

## **BIOCON LIMITED**

## Investors / Analysts Conference Call

## April 20, 2006

**Shiv Muttoo:** Good afternoon everyone and thank you for joining us on Biocon's FY06 results conference call. Joining us from Bangalore are Ms. Kiran Mazumdar-Shaw, Biocon 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 discussions maybe forward looking in nature based on the management's current expectations and may involve risks and uncertainties. A detailed statement in this regard is available in FY06 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 year.

**Kiran Mazumdar-Shaw:** Thank you, Shiv and thank you all for participating in this conference call where we would like to share with you our fiscal year FY05-06 numbers.

The performance highlight indicates that on an annualized basis the total income increased by 9% to Rs. 793 crores, the operating profits stood at Rs. 234 crores, operating margins stood at 30% for the year which we feel is a very healthy margin level to operate at, especially in view of the fact that the Company is really embarking on a very strong innovation discovery led pathway, which entails a lot of R&D investment. R&D investments has gone up by 76% to Rs. 76 crores and we have actually clocked and registered a PAT of Rs. 174 crores, which although reflects a decline of 12%, if viewed in context with the Q4 numbers, you can see that we have actually shown a 20% top line growth, and a 13% PAT growth over the corresponding quarter last fiscal.

This we believe should reflect the kind of reduced pricing pressure on our statin segment. It also reflects the contributions made by some of our newer segments like, the insulin, branded formulations, and of course the research services business has done outstandingly well - registering a 52% growth to Rs. 100 crores from Rs. 66 crores, and going forward we believe that the new growth segments will certainly show some continued growth. Having said that the year ahead will be a challenging year for us, because we will need to keep on investing in R&D and we will need to also take on account the impact of depreciation on the new facility, but we are still extremely optimistic about the Company's future in terms of new molecules and in terms of the path that we are taking. This is a very sustainable direction that the Company is taking in the long-term because we really would like to spend less and less on our generic statins kind of products and focus more on the sort of innovation-led molecules, but in that I would also like to say that in terms of generics, we are going to focus on the biogenerics kind of opportunities that are emerging for a Company like Biocon for instance the insulin product segment where we believe that the hurdles to get into regulated markets are going to be much higher than what we have seen for small molecules, and companies



like Biocon are certainly in a better position to take advantage of these emerging opportunities.

Our Nobex acquisition has given us a very, very rich innovation platform and we intend to leverage this platform through co-development, out licensing, and of course own development where the oral insulin and oral BNP programs now have got Biocon as a full owner. Oncology is another very important segment for us. Our first molecule, the anti-EGFR antibody is expected to at least get into the Indian market in this fiscal. The product itself will actually realize and contribute to our numbers only in the next three to four years, but it is very important step that we are taking because oncology is a very important segment for us.

We would also like to stress that the Biocon's recent biologic facility actually has also put Biocon in a very strong position in terms of bio-manufacturing and bio-processing. We will be the only large scale producer of antibodies and other cell culture products in India, and using all these capabilities we see ourselves as being extremely attractive alliance partners for new molecule development and this will obviously give Biocon a very extended pipeline of proprietary products.

Overall, I believe that Biocon has a very interesting and a very, very exciting future in terms of all that I have talked about. What I would also like to wrap up with is saying that Biocon as a group has a very balanced portfolio, which kind of encompasses services and product, which encompasses generic small molecules, generic large molecules, which encompasses generic products and novel products, which encompasses enzymes, so I really believe that if one was to look at Biocon as an integrated model it is also a very attractively risk mitigated model in terms of its balanced portfolios and overall I am very enthusiastic about the future of Biocon.

**Moderator:** Madam, shall we take the questions now?

Kiran Mazumdar-Shaw: Yes, sure.

**Moderator:** Thank you very much Madam. We will now begin the Q&A interactive session. Participants who wish to ask questions, please press \*1 on your telephone keypad. On pressing \*1, participants will get a chance to present their questions on a first-in-line basis. To ask a question, please press \*1 now. First in line, we have Mr. Ranjit Kapadia from HDFC Securities. Over to you Sir.

**Ranjit Kapadia:** My question is about the other expenses, in the last quarter the other expenses has jumped by 37% as against our overall 31% for the full year, if you can throw some light on that?

**Murali Krishnan:** The increase in other expenses is largely due the incremental R & D spend as well as higher selling expenses.

Ranjit Kapadia: Okay, thank you.

**Moderator:** Thank you Mr. Ranjit Kapadia. Next we have Ms. C Visalakshi from DSP Merrill Lynch, over to you Madam.



**C Visalakshi:** My first question is on the oral insulin, can you update us what is the status in terms of the development program?

**Shrikumar Suryanarayan:** We have submitted the application to the regulatory authorities in India. We are expecting final clearances in the very near future. Once we get the approval we can begin to plan our first stage of human clinical trial.

**C Visalakshi:** In terms of any licensing deals for the project, is there any strategy on that front?

**Shrikumar Suryanarayan:** Well, oral insulin is a very unique molecule, and Biocon has obviously been in discussion with many parties who have expressed some interest, but the value of the molecule is much more as we progress further along the clinical path and we have decided that its important for us to capture the maximum value of the molecule, because it's such an exciting molecule As far as we know, we are the only Company in the world who has such a program and also has an integrated source of insulin to offer, so we are in a strong position and we want to capture all the value we can.

**C Visalakshi:** Okay, and could you give us an update on insulin registrations for the semi-regulated market, how do you see cash flows from that stream coming?

**Rakesh Bamzai:** Insulin registration is a process that Biocon has started one and a half years back and we are looking at registration in excess of 25 countries. The process is on right now and one registration is almost complete. We are expecting orders from this particular country in this month itself.

**C Visalakshi:** Any further details on this country in terms of market size.

**Rakesh Bamzai:** It is a very big order. We cannot reveal the country because of competitive reasons.

**C** Visalakshi: Okay, so overall insulin as a revenue stream, is there any guidance in terms of what sort of revenues should one expect over three or nine months?

**Kiran Mazumdar-Shaw:** No, we do not want to breakup the revenue, product wise, because this is very sensitive information, but suffice to say that insulin is going to be one of the growth drivers for the future.

**C** Visalakshi: Okay, and finally could you provide an update on the head and neck cancer product, which is scheduled for launch?

**Kiran Mazumdar-Shaw:** Well, in terms of the head and neck cancer product, we are in the process of submitting a dossier for regulatory approval and we expect to hopefully come through within the next few months and therefore we believe that we should be able to enter the Indian market later this year.

**C Visalakshi:** Okay thank you so much Kiran.

Kiran Mazumdar-Shaw: Thanks.



**Moderator:** Thank you Madam. Next in line, we have Mr. Abhay Shanbhag from HSBC Securities, over to you Sir.

**Abhay Shanbhag:** Congratulations on the good set of numbers. A couple of questions on the research services, you have seen pretty robust growth in the fourth quarter at about 68% so do we expect these sort of numbers to continue on the sustained bases, Rs. 30 crores plus per quarter in the near future?

**Kiran Mazumdar-Shaw:** The research services are definitely going to be a very important growth driver for us. I would not like comment on whether we will keep delivering very high growth, but we are very encouraged by the business prospect that we are seeing for, both Syngene and Clinigene and the year ahead is also going to see some good growth for these segments.

**Abhay Shanbhag:** The capacity expansion in Syngene was expected to continue, so do we see more capacities coming in say next two years so that one can capitalize on the growth opportunities in these segments?

**Kiran Mazumdar-Shaw:** Yes, you are absolutely right. We have prepared for this and in fact the second phase is almost nearing completion, so in the next two months Syngene will move into the second phase as well.

**Abhay Shanbhag:** Okay, on enzymes, for the last four quarters, I mean, preferably almost for the entire year there has actually been a decline in revenues, so is there a capacity constrain, is that going to be an issue or what is?

**Kiran Mazumdar-Shaw:** Last year we have had a capacity constraints because as you know our new facilities were not up and we had to sort of eat into the enzymes capacity to deliver on our pharmaceutical products, but going forward the new facility will be able to release that capacity for enzymes, so this year we expect to see growth.

**Abhay Shanbhag:** Okay and simvastatin patent expires in June, so say in next couple of weeks or something like that do we start seeing supplies of Simvastatin to the US market?

**Kiran Mazumdar-Shaw:** Well, this particular segment is fraught with a lot of uncertainty because we are not quite clear about the authorized generics, 180 days exclusivity, and many other aspects, so until that becomes very clear, we are seeing limited off take with everyone is playing a wait and watch approach.

**Abhay Shanbhag:** Okay, so there are possibilities of some delay in simvastatin launch as far as the US market goes?

**Rakesh Bamzai:** Simvastatin is going to be our one of the revenue drivers in United States, when the generic market opens up either in June or Dec 2006.

**Abhay Shanbhag:** Okay, but what we saw for Prava, because there was definitely a much high element of doubt and now it has become certain that there is going to be



exclusivity, but in simvastatin, most of us believe that there is no exclusivity, so is that a bit of an issue now that exclusivity could actually come in?

Rakesh Bamzai: Yes.

Abhay Shanbhag: Okay, fine. Thanks a lot.

**Moderator:** Thank you Mr. Shanbhag. Next, we have Mr. Shubham Mazumdar from Macquarie Bank, over to you

**Shubham Mazumdar:** I have two-three questions. One, I do not know whether you answered this before, but you can tell us that we seem to be having quite a bit of increase on the SG&A front, other expenses really so what is the outlook for the coming year, if you can just tell us on the key aspect of SG&A?

**Murali Krishnan:** We do not give any outlook on Sales and Expenses. Unfortunately we will not be able to give any numbers on this.

Shubham Mazumdar: Okay, would you be able to tell us the capex guidance for 2007?

**Murali Krishnan:** Syngene it is going to spend about Rs. 60 crores for the second phase of expansion and Clinigene is expected to spend about Rs. 5-6 crores on the new facility. Biocon it is expected to spend about Rs. 50 crores over the next one year for adding on labs and other balancing equipments. Additional expenditure will be in line with customer requirements and targeted at new business areas.

**Shubham Mazumdar:** Okay on the oral insulin program, Nobex had filed for bankruptcy and you have acquired Nobex completely now, does that in any way alter going forward take backwards the timeline on the oral insulin project. What is your take really on the Nobex acquisition?

**Shrikumar Suryanarayan:** One of the very positive facts about the Nobex acquisition, is that Biocon is in a position to monetize this molecule at its own terms. It has also has brought in a lot of certainty about the other oral delivery molecule that we are working on, which is oral BNP. The timelines are not going to be affected as Biocon was always responsible for driving the development from this point onwards.

Shubham Mazumdar: So, any kind of timeline you would like to give at this point?

Shrikumar Suryanarayan: In any new drug molecule development, we have to go phase by phase, and as I said to a short while ago to Visalakshi, we have submitted the application to the Indian authority. Once the approval comes through, we can start planning our Phase I trials accordingly and then after that we have to go into Phase II and Phase III.

**Shubham Mazumdar:** Okay, and with regard to your domestic market insulin business, how has the ramp up really been over the last one or two quarters. How many states are you now present in, what percentage of the addressable market do you think you are addressing now?



**Rakesh Bamzai:** Insulin is being marketed as INSUGEN in about 16 states across India with a strength of around 150 people. We are going to double this strength by the end of this year, with the objective of making INSUGEN one of the top brands.

Shubham Mazumdar: Right. Thank you and all the best.

Rakesh Bamzai: Thank you.

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

**Monica Joshi:** Good afternoon everybody. My question first relates to the head and neck cancer molecule, just last month Bristol-Myers Squibb claimed that they have the first approval in monoclonal antibodies for head and neck cancer, so if you could give us some idea how is what you are developing different from what Bristol-Myers could have to get some feel on the success of this molecule?

**Kiran Mazumdar-Shaw:** I will ask Subhir Basak who heads our oncology division to answer this question.

**Subhir Basak:** This Erbitux molecule you talked about is a pretty old molecule. It has been in the market for almost five years and was developed about 10-15 years back. It is a chimeric molecule, while what we are working on is the humanized version of the same monoclonal antibody, which is where actually the technology of the future lies.

**Monica Joshi:** Okay, because I was under the impression and this was approved on March 1<sup>st</sup> 2006

Kiran Mazumdar-Shaw: But it was already approved for colorectal cancer.

**Monica Joshi:** Okay, so it should not cause any kind of an immediate threat to what you are developing, is that right?

**Kiran Mazumdar-Shaw:** No, we are strongly differentiated in the fact that ours is a humanized antibody, and also the fact that we are an indigenous Company where we will certainly hope to have some competitive advantage.

**Monica Joshi:** Okay, there was some news about you importing some drugs from China without an import license do you have any liability on this account?

**Kiran Mazumdar-Shaw:** No not at all, it is something that we have addressed and rectified and the matter stands rectified.

**Monica Joshi:** So, there will be no liability on Biocon or any payments or nothing like that?

Kiran Mazumdar-Shaw: No.

**Monica Joshi:** Okay, also your debtor days seems to have really been high, so is their any specific reason for this?



**Murali Krishnan** Last year it was about 73 days and this year it has increased to about 85 days largely on account of higher domestic sales.

**Monica Joshi:** Fair enough. Now that you have huge capacities inaugurated just recently do you foresee any opportunities for Biocon being one of a good players in contract manufacturing for biopharmaceuticals?

**Kiran Mazumdar-Shaw:** We would rather not do a contract manufacturing, but what we would like to do is an alliance or partnership model to leverage these kind of capabilities.

Monica Joshi: In the sense, if you could elaborate please?

**Kiran Mazumdar-Shaw:** There a number of companies who are looking for these kind of capacities. Biocon is trying to see how it can leverage on these capabilities through alliance model that will give Biocon some rights to certain markets.

**Monica Joshi:** Okay, in the sense that maybe that you would have some sort of a profit sharing agreement on the front end or something?

Kiran Mazumdar-Shaw: Yes, exactly.

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

**Moderator:** Thank you Ms. Joshi. Next we have Mr. Nimesh Mehta from Edelweiss Capital, over to you Sir

**Nimesh Mehta:** I am requesting a full breakup of the biopharmaceutical space first quarter as well as for the full year?

**Kiran Mazumdar-Shaw:** We cannot give you a breakup of the biopharmaceutical space for confidential reasons.

**Nimesh Mehta:** I wanted to know an update on the FDA inspection for your expanded Statin facility?

Kiran Mazumdar-Shaw: Yes, it will take place very shortly.

Nimesh Mehta: And how long will it take to get the facility approved?

Kiran Mazumdar-Shaw: Very soon.

**Moderator:** Thank you. Next in line, we have Mr. Dipen Mehta from Dipen Mehta Share and Stock Brokers, over to you Sir.

**Dipen Mehta:** Yes, congratulations on good set of numbers. I wanted to understand that we have already inaugurated a major factory on the 17<sup>th</sup> April, and that completes a large part of your capital expenditure as I understand. Now, do we have to wait some more time for US FDA approval for this facility or because as I understand from your communication in the past, the facility is in that statin markets in US, you are stranded in such a way that this would go on stream and statin would go off patent in US, so I just wanted to understand that aspect, maybe you answered that earlier, I am not sure?



**Kiran Mazumdar-Shaw:** No, the facility that was inaugurated on the 17<sup>th</sup> of April was actually a biological facility, which is really going to address the antibody manufacturing requirements of the Company and some other recombinant therapeutics. As far as the other facilities are concerned, these will be operational from this quarter and till we get our US FDA approval it will also supply to the European market, so it is going to be fully utilized in terms of our market opportunities.

**Dipen Mehta:** But, when do you expect US FDA approval, if you can give us some idea on that count?

Kiran Mazumdar-Shaw: Very soon

**Dipen Mehta:** Okay good, that means that the whole strategy of having these facilities in places just prior to statin going off patent in US is well on track, right?

**Arun Chandavarkar:** See, basically this facility was put up to add to our capacity. Our existing capacities are already qualified, so it just means we have to balance the regional mix of which facility caters to which market, and this new facility coming on stream allows us to shift the rest of the world and European Markets to the new facility with immediate effect and utilize our existing approved facility for the US opportunity until the new facilities is approved.

**Dipen Mehta:** Okay, and that you expect will happen in Q1 of FY07, am I right?

Arun Chandavarkar: I cannot be so accurately predictive but we hope to have it very soon.

**Dipen Mehta:** Therefore, one can expect a scale up in operation from Q2 or FY07 given the assumption that as and when the capacity goes on stream, there is a market for your product?

Arun Chandavarkar: Scale up in operations with reference to the US market, yes.

**Dipen Mehta:** Okay, so that means, just to reconfirm that from Q2 FY07 onwards there would be a major improvement in terms of top line and bottom line

**Arun Chandavarkar:** I cannot say that, because as I told you we are already catering to the US market from our existing facility.

**Dipen Mehta:** But if you have planned such a huge expansion

**Arun Chandavarkar:** This facility will only allow us the flexibility of using either facility for the US market.

Dipen Mehta: And we are still not clear about the launch in the US market, am I right?

**Arun Chandavarkar:** What do you mean by launch, because we are already supplying out of the existing facility to the US, and as Rakesh mentioned earlier initial quantities of simvastatin to the US market have commenced and as he mentioned larger quantities



will commence once the product actually goes off patent end of June and pravastatin as you know comes off patent only in October, so that is still a few months away.

**Dipen Mehta:** June and October are key months from the Company's point of view and therefore they are the dates we should be watching out for in terms of launch from Biocon or supply to US from Biocon, is that correct?

**Arun Chandavarkar:** June and October represents the patent expiry date, so around that period will be when the respective products will start getting shipped to US, subject to extension on account of 180 days exclusivity.

**Dipen Mehta:** As of now, does the Company have capacity constraints and also second to that is that once this expansion goes on stream, what is the increase in terms of capacity, is it doubling the capacity, tripling the capacity?

**Arun Chandavarkar:** When we were referring to our capacity constraints we were referring to why our enzyme business had not grown last year and when the new capacity comes on stream, which will happen this quarter, it gives us the flexibility to not only make pharmaceutical products for rest of the world and Europe, but also add to our enzymes.

Dipen Mehta: Thank you and all the best.

**Moderator:** Thank you Mr. Mehta. Next, we have Mr. Prashant Nair from Citigroup, over to you Sir.

**Prashant Nair:** I have a few questions, the first one relates to your depreciation when would you start recording the depreciation on the expanded facilities, would that start coming through in the next year and ....?

Arun Chandavarkar: In the later part of Q1.

**Prashant Nair:** Okay. Could you give us some indication of how you see the trend on this front? You had depreciation of around Rs. 8 crore in the fourth quarter this does not include any thing from for the new capacity?

Arun Chandavarkar: It does not include any Depreciation, account the new facility.

**Prashant Nair:** Okay, fine. The second one was just wanted to confirm the capex number which you had earlier, would it be around Rs. 100 crore cumulatively across...

## Arun Chandavarkar: Yes.

**Prashant Nair:** Okay, my third question was related to simvastatin did you have any revenues of launch quantities to the US in the forth quarter from this product.

**Murali Krishnan:** Yes, as Kiran mentioned earlier, some small quantities have started going. People are adopting the wait and watch approach.

**Prashant Nair:** Okay, and finally just an additional clarification on the head and neck cancer product you expect launch sometime in the current fiscal and you mentioned that



you will be filing for approval, now I wanted to know, have you concluded all trial from your front and you just have a wait for approval from the regulatory authorities or have some trials got to be completed yet?

**Shrikumar Suryanarayan:** Biocon has completed all the trials and we are in a process of compiling this document, putting it together, and submitting it to relevant authorities for approval.

**Prashant Nair:** All right, thanks a lot and all the best.

Shrikumar Suryanarayan: Thank you.

**Moderator:** Thank you Mr. Nair. Next, we have Mr. Ravi Agarwal from JP Morgan, over to you Sir.

**Ravi Agrawal:** Regarding simvastatin in the US, can we have a sense as to what are the nature of the agreements, which we have signed with our partners is it cost-plus or profit sharing, how is this contract essentially been designed?

Rakesh Bamzai: Due to confidentiality reasons, we are unable to disclose the models.

**Ravi Agrawal:** What I actually wanted to get a sense of was whether the revenues as an when they come, do we book them on a cost basis on our top line and then take profits towards the end of the year or do we....?

**Rakesh Bamzai:** Currently, all the revenues are being booked and accounted for, at the point of sale.

**Ravi Agrawal:** Okay, thank you very much, and another question on investments. Actually, we have investments of around Rs. 100 crore in our balance sheet, could we have an idea as to how much is now invested in Vaccinex and Nobex out of this Rs. 100 crore, or how is this been accounted for?

**Muralikrishnan K N:** The Vaccinex and Nobex investments as at 31 March, 2006 is about Rs. 52 crore.

Ravi Agrawal: Combined is Rs. 52 crore?

Muralikrishnan K N: Yes.

Ravi Agrawal: Any breakup you might want to share?

Muralikrishnan K N: Rs. 18 crore is Vaccinex and Rs. 34 crore is Nobex.

**Ravi Agrawal:** Okay, and for the contract research business any idea as to what is the tax rate we look in contract research, how much of tax are we looking at in this business, in Syngene?

**Chinappa M B:** Income tax on account of Syngene is expected to be constant in absolute terms, because all the new expansion is happening under an EOU scheme, which is exempt from tax up to 2009.



**Ravi Agrawal:** So we are essentially saying whatever tax liability we have currently in absolute terms is what is going to remain and in incrementally there is no income tax?

Chinappa M B: Yes, tax payout will remain around existing levels.

**Ravi Agrawal:** Okay, and one housekeeping question, how much is the revenue breakup for R&D and for power in this quarter and for the full year?

**Muralikrishnan KN:** The R&D spend for the year is about Rs. 76 crore. The Revenue expenditure is about 25, the balance is capital in nature.

**Ravi Agrawal:** For the year and for the quarter?

**Murali Krishnan:** No, I do not have the quarter numbers, We normally provide this information on an annual basis.

Ravi Agrawal: And the power cost on consolidated basis?

Murali Krishnan: That is about 5 % of Sales.

Ravi Agrawal: Okay. Thank you.

**Moderator:** Thank you Mr. Agarwal. Next, we have Mr. Rahul Baijal from Voyager Capital, over to you Sir.

**Rahul Baijal:** I want to understand better the growth drivers behind the research services business, well I can see that the quarterly run rate has almost from Rs. 20 crore about a year back has now crossed more than Rs. 30 crore. So I just want to understand better within clinical research and contract research, which areas are growing faster than the others and whether that is a function of increasing traction from the same clients, or from more clients, can you throw some light on that?

**Kiran Mazumdar-Shaw:** It is a combination of factors. What you have seen this year is largely coming from Syngene and that is really about the contract research space. Clinigene is not yet contributing significantly to the research services space, but going forward, you will see large numbers coming from Clinigene as well, but it is really a balance of existing customers and new customers.

**Rahul Baijal:** Okay and within Syngene, what kind of projects are coming in terms of they are mainly contract research are you also setting up contract labs on the contractual bases with the global clients or what kind of ramp up are you seeing?

Goutam Das: Largely contract research.

**Rahul Baijal:** Okay on the clinical research side, are we seeing any potential changes in regulations within India, which can help scale up this business faster from an Indian Company perspective.



**Arvind Atingal:** In the area of biotech recently there is a recommendation that has been accepted and that the changes especially regarding the time and also the number of clearances we have to go through, will certainly help clinical research.

**Rahul Baijal:** Okay and within Clinigene are we also doing bioequivalence, bioavailability studies, or we are just doing something else?

Shrikumar Suryanarayan: About 25% of the work is BE/BA studies

Rahul Baijal: Okay and what is the remaining within Clinigene?

Kiran Mazumdar-Shaw: Clinical trials.

Shrikumar Suryanarayan: Clinical, operations, and the lab.

Rahul Baijal: Okay. Thank you very much.

**Moderator:** Thank you Mr. Rahul. Next, we have Mr. Ashwin Agarwal from Akash Ganga Investment, over to you Sir.

**Ashwin Agarwal:** Congratulations to the Biocon management team to deliver a good set of numbers in the challenging period. My question is to Ms. Kiran. Madam, you pointed out that you have rightly picked in a number of initiatives on the innovation side to transform this Company, from API to a discovery-led Company. By when do you feel your diversified and a huge product basket would start delivering on the top line what is your, means, I am talking for the next three to five years, how do you see this initiative panning out in terms of revenues and profitability?

**Kiran Mazumdar-Shaw:** Well, in terms of our generic portfolio, this is like a near term kind of business to look at and this obviously is definitely going to come from our existing businesses and of course as I mentioned insulin could be one of the short to medium term kind of growth contributor, but if you look at the new molecules space you have to wait a little longer. HR3 has already come in, but you are really going to see that opportunity pan out really in the next four to five years as well in terms of numbers.

**Ashwin Agarwal:** And will that be initially only for head and neck and later it can be taken for other indications?

**Kiran Mazumdar-Shaw:** What we will do is we will launch if for head and neck, but then we will quickly start developing it for other indications, which is quite well known.

**Ashwin Agarwal:** Can you fill us in on the update on the progress of the research programs of BMS, since **Exubera** has now been approved and probably in the market?

Kiran Mazumdar-Shaw: We are not able to share that information.

Ashwin Agarwal: But is it on right track, it is moving ahead?

**Kiran Mazumdar-Shaw:** We are not guiding that project, so we are not able to tell you that.



**Ashwin Agarwal:** And, can you comment on the Bentley international insulin progress of, because you have an API supply arrangement with them?

**Shrikumar Suryanarayan:** Bentley, one part I will ask Dr. Arvind to talk which is clinical development and on business part, the project is going on well. We have signed a supply agreement for this novel device which is an intranasal insulin device, and we are very anticipate sales in next four to five years.

**Dr. Arvind Atignal:** The clinical development program including dose escalation studies are underway.

**Ashwin Agarwal:** Lastly, can you all fill us in on the progress for filing for bio similars as per the EMEA guidelines for the EU countries?

**Arun Chandavarkar:** We were waiting for the final guidance to be issued and now that in the month of March, EMEA issued the final guidance. We at least have a roadmap ahead of us which tells us were we stand with reference to the preclinical and clinical work that we have already done in India and what remains to be done to fit in the gaps to make it acceptable by EMEA. So this is a very active and high priority project for us.

Ashwin Agarwal: So, for which products would you be filing?

Arun Chandavarkar: First bio-similar we are talking about is of course insulin.

Ashwin Agarwal: And by when should this be filed or submitted?

**Arun Chandavarkar:** Well, since we are in the process of assessing where we stand, at this point, I cannot tell you, but we hope to start a dialogue in terms of how we want to go with immediate effect.

Ashwin Agarwal: Thanks a lot and all the best to the team.

Arun Chandavarkar: Thank you.

**Moderator:** Thank you Mr. Agarwal. Next in line, we have Mr. Anshu Govil from CLSA, over to you Sir.

**Anshu Govil:** My question is about the Syngene and the clinical division, how many people have been added in the last 12 months and what is the current number of total people employed in these divisions?

**Goutam Das:** Current number is about 600 between both these companies and last year we added about 150 plus.

Anshu Govil: 150 plus on a net level?

Goutam Das: Yes.

**Anshu Govil:** And expectation going forward?

Goutam Das: Going forward, we expect similar numbers of additions.



**Anshu Govil:** And, another thing on your new capacity for statin for which you have invested around \$100 million. What is we expected ROI now post all the price erosions, etc. that have happened?

**Murali Krishnan:** We would like to answer this in the next session after we have commenced supplies to these markets and we have a fix on prices and volumes.

Anshu Govil: Thanks a lot.

**Moderator:** Thank you very much Sir. Next is the follow-up question from Mr. Ranjit Kapadia of HDFC Securities, over to you Sir.

**Ranjit Kapadia:** You have mentioned about the reduced pricing pressure in the statin segment. Can you elaborate a little further on this?

Kiran Mazumdar-Shaw: Rakesh will answer this.

**Rakesh Bamzai:** It is a reality that all the products that are manufactured in larger quantities across the globe face price pressures. We have been able to increase market share for all the products that we manufacture and sell in United States, Europe and other markets. Our competitiveness through technologically advanced process has prepared us to face competition and do well in those circumstances.

**Ranjit Kapadia:** And how you are going to face the competition in US and how many players are there in the US, how many players you expect to compete with?

Rakesh Bamzai: The US position is still uncertain.

Ranjit Kapadia: Thank you.

**Moderator:** Thank you Mr. Kapadia. Next is the follow question from Mr. Nimesh Mehta of Edelweiss Capital, over to you Sir

**Nimesh Mehta:** I wanted the R&D guidance going forward, right now for the whole year, I understand it is Rs. 25 crore, what you expect that to be in the next three years, because there are a lot of R&D projects here taking up now?

**Kiran Mazumdar-Shaw:** Nimesh, this is a very difficult question to answer with any accuracy because it would, all I can say is it will increase but by how much it all depends on the regulatory path and the development path. If we make rapid progress on the regulatory path, then the investments will increase. The increased spend on R&D is really in the area of clinical development.

**Nimesh Mehta:** My next question is related to the oral insulin program, the IP of which we have acquired from Nobex, you said that you are filing the molecules to the Indian authorities am I correct.

**Kiran Mazumdar-Shaw:** Yes, we are expecting an approval from the Indian regulatory authority to allow us to commence Phase I clinical trials.



Nimesh Mehta: And the regulated market?

**Kiran Mazumdar-Shaw:** Phase I is in India and then of course the regulated markets. We expect to be submitting an IND with US FDA later this year, so that is the time when we will look at the regulatory requirements of the US.

Nimesh Mehta: Okay, thank you very much.

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

**Sameer Baisiwala:** What is the update on the deals with innovator companies on the statin please?

Rakesh Bamzai: It depends on when they want to launch the product.

Sameer Baisiwala: I am sorry?

**Rakesh Bamzai:** They have projected it after 2007, but we are not actually sure when they want to launch the product.

**Sameer Baisiwala:** You are not too sure whether you would have commercial sales or your partners would launch these drugs?

**Rakesh Bamzai:** Well, our sales will depend on the launch date of our partners and we have no control on their launch date.

**Sameer Baisiwala:** Fair enough, but going the way the clinicals are going any time lines in mind about NDA submission, approval on that basis can you say that you will start the supplies in 2007 or something like that?

**Rakesh Bamzai:** Internally, we expect sales to commence from 2007, but as I said this is dependent on our customers.

**Sameer Baisiwala:** Correct me if I am wrong, there seems to be little less confidence or optimism about this innovator deal as compared to what we had heard you about previous call or even the one before that, has there been any dilution in this aspect of the business?

**Kiran Mazumdar-Shaw:** Absolutely not, we are all just weary from all the presentations, but certainly we are extremely enthusiastic about the innovator deals and that is definitely going to be one of the growth drivers for the statin segment.

Sameer Baisiwala: Okay, thank you very much.

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



**Shiv Muttoo:** Thanks Parimala. On behalf of the Biocon management team, I would once again thank you for your participation and with that we would like to close this conference call and back to you Parimala.

**Moderator:** Thank you very much Sir. Ladies and Gentlemen thank you for choosing WebEx conferencing service. That concludes this conference call. Thank you for your participation. You may now disconnect your lines. Thank you and have a nice day.

- ENDS -