



BIOCON LIMITED

Analyst / Investor Conference Call 18th January 2007, 3:00 PM IST

Moderator: Good afternoon Ladies and Gentlemen, I am Rekha, moderator for this conference. Welcome to the conference call of Biocon Limited. I would now like to hand over the conference to Mr. Nitin Tandon, of Citigate Dewe Rogerson.

Nitin Tandon: Thank you Rekha and good afternoon everyone. It is very good to have you with all of us on this Biocon nine months' FY2007 results conference call. We have with us on this call from Bangalore Ms. Kiran Mazumdar Shaw, Chairman and Managing Director of Biocon Limited, and also her colleagues, who are a part of the Senior Management Team. We will begin this call with opening remarks from the Biocon Management Team followed by a Q&A session where you can ask your questions and discuss key issues. Now I would like to invite Ms. Kiran Mazumdar Shaw to briefly discuss the company's performance for the nine months ended December 31, 2006. Over to you Kiran.

Kiran Mazumdar Shaw: Thank you Nitin, good afternoon to everyone. I would like to start by wishing all of you a very happy new year. I am pleased that we could deliver a very good set of results in the third quarter, driven by important initiatives taken at the beginning of this particular fiscal. As a result of which, we have been able to address both margins and price realizations. The third quarter actually has delivered robust profits driven by a few factors. One of course is the opportunity to enter the US market for Simvastatin and here we have had better price realization and margins largely because of the operational aspects of Biocon Park. At Biocon Pak, the plant and facilities have become fully operational and this has meant that we been able to reduce the cost of manufacturing largely because we have now not had to depend on the use of expensive intermediate and the complete manufacturing has been conducted at Biocon Park. This itself has allowed us to realize better margins on all our APIs manufactured at Biocon Park. In addition to that our research services businesses have continued to grow well and they have contributed very significantly to our bottom line. The third important driver of growth has been our technology and licensing fees. Again, this is going to be a very important part of our future business segment and here again a number of technologies and various programs have been licensed in several ways. So, overall, I think we have very effectively realized a lot of the strategic efforts that we have been investing into and we are confident to deliver a sustainable growth and profitability in the road ahead.

Another comment that I would like to make here is the fact that the results should be seen in context of doubling of R&D spend both for the nine-month period as well as for the quarter itself, where R&D spend has gone up from Rs 15 crore to Rs 30 crore for the 9 months' period and from Rs 6 to Rs 13 crore for the quarter alone. As you know R&D continues to be a very important focus for Biocon considering the fact that our discovery pipeline is really an important part of our way forward. We are making very good progress on all the molecules that we are developing. BioMab EGFR has made a very good debut in the Indian market and I am pleased that we have been able to license this molecule for the Pakistan market so quickly and this is something that we will continue to focus on in terms of expanding the market reach for this product. We will be looking at doing similar licensing arrangements with Sri Lanka, Bangladesh, the GCC region and South Africa. We will also be looking at licensing opportunities in the next fiscal for some of the other important programs that we are developing where oral insulin and T1H are now expected to enter Phase II clinical development later in 2007. So, we believe that we are now in a very sound and healthy position to deliver sustainable growth and sustainable profitability and we look forward to completing this fiscal and starting the next fiscal on a very strong note. So, with that I would like to open this conference call up for a Q&A session. Thank you.

Question and Answer Session

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

First question comes from Mr. Kesvinder Singh Suri of Span Capital Services.

Kesvinder Singh Suri: Good afternoon and congratulations on the good set of numbers. Can you provide some more information with regards to your Pakistan licensing lease?

Kiran Mazumdar Shaw: We have entered into an exclusive licensing agreement with a company called Ferozsons in Pakistan which has been ranked as the number one national oncology company, after having gone through a very careful selection process. The Pakistan oncology market is valued at approximately Rs 70 million and monoclonal antibodies are one of the fastest growing categories with a compounded annual growth rate of 30%. We believe that we along with Ferozsons will be able to create a very significant market for our antibody in the next 4 to 5 years. As I have already mentioned, we expect BioMab EGFR to become a 100-crore brand in this period.

Kesvinder Singh Suri: Could you just share some of the economics of the deal in the sense would you be having royalty sharing, profit sharing how would you catalogue it?

Kiran Mazumdar Shaw: Well, I think we are unable to give you the details of this particular licensing arrangement. It will suffice to say that it is a very attractive deal.

Kesvinder Singh Suri: Did you receive some amount up front?

Kiran Mazumdar Shaw: We can't share this information with you. Sorry.

Kesvinder Singh Suri: Thank you.

Moderator: Next question comes from Mr. Pawan Nahar of Kotak Securities.

Pawan Nahar: Hi, congratulations to the management on a very good set of numbers. My question is if you could give us a break up of your license the contract research as such and the business that you have, how much is the licensing fee and how much is the contracting fee?

Murali Krishnan: The licensing fee is over Rs 12 crore and the balance is contract research.

Pawan Nahar: So, basically we have done about Rs 26 crore of license fees in the first 9 months?

Murali Krishnan: That's right, close to that.

Pawan Nahar: Great. Do you think that given this number it could be lumpy in the third quarter, and will we see a repeat of this number next year again?

Kiran Mazumdar Shaw: We expect to repeat these numbers again, as we believe that now we have entered into a licensing mode and you will see these kinds of numbers coming this year and in the future.

Murali Krishnan: On an annual basis it will happen, but may not happen on a quarterly basis.

Pawan Nahar: Correct. Your contract research business is now growing at about 30% including this. Do you think that this can accelerate going forward or will remain the same?

Kiran Mazumdar Shaw: I think this will be at pretty sustainable level I would say.

Pawan Nahar: 30% is sustainable level?

Kiran Mazumdar Shaw: Yes, 30% is a sustainable level.

Pawan Nahar: Okay and the other thing I wanted to ask you again was about Bio-pharmaceutical business – in the last two quarters you have done about Rs 180 crore average. Do you think that this number is sustainable? Can it go up, going forward in the next 2, 3 quarters?

Rakesh Bamzai: This business is going to grow a bit in the coming quarter which is January to March and we have plans in place to get a reasonable growth in the next year as well.

Pawan Nahar: Okay. I just wanted to understand a little on the statins opportunities. In the US, I believe there has been immense amount of pressure, discount on Simvastatin and plus I believe as I understand a lot of the guys have their own API whereas Dr. Reddy's is the only one that does not have a base so what's the kind of market are you seeing going forward?

Rakesh Bamzai: Today we have 4 customers for Simvastatin and we have 2 more in pipeline. We should have about 20% market share and be able to consolidate or grow further in the next quarter.

Pawan Nahar: And for Pravastatin?

Rakesh Bamzai: Pravastatin molecule sale has come down generally because of the impact of Simvastatin. In Prava again we would have 3 to 4 customers.

Pawan Nahar: Okay. Rakesh, my question here is in the next financial year what is going to be the growth driver? Insulin again I think will take a little time for sales to ramp up and similarly for monoclonals, so what is going to be the driver?

Rakesh Bamzai: There are various verticals that Biocon is concentrating on – statins, immunosuppressants, oncology and insulin and all these segments are expected to be growth drivers in the next quarter in the next year.

Pawan Nahar: Okay, overall do you think we can grow as a company 15% on the top line this year?

Rakesh Bamzai: I don't want to comment, but I can tell you that we are doing all that is possible to grow.

Pawan Nahar: Okay fine, thank you.

Moderator: Next question comes from Mr. Ashi Anand of Prudential ICICI.

Ashi Anand: Hi, congratulations on a good set of numbers. My question was with regards to our progress on biosimilars one on insulin and how many countries do we now have filings and how many countries have we started selling? What is the progress on EPO and GCSF with reference to Indian market?

Rakesh Bamzai: Today, we have registrations of Insugen brand in 5 countries. But going forward in 2007 we would have our registration completed in 25 countries and in 4 to 5 years we are targeting 75 countries. We are trying to build Insugen as a very big global brand. Answering

your second question on Erythropoietin and GCSF, we should be marketing these products first in India, once the regulatory process in the country is completed and then we are going to go to other countries and market these products in these countries.

Kiran Mazumdar Shaw: I would just like to add to what Rakesh said that both GCSF and EPO have completed their trials in India and are awaiting regulatory approval so we do expect to be in the Indian market if not by the end of this fiscal for sure in the beginning of the next fiscal.

Ashi Anand: Okay, and with regard to the European market, at what point do we actually start filing for registration in that market for insulin, or GCSF or EPO?

Kiran Mazumdar Shaw: Well insulin is the first real focus for Biocon and we have already started the registration process in Europe and we expect that this process will take about 18 months.

Ashi Anand: Okay, and lastly with regards to our progress in oral insulin?

Kiran Mazumdar Shaw: Oral insulin as I mentioned will start Phase II clinical trials later this year.

Ashi Anand: Okay, thanks a lot.

Moderator: Thank you sir. Next question comes from Mr. Sukhwinder Singh of Anagram Securities.

Sukhwinder Singh: Hi, good afternoon. As far as reduction in expenditure is concerned is there a further possibility of reduction possible as a percentage of sales going forward?

Murali Krishnan: We will always strive for that.

Sukhwinder Singh: Can we have what the percentage that would be?

Murali Krishnan: We cannot quantify that but that is definitely our focus point.

Sukhwinder Singh: As far as Syngene and Clinigene is concerned how much is the current HR strength and the like target for the next one year?

Murali Krishnan: Syngene is about 600 and Clinigene is getting close to 100. Syngene could add about another 300 plus over the next 1 year.

Sukhwinder Singh: One last question on the trials. I just want to understand what are these label expansion trials and how does it differ from the normal clinical trials? And when these label expansion trials are over what is the next step for BioMab?

Kiran Mazumdar Shaw: When you look at a molecule in the cancer segment, generally speaking these molecules can be used in a number of types of cancers. But when you do the clinical trials you actually start with one particular type of cancer which is in our case head and neck cancer. Right now there will be off-labels used by the doctors, but really if you want it to be used extensively in certain indications like brain tumors, or non small-cell lung cancer or colorectal cancers, or pancreatic cancers, you do need to do trials in these particular segments. These trials basically allows you to then expand the market for this molecule – to different type of cancers.

Sukhwinder Singh: Sure, thanks a lot.

Moderator: Next question comes from Ms. Visalakshi of DSP Merrill Lynch.

Visalakshi: Thank you and congratulations on a good set of numbers. My question is on your EBITDA margin improvement for this quarter. What would be the 2-3 key factors that you would attribute to this margin increase and could you give us some outlook as to where you see EBITDA margin levels in the coming year?

Chinappa: The EBITDA margin increase is really on account of the reduction in our material cost consequent to full manufacture of all our products as against the purchase of some advanced intermediates and I believe that we could sustain this EBITDA margin in the next financial year.

Visalakshi: Is there also some broad revenue outlook that you could give us in terms of the revenue growth outlook in the coming year?

Murali Krishnan: No, unfortunately no.

Moderator: Thank you madam. Next question comes from Mr. Ravi Agarwal from JP Morgan India.

Jesal Shah: Hi, this is Jesal Shah. Actually I have a number of questions. To start off with if you can give some color on what is the nature of the milestone income that you have received in the first 9 months?

Rakesh Bamzai: These are a combination of work that we have done in research and marketing. It is a combination of dossier developing, licensing, milestones for marketing authorization in few regions and so on.

Jesal Shah: Can you explain to us which market it pertains to?

Rakesh Bamzai: Combination of all the markets actually. I don't have the list here but it is a combination of many markets and many things.

Jesal Shah: So basically this is some kind of work which you have done for some clients pertaining to registration of their products in those markets?

Rakesh Bamzai: Basically formulation development related work which is not done as a contract for other people. It is our IP, our work which we have capitalized.

Jesal Shah: I am sorry. If it is formulation development work, should it not...?

Kiran Mazumdar Shaw: Dossier development. I would say that it pertains to dossier development of a lot of our own products which we have licensed to a number of companies.

Jesal Shah: Right. So, I guess this is the dossier income which you have received on the product which was already registered by Biocon and which have not been out licensed to various companies?

Kiran Mazumdar Shaw: Yes.

Jesal Shah: So that kind of business we understand pertains more to Europe. Is that also what you feel?

Kiran Mazumdar Shaw: No, everywhere – US, Europe and other parts of the world.

Jesal Shah: Right. Would you like to tell us how many dossiers you have registered since this is out-licensing those dossiers, how many such dossiers you have with you?

Kiran Mazumdar Shaw: This is fairly sensitive information so I don't think we can share too much with you.

Jesal Shah: Okay. Then moving on to Syngene business can you give us some idea as to what is happening to pricing there? Would it be right to say that we see some kind of compression in the EBITDA margin in that business on both y-o-y as well as sequential basis?

Gautam Das: This is Gautam. We don't see too much of price erosion as it is a very stable business at this point. We also don't anticipate any erosion in the EBITDA margin on Syngene.

Jesal Shah: So according to you the margins in Syngene business have been flat, maintained at this level

Gautam Das: It is sustained.

Jesal Shah: Okay. Then moving on to your Biopharmaceutical business, if you can just give us a break up of how much is the contribution of US supplies of statins?

Rakesh Bamzai: It is actually one third in US, one third in Europe and one third from the rest of the world including India.

Jesal Shah: So this one third is one third of the total Biopharmaceutical business?

Rakesh Bamzai: Yes.

Jesal Shah: But the US business would have kicked off only this quarter right?

Rakesh Bamzai: We have been doing business in the US for a couple of products in the past but this December quarter and the previous quarter were actually good because of the launch of Simvastatin in US.

Jesal Shah: And how much will that proportion be, let's say in the past where you were already selling some products in the US?

Rakesh Bamzai: We have done well in the US with the launch so in the last two quarters, business out of the US has doubled.

Jesal Shah: Right. So, you said you have 20% market share in Simvastatin. What about Pravastatin?

Rakesh Bamzai: Pravastatin market has come down because of Simvastatin impact. We should have about 4 customers in Pravastatin and we expect a 15% to 20% share.

Jesal Shah: Right. What kind of pricing have you seen in these two products?

Rakesh Bamzai: As of now the price has slightly come down, but it is much better than what we are getting in Europe.

Jesal Shah: For both the products?

Rakesh Bamzai: Yes.

Jesal Shah: Okay and what about the contribution from insulin and immuno suppressants?

Rakesh Bamzai: This quarter we have done very well in these two products as well and I was telling in the beginning that insulin is going to be one of the major growth drivers for us in this quarter and in the next year.

Jesal Shah: Right. Would you like to tell us how much it has contributed this quarter – as a percentage of Biopharmaceuticals or some rough idea?

Rakesh Bamzai: Actually we don't give these numbers but from marketing we can tell you that we are focusing a lot on insulin.

Jesal Shah: One last question – on other expense where we have seen a decline both sequentially and y-o-y, can you explain to us why that has happened?

Chinappa: Jesal this quarter we have seen a sharp movement in the exchange rate and therefore sales have been a bit lower on account of the appreciating rupee. Part of that has been countered with a million dollar plus of forex gain, which shows up as a reduction of the other expenditure. This is largely offset on the other side with higher R&D expenses. Therefore, other expenses are roughly in line with the previous quarter but marginally lower because of the exchange gain.

Jesal Shah: In the previous quarter, other expense was about Rs 17 crore. Is that also the number you have in your mind?

Chinappa: We had about Rs 50 crore of other expenses in the previous quarter and this quarter it is Rs 48 crore.

Jesal Shah: Okay and the R&D expense have gone up from Rs 10 crore to Rs 13 crore. So therefore the other expenses have fallen about Rs 5 crore, and that is completely because of FOREX?

Chinappa: Yes.

Jesal Shah: Okay. What's the net asset or liability in foreign exchange that you have?

Chinappa: We attempt to balance our Net positive FX position with forward cover and FOREX borrowing. On a forward outlook, we are FOREX positive. Our annual flow is about USD 100 million plus inflow and USD 40 million outflow.

Jesal Shah: Right, that's on the P&L side, but on the Balance sheet side are you net asset or do you have net liability?

Chinappa: Our net forex asset position is balanced with forward cover and therefore our balance sheet position is neutral.

Jesal Shah: Right, so whatever be it, be it net asset or liability you would have a corresponding FOREX forward cover?

Chinappa: That's right.

Jesal Shah: I see and what's your view on FOREX from here on?

Chinappa: We cannot comment.

Jesal Shah: Okay fine. I will jump back into the queue, thanks so much.

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

Nitin Agarwal: Hi, good afternoon everyone. Congratulations on an excellent set of numbers. I had two questions, one is on immuno suppressants. In terms of immuno suppressants has any ANDA been filed using the DMFs that we filed.

Rakesh Bamzai: Not by Biocon. ANDAs have been filed by the partners.

Nitin Agarwal: But has the Biocon DMF been utilized? Has any of those ANDAs utilized Biocon DMFs?

Kiran Mazumdar Shaw: Yes. Based on the ANDA's , Biocon has already been inspected by the USFDA.

Nitin Agarwal: Okay and the second question is on the monoclonal antibody facility that we have, currently I assume that the utilization rates in that facility would be relatively lower. How do we see the utilization rates in that facility ramping up?

Kiran Mazumdar Shaw: Well first and foremost the second antibody is also coming into the pipeline and so for that also, we need some manufacturing capacity, but of course other than that the Gulf market and all these other markets are opening up for BioMAb. We will also in the future be supplying this product to various other partners of BioMAb in other parts of the world.

Nitin Agarwal: As far as the other parts are concerned are there any BioMAb trials going on in the regulated markets?

Kiran Mazumdar Shaw: There is a big trial going on in Europe and in Japan and US also has received permission.

Nitin Agarwal: In Europe and Japan are there any time lines for the commercialization? When is that expected?

Kiran Mazumdar Shaw: Yes, I think in Europe they expect to commercialize this product early next year that is 2008.

Nitin Agarwal: And the production for these supplies will be done out of the Indian facility?

Kiran Mazumdar Shaw: Well both from here and from the Cuban facility.

Nitin Agarwal: Thanks very much.

Moderator: Thank you sir. Next in line we have Mr. Ashwin Agarwal of Akash Ganga Investment.

Ashwin Agarwal: Congratulations to the management team on a very good set of numbers and a very encouraging initial comment. I would like to know whether there are any one-off supplies of statins for inventory build up for Simvastatin in this quarter. Or this will be sustained in Q4 as well?

Kiran Mazumdar Shaw: This should be sustained in the last quarter.

Ashwin Agarwal: Okay, so Q4 should also be very strong.

Rakesh Bamzai: Yes.

Ashwin Agarwal: Secondly I had a question for Dr. Kiran Mazumdar. You gave very encouraging initial comments and you also spoke about your R&D initiatives. So as a long-term investor can one say from next year onwards on an annual basis Biocon would deliver secular and steady growth to achieve your vision?

Kiran Mazumdar Shaw: It is difficult for me to give you a hard and fast answer because you know that many of these things are dependent on regulatory approval. As a result of which it is very difficult to predict when exactly the trigger points would occur. But all the same I would like to assure you that we are very confident that we will be able to have steady sustainable and good growth.

Ashwin Agarwal: By when do you see the Europe markets opening up in terms of biosimilars, insulin and other products? By when would Biocon products be in the market place?

Kiran Mazumdar Shaw: I think in about 18 months we expect the European market to open up for our insulin at least and then of course for other biosimilars as well.

Ashwin Agarwal: And you would have specific alliances for the EU for each of these markets.

Kiran Mazumdar Shaw: It will be a combination of hopefully us being able to market on our own and through some limited partners.

Ashwin Agarwal: Okay, thanks a lot and congratulations once again.

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

H.R. Gala: Congratulations to the team of Biocon for a good set of results. I have a few questions. The first question pertains to the build up of inventory at Rs 170 crore vis-à-vis Rs 110 crore as on March 2006. Is it mainly for Simva that we will be supplying for the U.S. market in the next quarter?

Murali Krishnan: Yes. It includes Simva. We have been building up our inventories in anticipation of markets opening up and also as of the last quarter, the new facility was not inspected. The inspection has just been completed, at the end of December 2006. So we had built up those inventories as well, in anticipation of these markets opening up.

H.R. Gala: So did you expect to be greatly being watered down by the end of this fiscal?

Murali Krishnan: Yes, end of Q4 or early part of next fiscal.

H.R. Gala: Okay. One question pertaining to margin that has already been answered, that you expect the current type of margins to sustain over a period of time. There was one question asked in the beginning that I need a clarification that the Rs 116 crore of revenue that we have booked under the contract research and licensing fees for nine months, includes Rs 26 crore of licensing fees?

Murali Krishnan: Yes, approximately around that.

H.R. Gala: Okay, so I think in H1 FY2007 we had about around Rs 10 crore which means that around Rs 16 crore has been booked in the current?

Murali Krishnan: Around Rs 10 crore plus.

H.R. Gala: Okay and how much was it in the corresponding figure of the last year's Rs 70 crore?

Murali Krishnan: It was a very insignificant number.

H.R. Gala: Okay. Thank you very much and wish you all the best.

Moderator: Thank you sir. Next question comes from Mr. Anoop Motiani of Gardenia Cosmo Trade.

Anoop Motiani: Yes ma'am. Thank you and congratulations. I would like to ask you about the monoclonal bodies entering into the US. So by when do you think you can introduce the monoclonal bodies into the US?

Kiran Mazumdar Shaw: The monoclonal bodies that we have are at the moment is for restricted territories. However, we could be supplying product once the licensee for the US markets get marketing approval. We also have the second product, for rheumatoid arthritis for which we have global rights. But that of course will take at least a few more years before we even address the U.S. opportunity.

Anoop Motiani: Okay thank you.

Moderator: Thank you sir. Next question comes from Mr. Sameer Baisiwala of JM Morgan Stanley

Sameer Baisiwala: Hi, on oral insulin we have completed the Phase I clinical trials and expect to take it to Phase II in the later part of this year. Why is there a time gap?

Srikumar Suryanarayan: The Phase I clinical trials have been completed, and after that we had to compile all the data and submit it to the regulatory authorities. The Phase II clinical trial is actually a long-term trial. Now in order to do the long-term trial, one has to finish all the toxicity studies for that similar long-term in animal model before going to human beings; so we are waiting for all of that to be completed and filed along with the results so that we can go into the Phase II trials. So we should be ready to do this filing sometime in the latter half of this year and then we allow ourselves some time for regulatory approval. So we feel that it is safe to estimate that this year we will go into Phase II clinical trials.

Sameer Baisiwala: Okay and when will you be looking to doing these clinicals outside India and how long would a Phase II trial take?

Srikumar Suryanarayan: The process of developing a molecule in different territories is a parallel process. We can do a Phase I to Phase III in India, and we can parallelly carry out another process outside. I think it is a matter of balancing the cost versus the risk and the opportunity. And at this point of time we are on our way to doing the processes that are necessary to start the Phase I clinical trials outside of India. In other words, we have a certain degree of confidence that we are prepared to take the investment outside of India.

Sameer Baisiwala: Okay and how long will the Phase II study take to consummate here in India?

Srikumar Suryanarayan: From the start of the study, it takes about six months including the reports and then we have to prepare for the Phase III clinical trials. So it takes some time.

Sameer Baisiwala: Okay. My second question is about the R&D expense. Where does the company see the percentage of sales this number going in the next year?

Kiran Mazumdar Shaw: I think it will be around 8% to 10% going forward.

Sameer Baisiwala: Okay and the next question is how do you see the capacity utilization ramp up for the new fermentation facility?

Kiran Mazumdar Shaw: It has already been ramped up and starting to get almost fully utilized.

Sameer Baisiwala: Okay the last question is that we understand that for the Simva and Prava, for the formulators the prices are probably down 98% or maybe even more. What implication does it have on the pricing for the manufacturer?

Rakesh Bamzai: The prices have come down and everybody was expecting that and therefore it has not surprised anybody in the market. But from here on, we think that it is going to stabilize.

Sameer Baisiwala: Okay but my question stems from the fact that a lot of your sales must have been a pre-launch quantity. What is the post-launch when we actually have this kind of price erosion?

Rakesh Bamzai: We have supplied to the customers for preparing them for the launch, and we have also repeat purchases from all these customers for second phase of launch where we have received orders.

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

Moderator: Thank you sir. Next question comes from Mr. Akshay Shah of Quest Investment Advisors.

Akshay Shah: Good afternoon. Just one clarification - in the beginning of the question and answer you said that you expect the BioMAb to be a hundred crore brand. Is that including India and the other markets like Pakistan which you have started and Sri Lanka?

Subir Basak: Yes.

Akshay Shah: How many years are you looking at?

Subir Basak: 3 to 4 years.

Akshay Shah: 3 to 4 years over these markets. Okay. One more thing, the R&D you said is 8% to 10% of sales right – on consolidated sales?

Muralikrishnan : Yes. Including capex

Akshay Shah: Okay, thanks.

Moderator: Thank you sir. There is a follow up question from Ms. Visalakshi of DSP Merrill Lynch.

Visalakshi: Thank you. My question is on insulin licensing deal. Last time you mentioned that you concluded a licensing deal for the US. Is it possible to get more details on this? You also talked about an EU licensing deal to happen this year, is there any update on that?

Kiran Mazumdar Shaw: Due to confidentiality reasons our licensee itself has said not to disclose the deal. So we are not able to disclose it, but as soon as we can, you will be the first one to know.

Visalakshi: What about on the European side? Has that also concluded?

Kiran Mazumdar Shaw: No, in Europe we have tried to take a different strategy. We feel that we would like to do the registration processes on our own so that it gives us the flexibility to decide how we partner. We can realize far greater value that way.

Visalakshi: Okay. What about insulin registration for the Asian and Middle East market? Last time you mentioned that you started supplies to the same market but this time, at the current call you are talking about just 5 markets, is there some update?

Rakesh Bamzai: There are 2 types of businesses, one is insulin crystal sale and the second is Insugen sale which is the formulation of insulin. So, I was talking about the Insugen registration in these 5 countries.

Visalakshi: And that will ramp up to 75 markets?

Rakesh Bamzai: Insulin crystals we are selling to many more countries and that is a continuous growing business for us.

Visalakshi: Could you give us an update on these registrations? Where does it stand at?

Rakesh Bamzai: The registration of Insugen brand in other process in 25 countries we are expecting approval in the next financial year.

Visalakshi: Okay and what about the normal insulin registration, what is the status there?

Rakesh Bamzai: In some countries insulin crystals are required to be registered and in some countries there is no process of registration we have to just supply material via the Drug Master File and relevant process of regulation and get the approval. So, we have a pretty large number of customers and countries already where this process is completed.

Visalakshi: What is the tally right now?

Rakesh Bamzai: I don't know the actual number but it will be more than 20 countries, 30 to 35.

Visalakshi: And finally on this Syngene business, there has been a tapering of growth in this quarter compared to the previous quarter, is there a cause of concern?

Gautam Das: Not really.

Chinappa: Sometimes some costs are incurred ahead of ramp up in revenues and that's reflected in this quarter. There is no drop in margins.

Visalakshi: So could you sustain a 40% plus growth in the coming quarter?

Murali Krishnan: 30% plus we can do. We have already done 86 plus when compared to 96 crores last year. We are very close to last year's numbers. So the 30% is something that is possible.

Visalakshi: Thank you very much.

Moderator: Thank you madam. Next question comes from Mr. Nitin Agarwal of SSKI.

Nitin Agarwal: On the insulin in Europe, you are talking about the strategy of doing the registration yourselves so would Biocon be conducting the clinical trials required for insulin Biosimilar on its own.

Kiran Mazumdar Shaw: If required. We actually believe that given the kind of post marketing data that we have generated on the PMS that was conducted recently on 6,000 patients and considering the fact that all the clinical trials that Biocon did were comparative trials, we believe that even if we were called to do a clinical trial, it would be very small and we believe that may be we may not even need to do the trials

Arun Chandavarkar: One of the things about the clinical trials if required, we don't know if it is required, but if it is required after we discuss with the regulatory agencies there is also a possibility of whether that entire trial could be done here in India by using a new reference product. So if you are concerned about us managing a trial in Europe or the cost associated with that that is something we are conscious of.

Nitin Agarwal: Okay fine, thank you.

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

H.R. Gala: Just a clarification, when we talked about the milestone income, you mentioned about the dossier development efforts to be capitalized. Can you just elaborate a little bit more on that?

Murali Krishnan: Efforts being capitalized in the sense efforts being monetized. We have actually monetized all that work which we have done in the past.

H.R. Gala: It is other than out-licensing?

Murali Krishnan: Yes.

H.R. Gala: Okay, thanks.

Moderator: Thank you sir. Next question comes from Mr. Vihari Purushothaman of Enam Securities.

Vihari Purushothaman: Hi, I just had a couple of questions on Insugen and also on BioMAB. Basically in your export drive, as you go towards Europe and other countries for insulin, do you see competition heating up from players like Bioton of Poland, or another dominant player of China in terms of pricing pressure. What is the current status of the tie up with Bayer for marketing Insugen in China?

Rakesh Bamzai: We do expect competition in all the fields. Yes there will be Bioton and other people also in the market but I think we have done our home work, we have addressed those issues very well through technology and that's why we have a different technology to produce insulin.

Arun Chandavarkar: Actually our biggest competitors would continue to be Novo and Eli Lilly and as Rakesh said Biocon is used to competition and we have seen it in the statins, we have seen it in the generic space so in insulin also we are ready to face any competition. But at the moment if you see the competition that we are actually facing in the markets where we are selling our Insulin it is more from the Novo's and Lilly's rather than the companies you mentioned.

Vihari Purushothaman: Okay. And on the China tie up with Bayer?

Rakesh Bamzai: We have signed this agreement with Bayer for marketing Insugen. Insugen will be manufactured in Bangalore plant and will be exported to China out of this plant. Registration process is right now on-going and it is going to take another 18 months to 24 months to get our products registered.

Vihari Purushothaman: Okay. On BioMAB, when you said that you expect about Rs 100 crore in the next 3 to 4 years is this including expected sales from BioMAB for gliomas, colorectal, pancreatic etc?

Rakesh Bamzai: Yes.

Vihari Purushothaman: Okay. So what is the current sort of market you have for the monoclonals in the country?

Subir Basak: The monoclonals market is a rapidly expanding market. As indicated earlier it is growing at the rate of about 30% to 40% a year. Currently the market in India is roughly about 75 to Rs 80 crore. However our monoclonal antibody is the most affordable monoclonal antibody today in the Indian subcontinent. It has got a different value proposition than the currently imported monoclonal antibodies that are available in this part of the world.

Vihari Purushothaman: You said that the Pakistan market is about USD 70 million is it?

Subir Basak: Yes.

Vihari Purushothaman: Is that far bigger than the Indian market for monoclonal?

Subir Basak: No. USD 70 million is the entire oncology market of Pakistan.

Vihari Purushothaman: In India I think some time last year YM Bioscience also received DCGI approval for a MAB for head and neck. Is this product being sold?

Subir Basak: No, that is not true. First of all monoclonal antibodies that we have launched is the one that has got the DCGI approval. The name of the product is BIOMAb EGFR. YM Biosciences is doing clinical trials on another product which is a small molecule.

Vihari Purushothaman: Okay. I thought they received DCGI for BIOMAb in last year.

Kiran Mazumdar Shaw: Let me clarify this. YM Bioscience has the right for this monoclonal antibody for other markets. And I think what you saw was something that appeared on their website which claimed that the product got approval in India, but what they were referring to was our antibody. So they basically made a claim that the antibody was approved in India but it was basically referring to our antibody.

Vihari Purushothaman: Okay thanks.

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

Nitin Agarwal: Just a follow up question, we have been talking earlier about the statin combination works that we have been doing with some innovator companies. Can you just give us an update on that?

Rakesh Bamzai: I think we have already explained in the last quarter that there were 3 such projects going on and 2 of those projects we have already closed, signed up.

Nitin Agarwal: Okay, thank you.

Moderator: Next question comes from Mr. Ravi Agarwal of JP Morgan India Private Limited.

Jesal Shah: Hi, Jesal Shah again, if you can give us an idea about your CAPEX program for the next year?

Murali Krishnan: The CAPEX program as it stands now is in the region of about Rs 100 crore for regular on-going projects for the next year.

Jesal Shah: The second thing is, if you could throw some light on your marketing efforts in India both for insulin as well as for the BioMAB in terms of what kind of launch expenditures have you incurred, what kind of field support are you getting, and some flavor on marketing in India on

these products and also what kind of expansion in insulin market share have you since the last time we had the conference call?

Rakesh Bamzai: Okay we will break it up. My colleague Subir will tell about BioMAb and I will talk about Insugen and rest of the things.

Subir: For BioMAb EGFR, I cannot discuss the launch expenses, but I can tell you that our sales and marketing product specialists are all over the country so we have reach and frequency with all the top key opinion leaders around the country and in fact we have coverage even outside the country. We are covering all the top institutions that are oncology cancer centers and key oncology clinics all across the country.

Jesal Shah: Do you have a sense on how many patients have already come onto your product?

Subir: Yes, we have more than 150 patients.

Jesal Shah: Are these all for head and neck cancer?

Subir: I cannot break up the numbers but majority of the approved indication is head and neck and most of the patients are from the approved indication of head and neck cancer.

Jesal Shah: Right, are you seeing any particular region kind of contributing to this or is it coming equally from all over?

Subir: Yeah, it is basically coming from all parts of the country because doctors from all over the country are prescribing this product.

Jesal Shah: Right and where do you see this number reaching may be one year or two years down the line? How many patients do you hope to get?

Subir: Based on the very initial days of the launch, only about 3 or 4 months, our expectation is that obviously this will be the most affordable and accessible to patients in India. There are right now about 150,000 patients of head and neck cancer in India and our hope obviously is that this will be accessible to as many patients who can afford our monoclonal antibody.

Jesal Shah: Right on Insugen if you can throw some light?

Rakesh Bamzai: In Insugen, what we have done in last couple of quarter is that we have increased our field force from 135 to 250 because we wanted to reach Tier II and Tier III cities. So we have increased our sales of Insugen brand by two and half times in this year and we are continuing our efforts to make it a very big brand in India.

Jesal Shah: Right, so if you look at the marketing expenditure and therefore the profitability on that business, would you say its kind of making margins in line with the overall company or do you think it is less or more.

Rakesh Bamzai: It is a new business for us. Right now it is on the lesser side. But in the next few years healthcare will be one of the major drivers of business for top line and bottom line.

Jesal Shah: And what do you think is your marketing budget for next year to push Insugen especially given the changing market dynamics in India?

Rakesh Bamzai: This type of business surely needs good marketing muscle and budget and surely I think we have gone ahead in doing whatever is needed to make Insugen a very big brand in the country.

Jesal Shah: Okay, and just one last thing from my side on R&D expense. Can you just tell us, I mean now we are doing Rs 13 crore per quarter, as we look into the next year what do you think will be the absolute amount that you would incur on revenue R&D expense on a quarterly basis or annual number that you have in mind?

Murali Krishnan: As a percentage we have indicated on an annual basis, it would be about 8% to 10%. R&D numbers can probably make sense only on a broad annual basis because as Shri mentioned a lot of it depends on when certain events like Phase II Phase I take place, where we are doing the trials and depending on how many sites we are doing the trials, not just trials, even in terms of pre-clinicals, so it is very hard to predict it quarter wise.

Jesal Shah: Exactly, that is why I just wanted some annual idea if you can tell us.

Murali Krishnan: I think Kiran already mentioned it will be in the region of 8% to 10% going forward because going to Phase II that will be at a higher cost. This year it is about 5% and 6%, so next year it is further going to go up by another 2%.

Jesal Shah: So, on an absolute basis you think from 10 million it can go up to 30 million or something? Because if you have a strong revenue growth, do you envisage that I mean is that the incremental expenditure....?

Murali Krishnan: I think it is hard to give you absolute numbers because we are not forecasting the revenues here as well.

Jesal Shah: Right. Okay, thanks so much.

Moderator: Thank you sir. Next question comes from Mr. Rahul Sharma of Karvy Stock Broking.

Rahul Sharma: Madam, I just wanted to know the pricing of BioMAb in the Indian market per patient per year.

Subir: BioMAb is basically available in one pack Rs 45,000 MRP including taxes – one pack of BioMAb EGFR.

Rahul Sharma: For the whole year's treatment?

Subir: This is one course of treatment. Your question basically depends on what cancer you are talking about. For head and neck cancer basically you will need 6 cycles of BioMAb EGFR.

Rahul Sharma: So for one cycle it is Rs 45,000?

Subir: Yes.

Rahul Sharma: And how does it compare vis-à-vis the competitor who is there?

Subir: It is at a 30% to 40% discount of the competitor's product.

Rahul Sharma : Okay, thank you.

Moderator: Thank you sir. 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 and we look forward to seeing you at the next quarterly conference call. Thank you.

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