

## **BIOCON LIMITED**

## Q1/ FY 2010 Analyst / Investor Conference Call 23<sup>rd</sup> July 2009, 12:00 Noon IST

**Mansi Parekh:** Good afternoon everyone and thanks for joining us on Biocon's Q1FY2010 results conference call. We have with us on this call Ms. Kiran Mazumdar-Shaw, Biocon Chairman and Managing Director and also her colleagues who are part of the senior management team. We will begin the call with the opening remarks from the Biocon management followed by a Q&A session with all of you. Please also note that some of the statements made in today's discussions may be forward looking. I trust you all have received a detailed release on the Q1FY2010 results announcement along with the fact sheet, which has been e-mailed to you all earlier and is also posted on Biocon's website. Also today, Biocon will be holding their AGM; hence we will need to limit the call to one hour. The management will be happy to respond to your queries in a manner that will maximize the interaction in this time. Now I would like to invite Ms. Kiran Mazumdar-Shaw to briefly discuss the company's performance for the quarter ended June 30<sup>th</sup>, 2009. Over to you.

*Kiran Mazumdar-Shaw:* Thank you Mansi and good afternoon everyone. It is a great pleasure for me to welcome you all to this conference call where we would like to share our Q1 results for this fiscal year. I would like to start by saying that we are very confident that we will be able to deliver good numbers going forward, having taken a corrective step with respect for Forx hedging, from what we did last year.

As you can see from our performance in this first quarter, we have actually declared very robust growth, which has to be analyzed in two ways. If you look at our consolidated revenues, they have jumped 83% from Rs. 277 crores last year this quarter to 505 crores. Having said this, Rs. 190 crores of this revenue comes from AxiCorp, which did not figure in last year's financials. In terms of our EBITDA performance, again we have grown very robustly. This has increased substantially over the last one year to Rs. 111 crores and if you were to exclude AxiCorp, it has actually delivered handsomely at over 40%. PAT had to take a huge hit the first quarter last year, where we hardly were able to declare a PAT of Rs. 15 crores, on account of MTM losses. PAT has now jumped to Rs. 58 crores, which shows a huge jump of 283%. But having said that, I would also like to share with you the fact, and a very important one at that, which shows that even if you were to exclude the impact of MTM, we have actually grown PAT 42%. So I think this is a very positive note for us to all really be very pleased about.

AxiCorp is a distribution business with radically different operating parameters and therefore I would like to emphasize the fact that this is really a top line contributor with a very minimal contribution to bottom line. Bottom line contribution will only happen when our insulin gets marketing authorization in Europe and we expect this to take place over the next 18 to 24 months. We have started the registration process in Europe where we are conducting clinical trials, both phase 1 and phase 3, and this is something that we are tracking and monitoring very closely and hope that we can meet these kind of time lines based on the kind of data that we generate.



In this quarter's numbers what is very important and encouraging is the very strong performance by our services sector namely Syngene and Clinigene where Syngene actually has contributed very significant to this quarter's services numbers. The Syngene business grew from Rs. 38 crores last fiscal to Rs 58 crores Q1 this fiscal. Clinigene also grew from Rs. 6 crores to Rs. 9 crores and collectively, therefore they have actually registered a very strong and robust growth. Of course, profit after tax is a little muted largely because of the interest and depreciation components, which Syngene has to carry because of the large investments made. But having said that, I think these investments are really going to generate good growth and good return on investment for us. Large part of these investments was made to create a dedicated research facility for BMS. This is a business that has already started contributing quite significantly to Syngene's numbers which was almost close to 30% of Syngene's numbers from BMS contract services. We have also invested in setting up three clinical services as well as biological services and I think in the quarters ahead these are going to contribute again to the growth story of Syngene.

Now turning to Biocon, as you all perhaps know, we have recently announced a partnership with global generics pharma major Mylan and this is a partnership, which is very unique and very promising given the fact that it is well recognized the world over by the pharma sector, that the next wave of growth is going to emanate a) from novel biologics and b) from biogenerics. I am pleased to say that Biocon is well positioned to address both these opportunities. The biogenerics opportunity is large and very challenging and I think with this partnership that we have with Mylan, we bring together very strong capabilities to address this emerging opportunity. Only this morning President Obama made a firm commitment to Healthcare reforms and a very important part of this Healthcare reforms is going to be biogenerics or biosimilars. So I have no doubt that this is going to be a big play for Biocon in the years ahead. In terms of novel biologics also Biocon is making very good progress. We have three very important programs. Our oral insulin or IN-105 program, is actually in phase 3 clinical development and I am pleased to say that patient enrollment has been progressing very steadily and we will be able to meet our time lines in terms of patient enrollment and the clinical development. We expect to be able to share with you that data this time next year. CD6, or the T1h program, again, is making good progress. We expect to be able to share our phase 2 data for psoriasis and rheumatoid arthritis next guarter and we expect to commence phase 3 trials in psoriasis soon thereafter. Our BVX-20 program is in preclinical development and we expect to enter clinical development within the next 9 to 12 months.

What is important for me to emphasize here is the fact that Biocon is making a strong play in both these emerging opportunities. Big pharma itself is very focused on Novel Biologics and biogenerics and we are already becoming a very important part of that particular ecosystem.

Now, I will quickly focus on a few more aspects of our performance this quarter. You can see from our results that we have managed to recover from the MTM losses that we had seen last year and this is on account of the very prudent and cautious approach that we have now taken to foreign exchange hedging and going forward you will not see the kind of MTM losses that we had reported last year. In fact we have made sure that we gradually buffer ourselves against any kind of foreign exchange fluctuations by going in for an insurance approach rather than thru forward cover hedging approach.



In terms of our R&D spend; I would like to mention that we are very committed to R&D. So you are likely to see increased R&D spends especially as we get into clinical development. But having said that I think we are very confident that this will deliver handsome returns to us. Many of these programs in R&D, not just Novel Biologics, but also biogenerics, apart from the ones that we are developing with Mylan, especially in the insulin segment, are also beginning to enter a potential licensing and partnering phase. And we have several ongoing discussions both for Novel and biogenerics and these are something that we expect to be able to tie up over the next 12 to 18 months and there could be big upsides for us through these partnerships and licensing opportunities. So with that, I would like to stop here and then throw it open to Q&A session. Thank you.

## Question and Answer Session

*Moderator:* Thank you madam. Our first question comes from Mr. Nimish Mehta of MP Advisors.

*Nimish Mehta:* Biocon have reported some 700 basis points improvement in gross margins without AxiCorp. I want to know the reason for this. Also, how much is the impact of the Rs. 50 of hedging that you have taken against dollar for this year.

*Murali Krishnan:* The impact on account of Rupee being at about 50 levels is not very significant. The improvement is on account of combination of few factors such as, hedging Rupee at around 50 levels to a USD, improvements coming from reduction in raw material costs, product mix etc.,

*Nimish Mehta:* So this is largely because of the raw material...

*Murali Krishnan:* It is on account of combination factors mentioned earlier.

*Kiran Mazumdar-Shaw:* We have taken strong measures in terms of cost reduction, in terms of our material cost as well as the product mix. As Murali just mentioned this is largely the reason why we have improved our performance.

*Murali Krishnan:* In terms of FOREX, it has been hovering between 48, 49 & 50. One part of our hedgeing is between 46 and 54 and another part at 50 level. So the contribution coming from this factor alone is very significantl.

*Indranil Das:* The other point I would like to add, is the savings we actually gained form the power cost. By switching over from own captive generation to the grid power, we have had significant cost saving impact.

*Nimish Mehta:* You said it is because of the power...

**Indranil Das:** In the past, we were largely using captive power generated through the generators and from that we have moved on to the grid power, which is coming from the State Electricity Board. The cost of the power that we buy from the State Electricity Board is considerably cheaper than the in-house generator. So there is some savings from there as well.



*Nimish Mehta:* I see, okay. You mentioned about FOREX being somewhere about 48, 49 only, but that on a YOY basis would be still very impactful right, because last year you would have only registered...

*Kiran Mazumdar-Shaw:* Yes, but last year you have seen the MTM impact as well as the FOREX losses. So I really think that is already covered.

*Nimish Mehta:* Okay. My next question is regarding any update on Mycophenolate Mofetil launch, has that happened? Have you started any commercial launch?

**Rakesh Bamzai:** The product was launched in the US on 9<sup>th</sup> of May. There are around six players. 45% conversion into generic has happened in the first two months and we have a significant place there.

*Nimish Mehta:* Okay. So have we booked any sales in this quarter from that product?

*Rakesh Bamzai:* We booked sales in Q-1 and going forward the sales will continue.

*Nimish Mehta:* Any idea about how much is the price erosion that has happened in the generic place?

**Rakesh Bamzai:** If you check IMS data you will find, they are charge backs, and the indication comes only after six months once you have charge backs from the retailers to the company.

*Nimish Mehta:* Okay. And how many players are you supplying it to?

Rakesh Bamzai: We have three customers.

*Nimish Mehta:* Okay. Thanks very much.

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

Bino Pathiparampil: How much was the licensing fee revenue in the quarter?

*Murali Krishnan:* It is about Rs. 2.4 Crs.

*Bino Pathiparampil:* And has the AxiCorp started getting business from the AOK for the metformin product?

Murali Krishnan: Yes.

**Bino Pathiparampil:** Okay. Is that reflected in AxiCorp EBITDA, which seems to have increased a little bit in this quarter?



*Murali Krishnan:* The sale of Metformin got started only in June 2009 and we always consolidate Axicorp's number with one quarter lagging behind. So that impact will come only in the next quarter and that too is only for one month.

**Bino Pathiparampil:** Right. So this AxiCorp EBITDA seems to have actually almost doubled, although it is small. So where has it come from?

*Kiran Mazumdar-Shaw:* I think they have improved their performance, they seem to have got some good traction in some of their standard import business.

*Bino Pathiparampil:* Okay, right. And will the metformin product show any material impact on that EBITDA number?

*Kiran Mazumdar-Shaw:* Yes, it will only be better, because it is a slightly higher margin business.

**Bino Pathiparampil:** Your depreciation and interest costs last year if we see were actually moving high up from the first quarter to the last quarter. Is that likely happen this year as well or have you brought all the project-related costs on to the P&L?

*Murali Krishnan:* Some of the capitalization (eg. BMS facility) happened last year and rest of the capitalization in Syngene happened during this quarter. Full quarter impact for Syngene will be visible in Q -2 and thereafter it will not change significantly, since most of the major capex expansion plans have been completed for the time being. Deperciation charge for other companies will largely continue at the current levels.

**Bino Pathiparampil:** So, on a consolidated basis we can assume that the quarters ahead there could be some increase in depreciation.

*Murali Krishnan:* No, there will be some increase, for the reason stated earlier.

*Bino Pathiparampil:* The tax rate for this quarter seems to higher side. For the full year what do you expect the tax rate to be?

*Murali Krishnan:* At this point of time, we will have to assume that it is likely to continue. This is basically driven by the fact that most of the Indian pharma companies seem to be doing better than the global ones, because bulk of our orders are coming from the domestic pharma companies. Even though these products are getting supplied from our EOU or SEZ units and ultimately they get exported out of India, we don't get income tax break on this. Also, last year we got additional tax break on the MTM charge and this year since MTM is not there, that tax break is not available. So the higher tax charge is due to shift in sales from direct Export to through Domestic Companies and the MTM charge going away from our P&L.

**Bino Pathiparampil:** Right. And last quarter, Kiran you gave some very top line details about the insulin trials going on in Europe. I was wondering if you can give, a little more detailed picture of when you started and what stage it has reached or what kind of studies, etc?



*Kiran Mazumdar-Shaw:* For competitive reasons we really can't share with you details. But all I can say is that it is on track.

Bino Pathiparampil: Okay. Thank you very much.

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

**Abhay Shanbhag**: I have a question about immuno-suppressants part. Can you give some guidance as to what sort of numbers can we expect from immuno-suppressants this year as far as US, Europe go?

**Rakesh Bamzai:** See traditionally Biocon has had quite a strong play in the areas that we are in. We are going to be dominant in the United States and Europe. However, for competitive reason we are unable to give the exact numbers.

**Abhay Shanbhag:** Okay. And you said of the six players you have, three of them are your customers. Are you also supplying to Teva? Is Teva amongst all of them?

*Rakesh Bamzai:* No. We are not supplying to Teva.

**Abhay Shanbhag:** Okay. And in terms of Tacrolimus we have very little idea of the issues behind the delay of the generic launch. So any sort of guidance you can give as to when the product can be launched by the generic company in US?

*Rakesh Bamzai:* A PIL is going on, but everybody who is in this play expects the launch to happen in 2012.

Abhay Shanbhag: So, it is not going to be in the near term?

Rakesh Bamzai: No, not in the near term.

**Abhay Shanbhag:** Okay. The other was a question in terms of the domestic market. If I look at biopharma, the revenue growth is 9%. Obviously a lot of the growth has come from rupee on your exports because of the way rupee has depreciated. So in terms of your domestic business, what sort of growth have you seen?

**Rakesh Bamzai:** Domestic business is comprising of API and branded business together. It has shown a very good growth.

**Abhay Shanbhag:** And just the balance part, how much is it like? 15, 20% or what sort of...

*Rakesh Bamzai:* Because we started off only four years back, we are growing pretty well. This year our growth is in the range of 50% and above.

Abhay Shanbhag: And you are not going to give the exact numbers.

*Rakesh Bamzai:* We can't give the numbers but growth is 50% in the four divisions that we have in domestic, branded formulation.



Abhay Shanbhag: Okay fine. Thank you.

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

*Sameer Baisiwala:* Out of 45% or 48% conversion that we have seen, roughly how much is Biocon's market share?

*Rakesh Bamzai:* Again, because we have signed a CDA with our customers we can't reveal the numbers.

Sameer Baisiwala: No, I mean, is it 10% to 20%, is it higher, lower...

**Rakesh Bamzai:** It is pretty good. It is a decent market share that we have and this is going to grow further.

**Sameer Baisiwala:** One thing which surprises me is that if I look at your biopharma revenues, reported over last two quarters, sequentially there is hardly any meaningful growth to be seen. And if you are capturing this number in our books that means the business is hardly growing, is that a correct observation?

*Kiran Mazumdar-Shaw:* Well Samir, I think you have to look in terms of our revenue versus the PAT and EBITDA. When we talk about product mix, that's what we mean. It does not have to grow because there is a lot of business that could be growing in terms of volume, but not in terms of contribution to profits. But if you look at our growth in PAT and EBITDA, I think it clearly shows you that we are moving in the right direction where our product mix is becoming very healthy and deliberately so. We want to move away from the commoditizing kind of products and get into more high margin, high value products. Otherwise we could not have delivered these kind of PAT numbers.

*Sameer Baisiwala:* Sure. Is there any update that you can tell us about launching insulin in the US market?

*Kiran Mazumdar-Shaw:* Insulin in the US market is being controlled and managed by our partner there and I think the kind of time lines that we have disclosed for Europe are more or less the kind of time lines they also envisage.

Sameer Baisiwala: Okay, that's fine. That's all from my side. Thanks.

*Moderator:* Next question comes from Mr. Basavraj Shetty of Techno Group.

**Basavraj Shetty:** My question pertains to formulation business. How much has the formulation business contributed in terms of value and growth for this quarter vis-à-vis last quarter?

*Kiran Mazumdar-Shaw:* Well, we don't sort of break it up into that, but I think in the past we have kind of indicated to you that our branded formulations business is a little upwards of 10%. So right now also it would be in the range of 10 to 15%.

Basavraj Shetty: And growth as Mr. Rakesh mentioned is around 50%.



Kiran Mazumdar-Shaw: Yes, over 50%.

Basavraj Shetty: And can you just elaborate more on status of oral insulin?

*Kiran Mazumdar-Shaw:* Yes, I will let my colleague Harish Iyer do that.

**Harish lyer:** Oral insulin is currently in phase 3 studies in India. These are double blind studies in type 2 diabetics which are failing on metformin and the unblinding will happen in the second quarter of next year. We expect to announce the results, both within India and in some major conference next year. We are moving forward looking at the possibility of filing an INDA soon or an IMPV either in the US or Europe and also starting up additional trials so that we don't have to wait for the results of this to expand our knowledge base on how oral insulin works across the diabetics continues.

**Basavraj Shetty:** Right, so for US market INDA is in the future. So the studies are currently not focused for US market.

**Rakesh Bamzai:** I just want to also add that the study in India is going well, and the data that will come out of India will certainly be applicable to markets such as the US and Europe. We have made sure that we have a very strong clinical advisory group, which has some of the top key opinion leaders world-wide, and we are doing this trial based on their advice. We are using internationally accepted norms in terms of GCP and things like that, so we believe that the data will be very supportive of going to more advanced stage clinical trials in either the US or Europe.

Basavraj Shetty: But I suppose, even then you will need to conduct incremental trials...

**Rakesh Bamzai:** No, what we would do is, based on the results we get, we would probably be able to start with later phase studies and I think we can do that. We have had advice from experts who are both regulatory experts as well as clinical experts globally giving us advice on these matters.

**Basavraj Shetty:** Okay. And when you start phase 3, there will be lot of fund requirement, so any plans in terms of arranging the funds and maybe Mylan arrangement is inclusive of this?

*Rakesh Bamzai:* No, Mylan has nothing to do with this. This has been funded through internally accrued funds.

*Kiran Mazumdar-Shaw:* But going forward, certainly we will be looking at partnering to take this product to other markets. Obviously if you want to do phase 3 trials in US and Europe, it is going to require a huge amount of funding, and that's what we will do when we get into partnering this molecule.

Basavraj Shetty: And when do you expect to initiate phase 3 for US markets?

*Kiran Mazumdar-Shaw:* We will be completing our phase 3 trials in India next year and also we will be filing our INDs and IMPDs slightly ahead of that, so we expect to actually start advanced clinical trials in either US or Europe sometime latter half of next year.



**Basavraj Shetty:** Okay and regarding insulin analog strategy for European markets, can you just throw a little light on that?

*Kiran Mazumdar-Shaw:* We are in the process of registering our recombinant human insulin in the European market and the next product we will register is the insulin analog glargine, so that will follow quickly. We are already in the process for beginning the regulatory process for glargine as well.

Basavraj Shetty: Thank you.

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

**Bhavin Shah:** I just wanted to know the licensing income component for the same quarter the last year.

*Murali Krishnan:* Q-1 of last year it was zero.

Bhavin Shah: Isn't it vis-à-vis Rs. 24 million that you said?

*Murali Krishnan:* That's right.

**Bhavin Shah:** Okay and any investments required for building up capacities for the Mylan deal that is going to contribute may be later down the years?

*Kiran Mazumdar-Shaw:* Well, Mylan will show up some amount of income going forward and this is largely because of some of the IP's and milestones that we will be delivering for this partnership.

Bhavin Shah: Okay. Was BMS contribution 30% of Syngene's turnover?

Kiran Mazumdar-Shaw: Yes, roughly.

Bhavin Shah: Okay and that is to escalate going forward?

Kiran Mazumdar-Shaw: Yes.

Bhavin Shah: Thank you so much

*Moderator:* Next question comes from Mr. Nitin Agarwal of SSKI Securities.

*Nitin Agarwal:* We have had these couple of deals between Pfizer and Aurobindo and between Dr. Reddy's and GSK and these companies have gone to sourcing arrangements with the Indian companies and we have got a very differentiated product portfolio. Do we see a possibility of this kind of a broad based alliance to supply to rest of the world markets really coming through for us?

*Kiran Mazumdar-Shaw:* See, these arrangements that you are seeing is really about these large pharmas looking at emerging market opportunities. If you look at our deal with Mylan it is very similar to this kind of a deal where we are looking at the emerging opportunity for bio generics, both in the emerging markets and in the regulated markets.



One of the things I want to mention here is that this biotech space is very different from the small molecule space. In the small molecule space, you have already got products registered and being marketed in many of these markets, whereas in the biologic space the whole process of registration is very different. It is not about BA/BE, it is about conducting clinical trials. So the kind of partnerships that you are likely to see between us and others will be slightly different to what you are seeing. So, it is not about just forcing. Yes, in the small molecule market it is really about having access to low cost manufacturing. In our case it is not just about low cost manufacturing. I think people are looking at the regulatory requirements of these products. So there are other kinds of parameters that are taken into consideration when you look at these kind of deals in the biotech space.

*Nitin Agarwal:* You touched on the registration bid where we had this deal with Bayer for insulin in China. Bayer apparently a couple of weeks back went ahead and signed up with Bioton for their product which is already registered in the Chinese market. So where does this really leave us vis-à-vis the Chinese market?

*Kiran Mazumdar-Shaw:* We had mentioned this in many calls ago saying that we were getting a bit concerned about the very slow pace of regulatory progress being made in our Bayer deal for insulin and based on that we actually agreed to basically pursue it ourselves. So that is what the arrangement was. We basically agreed with Bayer to sort of pursue it ourselves because we felt that we could actually perhaps pursue it much faster than what Bayer was and Bayer in the meantime obviously has found somebody who has had a registered product in China which suited them better. So, I think that is the decision we have taken and that is a very amicable agreement that we got to with Bayer where we realized that it would take much longer for Bayer to move with our product than with a readymade product and so we have decided to take back the program and go with it ourselves.

*Nitin Agarwal:* So, where are we with respect to the registration process now. Are we doing it on our own in China?

*Kiran Mazumdar-Shaw:* Yes, that is what we are planning to do with a partner.

*Nitin Agarwal:* So, we haven't quite started yet on...

Kiran Mazumdar-Shaw: No.

*Nitin Agarwal:* What would be the interest income for the quarter?

*Murali Krishnan:* It is between Rs 4 to 5 crores.

*Nitin Agarwal:* Okay sir, thank you very much.

*Moderator:* We have a follow up question comes from Mr. Nimish Mehta of MP Advisors.

Nimish Mehta: I just wanted to know if you can share the Syngene margins as of now?



*Kiran Mazumdar-Shaw:* If you look at Syngene's numbers, they delivered Rs. 58 crores top line with an operating margin of about 39%.

*Nimish Mehta:* Okay great and you mentioned that you will not have to put up any capacity for the Mylan deal, right?

*Kiran Mazumdar-Shaw:* No, we have to put it up, but at an appropriate time where we have decided to of course share the cost of putting up such a facility.

*Nimish Mehta:* Okay, thanks very much.

*Moderator:* Next question comes from Mr. Manoj Garg of Emkay Shares.

*Manoj Garg:* Any update on the recent announcement by DCGI about carrying on trials for this Glargine insulin?

Kiran Mazumdar-Shaw: What is it?

Manoj Garg: Because there was some news that there are some cancer ...

*Kiran Mazumdar-Shaw:* No, let me explain it to you, I don't think this news is well understood. The only news item that was reported was that there was a concern about a report that came out based on some data analysis of study that Glargine may be linked to cancer, but this has been totally disputed by both the US FDA and the IMIA and DCGI in response to that particular report also put its own thing saying that this is something that we are aware of, but we will be watching the situation. In fact all the regulators have said that please do not change the treatment regimen because there is no substance to the data or the report that has been put out. So, until we get more deeper sort of understanding of this data please do not change the regimen, that's all the report they put out.

*Manoj Garg:* Okay and how big is this market in India right now, since there is Wockhardt and you?

Kiran Mazumdar-Shaw: The whole insulin business?

*Manoj Garg:* Insulin analog business?

*Rakesh Bamzai:* Rs. 150 crores is the total analogs business, in that Glargine should be around Rs. 50 crores.

Manoj Garg: And apart from Wockhardt and you, I think there is no one else?

*Kiran Mazumdar-Shaw:* No, Aventis is the main company.

*Manoj Garg:* That's all from my side.

*Moderator:* Next question comes from Mr. Alok Dalal of MF Global.



*Alok Dalal:* What kind of launches are we likely to see in the next few quarters in the domestic market?

*Kiran Mazumdar-Shaw:* We have four divisions; we have a diabetology division, a nephrology division, a cardiology division and onco-therapeutic division. Last quarter we had launched Basalog and we expect to make other several launches in each one of these segments.

*Alok Dalal:* The number of launches would be similar to what we launched last year or would be more than that?

*Rakesh Bamzai:* We are growing in size and reach, so we are launching more products this year than last year.

Alok Dalal: Okay, thank you so much.

*Moderator:* Next follow up question comes from Mr. Basavraj Shetty of Techno Group.

**Basavraj Shetty:** How much BMS contract contributed to the Syngene in terms of ballpark figure and...

Kiran Mazumdar-Shaw: About 30%.

Basavraj Shetty: And when it is going to peak up?

*Kiran Mazumdar-Shaw:* By year after next it should be at peak levels.

Basavraj Shetty: And what is the peak amount?

*Kiran Mazumdar-Shaw:* As Syngene's business grows you can almost expect it to remain at this kind of level in terms of contribution.

**Basavraj Shetty:** Right. I wanted to ask about the Mylan contract, it will be taking a little longer to actually contribute. So what exactly will the contract encompass in terms of products and markets, etc.?

*Kiran Mazumdar-Shaw:* There are near term opportunities which are the non-US non-European kind of markets which will certainly be something that both companies will approach in the next 24 months and then after that obviously we will be looking forward to the US and European markets opening up. So you can expect the US and European opportunities to start from about three to four years.

Basavraj Shetty: And even other emerging markets after two years?

*Kiran Mazumdar-Shaw:* Yes, emerging markets are all there starting with India and all the other parts of the world.

Basavraj Shetty: But when will the contribution from these markets be?



*Kiran Mazumdar-Shaw:* The total emerging market value for the bio generics is more than billion dollars today and this is expected to grow at 20% per annum for it is growing in a very prolific way and we think that of these, the kind of products we are working on are really the sort of the top notch bio generics. So there is a good opportunity for growth even in the emerging market.

Basavraj Shetty: Actually I wanted to understand when actual contribution will start?

*Kiran Mazumdar-Shaw:* After about two years time for sure.

Basavraj Shetty: Right, thank you.

*Moderator:* Next question comes from Mr. Girish Bakhru of JM Financials.

*Girish Bakhru:* How much was the R&D expense this quarter?

Murali Krishnan: It is about 20 crores.

*Girish Bakhru:* And regarding the Mylan's deal, do we expect any milestone payment this year?

Kiran Mazumdar-Shaw: Yes, we will see milestone payments this year.

*Girish Bakhru:* How much could that be, any idea?

*Murali Krishnan:* That depends on the achievement of various milestones and we won't be able to quantify that number today.

*Girish Bakhru:* All right. On the top line front how much of the revenue in the biopharmaceuticals excluding AxiCorp would be dollar denominated?

*Murali Krishnan:* It is somewhere around 50.

*Girish Bakhru:* And how much would be the constant currency growth in that?

*Murali Krishnan:* I don't have the numbers. We can give that to you off line.

*Girish Bakhru:* All right, thank you so much.

*Moderator:* Next follow up question comes from Mr. Nitin Agarwal of SSKI Securities.

Nitin Agarwal: At what stage are our Bio MAbs in terms of the clinical development?

Kiran Mazumdar-Shaw: Pre-clinical.

*Nitin Agarwal:* So you think two years is going to be enough for us to commercialize these molecules despite the regulations?

Kiran Mazumdar-Shaw: For the emerging markets, yes.



*Nitin Agarwal:* Okay fine and secondly in terms of potential licensing opportunities, the MAbs are already tied up. So beyond insulin and Glargine are there opportunities, which are there for us, which can generate licensing opportunities for us?

*Kiran Mazumdar-Shaw:* We do have very other programs, it is not just Glargine. There are many other programs that are in the pipeline, both novel and generic.

*Nitin Agarwal:* In the generics, which would be the segment that we would be looking at broadly speaking when you are talking about these opportunities?

*Kiran Mazumdar-Shaw:* There are a number of products we have, both in terms of other insulin analogs plus we have other biological therapeutics.

*Nitin Agarwal:* Okay, thank you.

*Moderator:* Next question comes from Mr. Balaprabhala Subramanyam of PCS Securities.

**Balaprabhala Subramanyam:** My question is about ABRAXANE of Abraxis BioSciences.We just heard a report that DCGI has recalled Albupax of Natco pharmaceuticals and Biocon is the distributor for ABRAXANE of Abraxis BioSciences. What is the size of that drug, are you the distributor for that drug in India or...

*Kiran Mazumdar-Shaw:* Yes, we have licensed ABRAXANE for marketing in India and obviously we see this as an important drug in the cancer space and basically I think what has happened is that Natco came out with its generic version of ABRAXANE and the regulators have found some quality discrepancies in terms of the product. So that is what has been evaluated and Natco has been requested to withdraw Albupax and address these quality issues.

**Balaprabhala Subramanyam:** Right, what could be the size of the market in India for ABRAXANE, approximately?

**Rakesh Bamzai:** The Paclitaxel segment for solid tumors is close to Rs. 50 crores and it is growing at around 18% every year.

**Balaprabhala Subramanyam:** Okay and is there any program on nanotechnology based drugs at Biocon too?

Kiran Mazumdar-Shaw: No, not at the moment.

Balaprabhala Subramanyam: Thank you very much.

*Moderator:* Next question comes from Mr. Hari Swaminathan, a private investor.

*Hari Swaminathan:* If you can share the existing structure that we have with respect to AxiCorp, the way we control the operations in AxiCorp, is it that it is being managed by the erstwhile management and Biocon is more of a remote management approach or is it that we have our Indian managers who have stepped down and who are managing it at an operational level?



*Kiran Mazumdar-Shaw:* Currently, we have a remote control management model with AxiCorp, but except that there is a routine review meeting which we have every month with AxiCorp and there are meetings where we go to AxiCorp and they come to Biocon. So that is the way we are managing at the moment, but all the financial and operating systems are all synchronized with Biocon's own system, so the IT support framework is well synchronized with Biocon's systems.

*Hari Swaminathan:* Okay, perhaps the rationale behind this question, which originated in my mind was that we have not really seen the benefits that an Indian manager or an Indian management can bring into an essentially European operation. The basic margins remain the same, so that was the reason that I...

*Kiran Mazumdar-Shaw:* Yes, but please note that the reason for us acquiring AxiCorp is very different to what other companies have done with their acquisitions. Their acquisitions were about generics and how to back end the manufacturing and what most of these companies have done is, bought generic companies with manufacturing operations in Europe which they have then shifted to India. So that is a very different kind of a business model than ours. We have actually acquired AxiCorp, not for manufacturing or the generics business, but to help us with marketing and distributing our own products like insulin when it finally gets registered. So today as far as AxiCorp's marketing and distribution business is concerned, we have nothing to value add by sending a Indian management or manager.

Hari Swaminathan: Thank you very much.

*Moderator:* Next question comes from Mr. Rahul Bhangadia of Lucky Securities.

Rahul Bhangadia: Could you share the size of the BioMAb molecule?

*Rakesh Bamzai:* It has crossed around 3,000 patient exposures as of now and it is growing at around 20%.

**Rahul Bhangadia:** Okay, the idea is just to understand whether the amount of R&D investments that we have made in this, are they justified by the kind of eventual sales and profits?

*Kiran Mazumdar-Shaw:* The investments are not being made just for BioMAbs. The R&D investments were made for three main things, which we have benefited significantly from. The first thing was to understand monoclonal antibody technology, which has been a huge benefit to us which is demonstrated by the Mylan deal itself. The second thing was to be able to understand the regulatory path for bringing new biotech molecules to the market, that's been a huge learning for us from the BioMAb experience which again allows us to look at some of the other molecules we are bringing to a licensing phase and the third most important aspect of the investments we made was to really be able to understand how to develop commercial scale manufacturing technologies for monoclonal antibodies and I am again pleased to say that we have the largest commercial scale monoclonal antibody operation in the country. So, we have to look at those R&D investments not only in terms of what happened to BioMAb, but I can tell you the return on that investment will pay for us many times over.



**Rahul Bhangadia:** Okay, this molecule is basically a second line treatment for cancer? Could you just throw a little bit of light on what is the potential market?

*Kiran Mazumdar-Shaw:* This is a product that is today approved for head and neck cancers and the normal sort of front line therapy for head and neck cancers, today is radiation and chemotherapy and what we have now done is, we have actually brought in BioMAb saying that in addition to chemo and radiation if you add BioMAb it has got a huge survival impact and we have just actually presented this 36 month data at ASCO. For the first time an Indian company is presenting survival data based on a proprietary molecule at such an important conference, which is really a matter of pride for us. We will now be presenting a 44-month survival data at the next big conference, which is ASTRO, which is the Association of Radiotherapy Oncologists. So I think that is another very important aspect to bear in mind. So, I think BioMAb is definitely being looked at as an important front line therapy along with chemo and radiation to increase survival.

Rahul Bhangadia: Okay and can we take this molecule anywhere outside India?

*Kiran Mazumdar-Shaw:* Well, we only have limited rights to this; we can only take it to our own immediate markets.

*Rahul Bhangadia:* Okay and this molecule, has it been launched internationally by the Cuban entity?

*Kiran Mazumdar-Shaw:* In many other markets, China, Latin America, in many other parts of the world, and they have also commenced trials in the US. So I think it is not in our purview because we don't have the rights to that molecule for US and Europe.

Rahul Bhangadia: Right ma'am, thank you very much.

*Moderator:* Next question comes from Ms. Purvi Shah of Dalal & Broacha.

*Purvi Shah:* My question was regarding the loans. Since our total loans has declined by around Rs. 105 crores roughly, I just wanted to know, are we having any further payments on the loan front as well as what would be the cost of debt?.

*Murali Krishnan:* The loans that we have borrowed are largely for the working capital of Biocon where as in Syngene, we have borrowed towards working capital as well as for CAPEX. This year we don't envisage any further substantial increase in loans. The cost of borrowing PCFC (packing credit foreign currency) loans are linked to LIBOR rates and it ranges from 5% - 6% p.a.

Purvi Shah: Thank you.

*Moderator:* Next question comes from Mr. Neelkanth Mishra of Credit Suisse.

**Neelkanth Mishra:** On the balance sheet, I see that fixed assets have dropped quarter on quarter, but intangible assets have picked up. Is there some reclassification that has happened?



*Murali Krishnan:* No, it is not reclassification. The intangible assets are the ones that are related to the investment that we made to buy out the IP assets for IN 105, the marketing rights bought out from the Cuban entity for the other emerging markets, GCC, etc., Added to these are the cost of doing clinical trials for our Insulin EU contries.

**Neelkanth Mishra:** Okay, so the 119 crores increase that we are seeing in the first quarter is all related to insulin trials and investments in AxiCorp, etc. and these are all made this quarter?

*Murali Krishnan:* No, 119 would not have increased in this quarter. Largely it has happened over the last year, this quarter it will be very insignificant.

*Indranil Das:* If you see the 31<sup>st</sup> March intangible figures for the group, it is 163 crores and as of 30<sup>th</sup> June it is 169, so there has hardly been any movement in intangibles. So what Murali was referring to happened in the previous year?

Neelkanth Mishra: Understood and the decline that we see in fixed assets perhaps...

Murali Krishnan: That will be on account of depreciation.

Neelkanth Mishra: Okay, thanks.

*Moderator:* There are no further questions. Now I hand over the floor to Ms. Kiran Mazumdar-Shaw, Chairman and Managing Director of Biocon Limited for closing comments.

*Kiran Mazumdar-Shaw:* Thank you very much for participating in this conference call and if there are any further questions please do not hesitate to contact my colleagues Mr. Murali Krishnan and Mr. Indranil Das and they will be very happy to clarify and answer these questions, thank you.

*Moderator:* Thank you, madam. Ladies and gentlemen, this concludes your conference for today. Thank you for your participation and for using Door Sabha's conference call service. You may disconnect your lines now. Thank you .

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