecting that. Pravastatin sales will commence closer to the third quarter, when the market opens for other generic players.

Prashant Nair: Okay, and what about the tax rate?

**Murali Krishnan:** In terms of tax rate, I do not think it should get too worse than what it is today because the new facilities are going to be either 100% EOU or SEZ units. So that effective tax rate should significantly come down to last year's levels or remain at current levels.

Prashant Nair: Okay, thanks.

**Moderator:** Thank you Mr. Nair. Next in line, we have Mr. Ashish Kacholia from Lucky Securities, over to you Sir.

**Ashish Kacholia:** Good Afternoon to the management team. My question is pertaining to the status of your anticancer molecules. Could you give us an update on that and what is the size of the market that the Company is targeting with these molecules?

**Kiran Mazumdar-Shaw:** Biomab®, which is the antibody for head and neck cancers, is the first molecule off the block in terms of market entry, which we expect to see later in the year. At the moment, we are in the process of submitting a request for its approval to the regulatory authorities based on the data generated on the human clinical trials conducted and this product actually is a first-in-class molecule of its kind in the country. We see that the incidence of head and neck cancers in India is very large so we do expect this particular molecule to have a significant market in terms of the oncology market itself. So I can



just project that we are confident that in the next few years this could be a Rs. 100-crore product and so this is what we are aiming for in terms of a market size. But in the meantime, we are also filling up our pipeline with some other very important molecules, including GCSF and EPO which are certain support care products. Then of course we have also had other oncology products in the pipeline like the products we are developing with Vaccinex plus some of the products that we have in terms of cancer vaccines and other antibodies. Hence I think we are beginning to fill up a very, very interesting pipeline and the most important focus at this point in time is to make a commercial success of Biomab®.

**Ashish Kacholia:** In Biomab® has there been a visible remission of the cancer rates in the patients who were undergoing the trials?

Kiran Mazumdar-Shaw: Yes, there has been a very significant remission.

**Ashish Kacholia:** Okay and has this product been given on a stand-alone basis during the trial or in combination with some other interesting molecules?

**Arvind Atingal :** The standard treatment is chemotherapy and radiotherapy. This is an adjuvant to chemotherapy and radiotherapy, and that is why we have four arms of this trial.

**Ashish Kacholia:** And in terms of your original research molecules this one will be the first off the block, is that right?

Arvind Atingal: Yes.

Ashish Kacholia: Apart from India, do you have the rights for this molecule for any other country?

**Kiran Mazumdar-Shaw:** We have the rights for the Indian subcontinent. We do not have the rights for the main markets which would be the US and Europe.

Ashish Kacholia: All right, thank you very much Madam and all the best.

Kiran Mazumdar-Shaw: Thank you.

**Moderator:** Thank you Mr. Kacholia. Next in line, we have Mr. Yogesh Hede from BRICS securities, over to you Sir.



**Yogesh Hede:** Good Afternoon to the management team. I have a question on the P&L. I can see that the other expenses have risen significantly; can I understand what is the R&D spend that the Company has done in this particular quarter?

**Murali Krishnan:** The other expenses in Q3 have significantly increased from Rs. 7 Crores to Rs. 20 crores. That is largely on account credit due to exchange gain in the previous year, coupled with the debit on account of exchange loss during the current year. Cumulative effect of this is about Rs. 8.2 crores.

Yogesh Hede: So the exchange losses are clubbed into the other expenses?

Murali Krishnan: Yes. Both the gains as well as losses are clubbed with the other expenses.

**Murali Krishnan:** The other reasons for the increase in "other expenses" are largely on account increased R&D spend and selling expenses.

Yogesh Hede: So what kind of R&D spends has the company incurred during the quarter?

Murali Krishnan: It is about 6% of the revenue.

**Murali Krishnan:** R&D Costs have been gradually increasing on a quarterly basis and as I said earlier, it will keep increasing going forward, as the new R & D programs for oral insulin etc., will require significant investment in R&D.

**Yogesh Hede:** Okay, can you just tell me about the other income which has come down from Rs.12 crore to Rs. 4 crore for the first 9 months?

**Murali Krishnan:** Yes, that is largely because last year we had the IPO proceeds which were invested in liquid funds with about 4-5% yields. These funds have all been deployed in the capex, during the course of this fiscal.

Yogesh Hede: Okay, thank you very much.

**Moderator:** Thank you Mr. Yogesh. Next we have Ms. Monica Joshi from Quantum Securities, over to you Madam.



**Monica Joshi:** Good Afternoon, can you just highlight what would be the deal with Nobex in case you have take over the IP.

**Kiran Mazumdar-Shaw:** Unfortunately, it is sub-judice at the moment so really we cannot discuss this with you.

**Monica Joshi:** Okay, let me put it the other way. If something does not happen, then would you be writing off the investment of \$ 6 odd million that you have done?

Murali Krishnan: This will be decided, based on the progress of the Bankruptcy proceedings.

Monica Joshi: Okay, thank you.

**Moderator:** Thank you Madam. Next in line, we have Mr. Rahul Sharma from Karvy Stock Broking, over to you Sir.

**Rahul Sharma:** Madam, I just wanted to know, what are the timelines for the launch of the head and neck cancer product? I just missed out on what was the exchange loss that you suffered in the quarter and what is the extraordinary income or expense on that account for the nine months?

Murali Krishnan: The exchange loss suffered for this quarter is about Rs. 1.8 crore.

Rahul Sharma: Okay, and what are the timelines for the head and neck cancer product?

**Kiran Mazumdar-Shaw:** As I said, we are in the process of submitting an application for approval with the Indian regulatory authorities and it is really up to them to give us the approval. It is very difficult for us to pinpoint when this approval will come, but we are hopeful that this will happen in the next three to four months.

Rahul Sharma: Okay, so you are probably looking at launch in the next fiscal?

Kiran Mazumdar-Shaw: Yes that's right.

Rahul Sharma: Second half probably.

Kiran Mazumdar-Shaw: Yes.



Rahul Sharma: Okay Madam, thank you.

**Moderator:** Thank you Mr. Sharma. Next we have Mr. Sameer Baisiwala from JM Morgan Stanley, over to you Sir.

**Sameer Baisiwala:** My question is about the new facility, where does it stand in terms of getting approved by the European and US authorities for the statin?

**Kiran Mazumdar-Shaw:** I think there are several customers who are triggering that inspection so we expect it to happen this calendar year.

**Sameer Baisiwala:** So would this be in time once the US market for Simvastatin and Pravastatin opens up?

**Kiran Mazumdar-Shaw:** Yes, in the sense that right now it does not matter because our existing facilities can actually address the markets when they open, but we will definitely need the new facility to be approved when the supplies ramp up and I think we will be well in time for that.

**Sameer Baisiwala:** So during that brief transition period, do you think that your volumes for the European market can be a little lower than what you are doing right now?

**Kiran Mazumdar-Shaw:** No, because in the interim, we expect to get the approvals to commence supplies to the European market and then we would wait for US FDA approval for ramping up the supplies to the US.

**Sameer Baisiwala:** So this implies that the European approval can happen as soon as the next quarter or so?

Kiran Mazumdar-Shaw: Yes it will.

**Sameer Baisiwala:** Can you update us about the innovative supplies of your statin, has there been any filing done or what are the timelines you are looking at?

**Kiran Mazumdar-Shaw:** Well our alliance partners in this particular sector tell us that they expect innovator products with statins to be launched in 2007.



Sameer Baisiwala: Okay, and there will be more than one product launch that we are talking about?

Kiran Mazumdar-Shaw: Yes we do have more than one innovator partner.

Sameer Baisiwala: By early 2007?

Kiran Mazumdar-Shaw: Early to mid to late, there are different kinds of products being developed.

**Sameer Baisiwala:** You mentioned about the research spend rising next fiscal, so from 6% this quarter what should be assumed for the next year?

Kiran Mazumdar-Shaw: Anything up to 8%.

Sameer Baisiwala: Okay, thank you very much.

**Moderator:** Thank you Mr. Baisiwala. Next is a follow-up question from Ms. C Visalakshi of DSP Merrill Lynch.

**C Visalakshi:** I had a question on the enzymes business. The performance in the last three quarters, has been pretty lackluster, so what is the outlook going forward? And number two would like to give a broad guidance on the overall revenue growth for the next year taking into account Simvastatin supplies for the US?

**Kiran Mazumdar-Shaw:** You know guidance wise I don't think we would like to make any kind of forecast, but I let Ajay answer on the enzyme business.

**Ajay Bharadwaj:** On the enzymes business, we had some problems with the capacity because it was being used for the other products and so we were not able to fulfill the entire demand that was there. But as the first objective going forward in this quarter, we would at least try and catch up on the lost business.

Visalakshi Chandramouli: Okay, thank you.

Moderator: Thank you madam. Next in line, we have Mr. Milind Bhangale from IL&FS.



**Milind Bhangale:** Good Afternoon everyone. I just wanted to ask that where do you see the full year estimate on the top line and bottom line?

**Kiran Mazumdar-Shaw:** I don't think we can give guidance, but you know you can just go by what you have seen in the last two quarters and we will be able to sustain these levels.

Milind Bhangale: But can you give any specific figure where you will reach?

**Kiran Mazumdar-Shaw:** I don't think I would like to do that because it has not been the practice and we do not want to start that.

Milind Bhangale: Okay, thanks.

**Moderator:** Thank you very much Sir. Next in line we have Mr. Abhinav Sharma from ICICI Lombard, over to you Sir.

**Abhinav Sharma:** I would like to know for the increasing top line, how much of that is contributed by increase in volume and how much by prices?

**Murali Krishnan:** We have many products going to different markets, world-wide. Also the product mix keeps changing. Hence, it is very difficult to exactly quantify the contributions.

**Moderator:** Thank you Mr. Abhinav. At this moment there are no further questions from participants, I would like to hand over the flow back to Mr. Shiv Muttoo for final remarks, over to you Sir.

**Shiv Muttoo:** Thank you Parimala. On behalf of Biocon's management team, I would like to thank you for your participation. The transcript of this conference call would be available in Biocon's website in the next three working days and thank you all once again.

Kiran Mazumdar-Shaw: Thank you very much.