

## **BIOCON LIMITED**

## Analyst / Investor Conference Call 23<sup>rd</sup> July 2010, 12:30 PM IST

**Moderator:** Good morning ladies and gentlemen. I am Shirley, moderator for this conference. Welcome to the conference call of Biocon Limited. At this moment all participants are in listen only mode. Later, we will conduct a question and answer session, at that time if you have a question, please press \* and 1 on your telephone key pad. Please note this conference is recorded. I would now like to hand over the conference to Ms. Urvashi Butani of Citigate Dewe Rogerson. Over to you ma'am.

**Urvashi Butani:** Thank you Shirley. Good afternoon everybody and thank you for joining us on Biocon Limited's Q1FY2011 conference call. We have with us on the call today 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 opening remarks from the Biocon management, followed by an interactive Q&A session. I would like to add that some of the statements in this call maybe forward looking statements and a note to that effect has been stated in the release sent out to you earlier. Now I would like to invite Ms. Kiran Mazumdar-Shaw to briefly discuss the company's performance for the quarter ended 30th June 2010. Over to you ma'am.

*Kiran Mazumdar-Shaw:* Thank you and welcome to this conference call for Biocon's Q1 results for the fiscal year 2011. I would like to start by saying that the set of numbers that we have shared with you this morning are extremely strong. We have delivered revenues of Rs 672 crores at a consolidated level with an EBITDA of Rs 141 crores and a PAT of Rs 77 crores. I think it is important to highlight here that we have had a 33% year-on-year growth both in terms of our top line and bottom line. Our operating margin has been sustained at 21% with AxiCorp's top line-driven business the main reason behind this margin level. Without AxiCorp, we have maintained the margin around 30% with all our businesses delivering strong numbers. In terms of head count, we have ~ 4,750 employees and we expect to hit the 5,000 mark very soon, probably next quarter.

There are some very important developments in this quarter. One is that we have received a nod from the German regulatory authorities to commence a Phase III trial for our biosimilar r-human Insulin and the patient recruitment for this trial will commence very soon. This will be our first Europe-based clinical trial and this is in preparation for going through the registration and market authorization for this product. Therefore, this is an important milestone that shows that we are on the right track in terms of our biosimilar insulin foray into Europe. The second important development is that we are on the verge of starting a Phase I trial under our US IND for the Oral Insulin drug for Type I diabetics. This is an important milestone for us because this is our first trial under the US IND which got approval in Jan 2010.

On the operational front, the branded formulations business has delivered very strong numbers this quarter and we believe that this segment will be a key contributor to growth in the foreseeable years. Within this, we will be setting up two new divisions in the coming quarter. One is a Dermacare and Immunotherapy division which is really going to be developed around our portfolio of Immunosuppressants and the novel Anti-CD6 antibody that is undergoing Phase III clinical trials for Psoriasis in India. The second division is Comprehensive Care which will focus on developing a basket of products for



the ICU setting in hospitals. Many of our existing products lend themselves to this profile and we will also add more products to strengthen our presence in this segment.

In terms of our research services business, we have seen growth at a top line but we are now addressing sustainability in terms of the bottom line and for this we have decided to adopt a strategy where we will be looking at offering some very high value added integrated drug development services. Although this will entail some investment which will appear as expense in this quarter and potentially reoccur in a quarter later, we expect to see some good realizations from these investments in the coming years. Clinigene is a very important business in terms of our future prospects but this business has been suffering on account of commoditization which has not allowed us to increase margins but with the new leadership at Clinigene we are now focusing on offering high margin, high value businesses.

AxiCorp continues to be a top line-driven business, but it is recognized as a very strong player in the German pharma market. It has a very strong recognition in generics, especially in the tender markets in Germany and we will continue to build on AxiCorp's very strong marketing and distribution capabilities. This is a business that will see margin improvement once our Insulin enters the German market. And if all goes well with our trials, this can happen as early as end-2012 or early 2013.

With those opening comments, we would like to get into the Q&A. Thank you.

Question and Answer Session

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

First question comes from Mr. Ashwin Agarwal from Akash Ganga Investments.

**Ashwin Agarwal:** Congratulations to Dr. Kiran and the entire team on delivering a very strong set of numbers.

Kiran Mazumdar-Shaw: Thanks, Ashwin.

**Ashwin Agarwal:** Dr. Kiran, I have a broad macro question. Many companies as you know have tried to develop various alternate forms of insulin, be it oral or inhaled, but for some reason or the other have not been successful. And with oral insulin, I believe the main issues are hypoglycemia. What is your feel on the product that we have developed, by when do you feel you could license this product and what is the potential of this product?

**Kiran Mazumdar-Shaw:** Well, firstly I want to negate the perception that our oral insulin is associated with hypoglycemia. This is the one differentiator that we believe is a very strong factor in favor of such a product because that is what actually prevents from delivering insulin orally. We believe that oral insulin offers a very interesting opportunity for diabetes management and we are planning to run these trials to see where the



product can be positioned best. We will start licensing discussions only after these results start coming in. Currently, we cannot have serious licensing discussions unless we have data on both Type II as well as Type I diabetes patients. That is why we started the Type I trials because we realized that it was going to be a gap in unlocking good licensing value. We will start these licensing discussions hopefully towards the end of this year once the data comes in.

Ashwin Agarwal: Thanks a lot and all the best.

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

**Bhavin Shah:** Thanks and congrats on the great results. Ma'am, just to follow up on the previous question, when do we expect some positive data coming out from the study on Type 2 diabetes for IN 105?

Kiran Mazumdar-Shaw: We expect the data to come in by the end of this year.

**Bhavin Shah:** Okay. In the domestic branded formulations business, what sort of growth are we looking at in the insulin franchise?

Kiran Mazumdar-Shaw: I will let Rakesh answer this question.

**Rakesh Bamzai:** We are rapidly gaining market share and the growth in the branded formulation business is close to 30%.

Bhavin Shah: Okay. Could you share some more data on Insulins please?

**Rakesh Bamzai:** We are growing fast in the Insulins segment and we have close to 10% market share in this segment.

**Bhavin Shah:** What is the quantum of investments highlighted earlier within the contract research business? How much would that be to get a transition into higher margin products?

*Kiran Mazumdar-Shaw:* It is difficult to share that information currently but it is not going to be difficult for us to support.

Bhavin Shah: Okay. But the results will start reflecting in the second half do you think?

Kiran Mazumdar-Shaw: Yes.

**Bhavin Shah:** Okay, great. Thank you so much.

Moderator: Next question comes from Mr. Krishnendu Saha of Quantum AMC.

**Krishnendu Saha:** Hi, thanks for taking my question. I wanted to understand how much expenditure on the R&D front will you be incurring and how much of that will be capitalized for your Insugen European Phase 3 and the IN-105 Phase 1 in the US?



*Murali Krishnan:* We did mention at the beginning of this fiscal, that it is likely to be upwards of about Rs 150 crores for the year.

Krishnendu Saha: How much will be capitalized?

**Murali Krishnan:** The capitalized portion will be small and most of it will be going through the P&L. Up until now, we have capitalized a little less than Euro 2 million.

**Krishnendu Saha:** The reason I asked is because the intangible assets have grown to Rs 253 crores as opposed to Rs 172 crores - that's a jump of around 47% over three months.

**Chinappa:** The increase in intangible assets represents the IP assets pertaining to T1h that was purchased from CIMAB during the quarter.

**Krishnendu Saha:** And that is the acquisition which we had done a couple of quarters ago?

*Murali Krishnan:* This acquisition happened during April '10 and hence it is getting reflected in this quarter.

**Krishnendu Saha:** Okay. One more question on the interest front - there is a sharp increase in your unsecured loan, while the secured loan seems to have gone down. Could you explain that?

**Chinappa:** The reduction in the loan happened towards the end of the quarter. The increase in finance costs is on account of the increased cost of hedging of the loan.

Krishnendu Saha: Increased cost of hedging of loan - how much is it? Is it like the option you had taken?

*Murali Krishnan:* Unsecured loans have gone down from Rs 182 crores to Rs 120 crores as Biocon repaid loans taken by BBPL after our acquisition of the remaining 49% stake in BBPL in April 2010.

**Krishnendu Saha:** And the interest cost also includes the hedging cost of Rs 3 crores, right?

**Chinappa:** Yes, that's correct.

Krishnendu Saha: Okay. Thank you, I will get back in the queue.

**Moderator:** Next guestion comes from Mr. Vikas Sonawale from Religare Capital.

**Vikas Sonawale:** Congratulations on your good numbers. I have question on Tacrolimus. After Dr. Reddy's, we have seen only one player getting the approval, and that too only for one formulation. Are we expecting two to three more players to get approval for this? How are things panning out on Tacrolimus?



**Rakesh Bamzai:** There are 6 to 7 Biocon customers awaiting approval. As of today, there are three approvals as you rightly said. Among those three, we have a partnership with one. Approvals are dependent on regulations and the FDA, so we will have to wait for more customers to come in.

*Vikas Sonawale:* Okay. And after Mycophenolate and Tacrolimus, which are the key products that may impact your this year's or next year's earnings?

**Rakesh Bamzai:** We are building up a pipeline of Immunosuppressants and this will be a focus area for us.

*Vikas Sonawale:* Okay. And on the Atorvastatin opportunity in the European market. Do you have any update on that?

**Rakesh Bamzai:** We launched before the patent expiry with an opening in Spain because of our IP. We are doing well in Spain and this is going to grow next year because that opportunity was very specific to Spain.

**Vikas Sonawale:** Right. And lastly, on the base business margin, somehow my calculations show that our base business margin excluding licensing income and AxiCorp are probably under pressure on account of a rise in staff and raw material costs. Is that assumption correct or is there something more on that?

*Murali Krishnan:* If you consider Q1FY11 vs. Q1FY10, there appears to be a 3% increase. However, if you look at FY10 or Q4 FY10, there is a decrease due to improved mix and better supply chain management.

*Vikas Sonawale:* And my last question - would you like to comment on the media discussed Siro acquisition?

Kiran Mazumdar-Shaw:. It is speculation and we would not like to comment on it.

Vikas Sonawale: Okay, thanks.

**Moderator:** Next question comes from Mr. Bino Patiparambil from IIFL Capital.

**Bino Patiparambil:** Hi, congrats on a good set of numbers. Earlier you used to give Biocon numbers without and with AxiCorp. Have you stopped that practice from here on?

**Murali Krishnan:** Yes, we have stopped that practice. Until last year, we used to give the numbers as they were not comparable. We started with Axicorp in mid 2008 and the whole of last year we went through four quarters with full AxiCorp numbers. The quarterly numbers are comparable now and therefore we have stopped giving it separately.

**Bino Patiparambil:** Okay. Can we at least get the top line number for Biopharmaceuticals?



*Kiran Mazumdar-Shaw:* The number with AxiCorp is Rs 672 crores and without is Rs 409 crores. (Rs 263 crores for the quarter).

**Bino Patiparambil:** Okay, great. And second, on the contract research side, you were talking about some modifications and investments which will be expensed. Can we get a little more colour on what kind of expenditure you are looking at and also the top line growth; does it seem to be that great over the last three to four quarters?

*Kiran Mazumdar-Shaw:* Yes, this is a business that needs a new direction. It has become commoditized and if we continue to offer the same set of services, then with the competitive landscape, we cannot really pull up those numbers. We feel that by getting into more high-end services, which will also give us better margins, we can address both the top line and bottom line growth. But the investments required are not huge.

**Bino Patiparambil:** Right. And so essentially we are looking at era of maybe low or moderate top line growth, but maybe margin expansion, is that true?

*Kiran Mazumdar-Shaw:* Yes, that's what we want to do by the end of this year. By the next half of this fiscal, you will probably start seeing that.

**Bino Patiparambil:** Right. And finally the research and development expenses as per the P&L in the last to last call you had mentioned that it will actually shoot up significantly this year, but the first quarter numbers does not show that much, so does it mean that we are going to see that big ramp up in the next three quarters?

**Kiran Mazumdar-Shaw:** Yes. this will depend on when we start the clinical trials. But we are certainly going to see these spends happen later this year. We mentioned that we are estimating this at about Rs 150 crores and that is quite a significant jump over last year.

Bino Patiparambil: Right. The total R&D spend will be Rs 150 crores for the year.

Kiran Mazumdar-Shaw: Yes.

Bino Patiparambil: Okay, great. Thanks very much.

*Moderator:* Next question comes from Mr. Vivek Kumar from SBI Capital.

**Vivek Kumar:** Good afternoon everyone. Just couple of questions from my side. How has AxiCorp done at the operating levels?

*Murali Krishnan:* It has been consistent with previous quarters.

**Vivek Kumar:** Okay. And going forward, since there is definitely a lot of emphasizing with playing on AxiCorp's bottom line growth to come in, when do you expect double digit margins to happen in AxiCorp, maybe few quarters down the line...?

*Kiran Mazumdar-Shaw:* No, I think we clearly mentioned that this will only happen after our Insulin enters that market and that will not happen for another two years.



**Vivek Kumar:** Okay. And with the domestic formulations you have just announced that two divisions are going to be launched in the second quarter FY11. Post this launch, do you expect the domestic formulations may grow at a very rapid pace or like say in excess of 30%...?

*Kiran Mazumdar-Shaw:* I think we have been growing quite strongly. In fact it is our hope that over the next three to five years we will have pretty strong brands worth Rs 50 crore each. That is our goal. Insugen is one such brand, Basalog is another and Erypro yet another. So definitely we hope to deliver over 30% growth in the branded formulations business this fiscal.

**Vivek Kumar:** Okay. Can we have some status on the insulin pens you are expected in September 2010?

**Rakesh Bamzai:** The pen development process is quite complex and we have to come up with the best possible pen in order to compete effectively. As per our plans, we will be in the market in June 2011.

**Vivek Kumar:** Okay, that's fine. And how has the BMS contracts progressed, I mean, with the utilization rate at BMS, will it be possible to comment, or have you seen full ramp up in the BMS contracts in this particular quarter?

*Chinappa:* It is 80% plus as at the end of the quarter.

**Vivek Kumar:** That's fine. The last question from my side - In terms of FOREX exposure, what is the exposure you have and what are the kinds of hedges you have?

**Murali Krishnan:** It is in line with hedging policy, which is to cover 100% of the first year and 70% of the second year's net exposure. We are covered fully through a range of zero cost options as well as some put options. Since there are multiple options, it is difficult to quantify the average rates. The first time we took a large hedge in the range of 46 to 54 and thereafter we took another put option at 50 rupees to a dollar. Some of these hedges have been replenished on expiry at different rates. The policy continues to remain the same.

Vivek Kumar: All the best. Thanks a lot.

*Murali Krishnan:* Thank you.

*Moderator:* Next question comes from Mr. Ajit Kumar an individual investor.

*Ajit Kumar:* Good afternoon ma'am. Thanks for the update so far. I have one question on Type 1 diabetes. My question is if everything goes well in the clinical trial, what is the time limit for the launch of Oral Insulin for Type 1 diabetes?

*Kiran Mazumdar-Shaw:* Since we are trying to partner this program with a global partner, we will jointly discuss this and decide when we want to launch it. So even though it might be possible to launch it in India, it also depends on the partner we choose.



Ajit Kumar: Any guess so far?

*Kiran Mazumdar-Shaw:* No. It is very difficult for us to give you any kind of information on what could be our possible launch date.

Ajit Kumar: Okay. Thanks a lot.

Moderator: Next question comes from Mr. Akshat Vyas from Anvil Stock Broking.

**Akshat Vyas:** Good afternoon ma'am. I want to know your total employee strength in Syngene.

Goutam Das: A little over 1400 and that includes people in the BMS facility.

Akshat Vyas: How much is BMS?

Goutam Das: About 400.

Akshat Vyas: Okay, thank you sir.

Moderator: Next guestion comes from Ms. Monica Joshi from Avendus Capital.

**Monica Joshi:** Hi, thank you for taking my questions. I think you did touch upon what you wanted to do on the research services side that is going to probably ramp up your expenditure. I understand if you cannot give more details because of your competitive reasons. But what we want to understand is what is it that you are looking at, are you looking at new business opportunities and why is this expenditure going to come under P&L? Is it that there is going to be a lot of hiring to be done....

*Kiran Mazumdar-Shaw:* Well, it is going to be a mix of things. There is hiring involved and there are some investments involved in terms of certain processes, certain skills etc.

**Abhijit:** One of the things we want to do is differentiate ourselves from the other CROs in terms of some of the things that they do. As Kiran rightly pointed out, this will involve hiring new people with specialized skill sets that would allow us to establish some domain expertise, etc. Also, offer something that is currently not offered in India and that would entail some additional expenditure.

**Monica Joshi:** And this particular thing refers only to Clinigene is it? Does it have to do with Syngene as well?

*Kiran Mazumdar-Shaw:* Yes, Syngene as well. In the case of Syngene, we are looking at this in terms of integrated drug development and that is a very different model which will require similar kind of expertise and investments.

**Monica Joshi:** Right. Ma'am the way we see it is, essentially when we are starting to see some bit of improvement and ramp up, there is always something that is driving down margins. Now that is a concern for the investor community and how do you address that, because clearly these things were not anticipated...?



**Kiran Mazumdar-Shaw:** Well, they will be delivering growth as well. Delivering 33% growth is not a mean feat. It is robust growth. I don't think investors should be concerned about what's happening because what we are trying to do is to really develop a risk balanced set of portfolios and opportunities. And we are maintaining the margins at 30%.

Monica Joshi: On the research services side ma'am, we have seen...

*Kiran Mazumdar-Shaw:* Yes, when you are looking at services, if we don't take proactive action now, we will have the same complaint of shrinking margins a few quarters down the line. We are trying to be proactive here. We don't want to have just a commodity offering.

**Monica Joshi:** Thank you for that. I appreciate it. I was actually referring to the revenue side of the research services business, roughly Rs 72 crores. We are not really going beyond that 70s...

**Kiran Mazumdar-Shaw:** As we try to grow and offer those services, if there is a competitive landscape and somebody is offering it at a lower price, it does not allow us to grow the top line as effectively. So that is why we need to buffer it with some high margin business.

*Monica Joshi:* Great. I think that's fine from my side. Thank you very much and wish you the best.

*Moderator:* Next question comes from Mr. Surya Narayan Patra from Systematic Shares and Stocks.

**Surya Narayan Patra:** Yes, congratulations for the good set of numbers. You have indicated that Rs 150 crore would be invested in R&D for the current year. What would be the investments for the Phase III clinical trials in Europe and Phase I in the US?

*Kiran Mazumdar-Shaw:* It is going to be a significant part of that Rs 150 crores.

Surya Narayan Patra: And this is for the injectable Insulin for the European market......

Kiran Mazumdar-Shaw: Yes.

**Surya Narayan Patra:** And you would be doing this by yourself only...

*Kiran Mazumdar-Shaw:* Yes. That is precisely why it is costing us so much.

**Surya Narayan Patra:** Okay, but when would you be partnering with somebody else for the US Phase 1 trials for Insugen?

*Kiran Mazumdar-Shaw:* We are looking at it but Europe is the most immediate opportunity and we will share that information with you a little later.

**Surya Narayan Patra:** Okay and when should we expect the out-licensing of this injectable insulin to various other European markets?



*Kiran Mazumdar-Shaw:* We expect to do it ourselves because AxiCorp is there to do that.

Surya Narayan Patra: That is for the German market.

Kiran Mazumdar-Shaw: Yes, but we will also use a pan European strategy for this.

**Surya Narayan Patra:** Okay, my next question would be the new unit you are setting up - Comprehensive Care Division - what sort of products would you be launching there and when would that be?

**Rakesh Bamzai:** Comprehensive care is an extension of the four divisions we have – for example when you have acute problems in Diabetology, Nephrology, Oncology, Cardiology and when there is a hospital setting or intensive care unit setting, Therefore, it is an extension of our existing businesses. We are launching the division in the month of August and we hope to ramp up in two years time.

*Kiran Mazumdar-Shaw:* We will add products in different disease settings. In certain cases, we will add some specialized anti infectives, pain relief agents and so on.

**Surya Narayan Patra:** Okay. Sorry to ask again - how long do you think the Phase III trials in Europe will continue?

Kiran Mazumdar-Shaw: One year.

**Surya Narayan Patra:** Okay and the last question - Since its acquisition, AxiCorp has been growing quite well quarter-on-quarter basis. Every quarter it is just beating the previous quarter number...how long can this story continue?

**Kiran Mazumdar-Shaw:** We hope it continues because Axicorp is doing very well. In fact AxiCorp is ranked as the 29<sup>th</sup> largest pharma company in Germany and it is considered one of the fastest growing pharma companies in Germany.

Surya Narayan Patra: And what would be driving this growth?

Kiran Mazumdar-Shaw: It is good marketing and distribution.

Surya Narayan Patra: Okay. Is it getting any significant support from Biocon?

*Kiran Mazumdar-Shaw:* Definitely. We are helping with the supply chain.

**Surya Narayan Patra:** Okay and what margin have you indicated for AxiCorp for the quarter?

Kiran Mazumdar-Shaw: It is a high single-digit margin.

Surya Narayan Patra: Okay, thank you.

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



**Sameer Baisiwala:** Hi, good afternoon everyone. On the insulin for the European markets - we are doing these clinical trials in Germany - could this data be used for other non-German markets or what more do we need to do?

**Harish lyer:** We will do trials outside Germany as well in Europe but those applications are still with the regulators and we have a multi centric trial approach across Europe.

**Sameer Baisiwalas:** Okay and any time lines when we can commence the trials in the non-German markets?

*Harish lyer:* Soon. It is a matter of timing for regulatory approvals.

**Sameer Baisiwala:** Okay and on these timelines, I think you mentioned that it would take one year to complete the trials and the launch is end of 2012....

*Harish lyer:* Yes, the duration of the trial is one year.

**Sameer Baisiwala:** Okay and we are baking in one and a half years for the dossier filing and approval?

*Harish lyer:* The first time you have to bake in some time for regulatory approvals and some time upfront for recruitment of patients.

**Sameer Baisiwala:** Okay, fair enough. And just on the US generic insulin, is there any update over there, how the partner is progressing?

Harish lyer: We are working on it.

**Sameer Baisiwala:** Any milestones in terms of clinical trials getting started/finished, dossier filing...

*Harish lyer:* No, we don't have anything more to share at this time.

**Sameer Baisiwala:** Okay and a final question on Tacrolimus. For the June quarter these things could end up being a little lumpy, so was there any meaningful contribution in the June quarter or not?

**Rakesh Bamzai:** Yes, I think we did well in the June quarter with all the immunosuppressants including Tacrolimus.

**Sameer Baisiwala:** That's all from my side, thanks.

Rakesh Bamzai: Thank you.

**Moderator:** Next question comes from Mr. Debanshu Patra from VCK Share & Stocks.

**Debanshu Patra:** Good afternoon ma'am, can you provide me the sales force breakup for the different domestic branded formulations segment?



Kiran Mazumdar-Shaw: It is about 900+ people.

**Debanshu Patra:** Can you give me the breakup for Diabetology, Onco-therapeutics, Nephrology and Cardiology?

*Kiran Mazumdar-Shaw:* Actually we have about 500 people in Diabetology, about 300 people in Cardiology and the remaining are in the other segments.

**Debanshu Patra:** Okay and can you specify the current doctor coverage and how much we are targeting in FY11?

**Rakesh Bamzai:** Doctor coverage?

**Debanshu Patra:** How many doctors are we planning to cover?

**Rakesh Bamzai:** You want to know our marketing plans? It is difficult for me to tell you that but I can tell you that we are focusing a lot on rural India this year and we are building up our business in the B, C and D level cities.

**Debanshu Patra:** Basically we are targeting tier 2 and tier 3 markets?

Rakesh Bamzai: Totally.

**Debanshu Patra:** Okay and any kind of outlook regarding this immunotherapy segment?

**Rakesh Bamzai:** Immunotherapy is a new division we are launching in the month of September and like other divisions we have aggressive growth plans. Once the division is launched in that particular quarter, we will give more information about it.

Debanshu Patra: Okay, thanks a lot.

*Moderator:* Next question comes from Mr. Ritesh Shah of IDFC Securities.

**Ritesh Shah:** Hi, good afternoon everyone. In the press release you mentioned something about restructuring the statins business, which has helped the growth this quarter. Can you throw some more light on that, please?

**Kiran Mazumdar-Shaw:** I don't think we said restructuring. We spoke about expansion. The press release spoke about expanding some of our facilities because of the Hyderabad acquisition.

*Ritesh Shah:* Does it really help you in terms of the cost profile of the products also?

*Kiran Mazumdar-Shaw:* And being able to manufacture much more.

**Rakesh Bamzai:** It helps in many ways as Kiran rightly said. It helps in building in more volumes, reduce costs, add more products and build further growth in that segment.



**Ritesh Shah:** And on the licensing income, it is obviously going to be lumpy, but the numbers that we have booked for the current quarter- is it any indication of how things could be in the remaining quarters?

**Murali Krishnan:** Not necessarily but it would be at least similar to what we got during last fiscal.

**Ritesh Shah:** And lastly on the insulin pens, Europe, if I understand correctly, is a pendriven business and since we have not really got our pen devices in place yet, does it impact our launch timings for the trials for the European market?

Rakesh Bamzai: No.

Ritesh Shah: Okay, thanks.

*Moderator:* Next question comes from Mr. Nimish Mehta of MP Advisors.

**Nimish Mehta:** Yes, thanks and congratulations on a good set of numbers. My first question is related to the biopharma sales excluding AxiCorp. We have seen a robust growth of about 37% even in that business and I understand you talked about branded sales, but that is still less than 20% of your total biopharma sales, so what are the other divisions broadly, if you can give us some color about the robust growth that has happened?

**Rakesh Bamzai:** The key drivers have been statins, insulin, immunosuppressants and some of the insulin formulations we have started marketing. In addition there is good growth in the branded formulation business.

*Nimish Mehta:* So, essentially across the board growth.

Rakesh Bamzai: Yes.

**Nimish Mehta:** Okay, fine. The second is, I am sorry if I missed this in between but what is the reason for your other expenses having come down on a YOY basis. Despite the strong growth on the top line we are seeing this...

*Murali Krishnan:* One is obviously some kind of the cost cutting in terms of certain aspects of the business that does not impact the growth.

Nimish Mehta: I see. So this is what we can take as our run rate going forward?

*Murali Krishnan:* It is likely to be around these levels.

Nimish Mehta: Okay, fine. Thirdly, I understand you had guided for R&D...

*Murali Krishnan:* We will have to keep in mind that some of the maintenance expenses do get lumpy. These costs may not get spread out evenly over the quarters.

*Nimish Mehta:* I see. So it can be higher this coming quarter.



Murali Krishnan: Yes, it can be.

Nimish Mehta: I see, okay. This quarter it is lumpy towards the lower side. Is that

correct?

Murali Krishnan: Yes.

**Nimish Mehta:** Okay, fine. The other question is on the R&D cost you mentioned at about Rs 150 crores for the full year. Is this just Biocon's portion? As I understand you are also getting reimbursed by Mylan because of the deal that you had struck with them?

Murali Krishnan: This is likely to be the net number.

**Nimish Mehta:** Okay and lastly how many products would you launch through AxiCorp in Germany this quarter or any colour as to what is the volume growth that we have seen there?

**Rakesh Bamzai:** There are many products. It is a multiple product driven business.

**Nimish Mehta:** Okay and anything that you received as licensing income for the quarter?

Murali Krishnan: Yes, it is reflected in the financials. It is about Rs 20+ crores.

Nimish Mehta: Okay, thank you very much.

*Moderator:* Next question comes from Ms. Priti Arora of Kotak Securities.

**Priti Arora:** Thanks. AxiCorp was supposed to win more tenders. Has that come in through this quarter?

**Rakesh Bamzai:** I think we have won two small tenders. We are looking at bigger tenders in the future.

**Priti Arora:** And when are those expected?

Kiran Mazumdar-Shaw: Third or fourth quarters of this fiscal.

**Priti Arora:** Okay and the tax rate is a bit higher than the previous two quarters. Is that going to normalize? What is your tax rate for the year?

*Murali Krishnan:* It is more or less at the same levels. It will be in the range of 15 to 20% range as we move towards the end of this fiscal.

**Priti Arora:** You are saying that it should be 15% to 20% for the full year? Why is that so given that you are present in an SEZ?

**Kiran Mazumdar-Shaw:** At the group level, it also includes AxiCorp where the rates are high.



**Murali Krishnan:** And also we sell some of these products in the DTA to our local customers in India who then export it. We don't get a tax break in this case.

**Priti Arora:** Okay and one more question on your insulin biosimilar which you are developing in Germany. Is it correct to say that you would also look for a partner for the rest of Europe which could lead to licensing income in future?

Kiran Mazumdar-Shaw: Yes, it can.

**Priti Arora:** So, what is the latest on that and when could we expect to hear something given that you are starting Phase III now?

*Kiran Mazumdar-Shaw:* We cannot discuss that right now and would like to share this once we are nearing that market registration.

**Priti Arora:** Okay and on Syngene - can I have the sales and EBITDA margin for this quarter please?

**Chinappa:** Total revenues from contract research services was Rs 78.5 crores including inter segment revenue with an EBITDA of Rs 15 crores.

**Priti Arora:** Okay and my last question - I believe there has been a biosimilar application by another company sometime last year which was withdrawn because of poor clinical data for biosimilar human insulin in Europe. Have you reviewed that and why was that withdrawn or why didn't the European authorities give that approval? What has happened there?

*Kiran Mazumdar-Shaw:* We cannot comment on that. All we know is that our data has been accepted and we are starting Phase III.

Priti Arora: Okay, thanks a lot.

Moderator: Next question comes from Mr. Harish Swaminathan, an individual investor.

**Harish Swaminathan:** Good afternoon, my first question is - can you indicate the likely timeframe for the IN 105 Type 1 clinical trials? Is there going to be a Phase I, then Phase II and then Phase III and the likely timelines for that?

Harish Iyer: Well, currently we plan to do Phase I. It is expected to start recruiting patients very soon. We expect this study to be completed by the end of this financial year and certainly depending on the data we plan to do additional studies in Phase I perhaps long term efficacy but it's too early to talk about that right now. We do have a comprehensive development plan and we will share it once we have finalized a global partner for this product and discussed it with them.

*Harish Swaminathan:* Okay and on the Type II, would you be sharing the un-blinded data once it is approved by the Indian authorities?

Kiran Mazumdar-Shaw: Well, it will be difficult to share it with the public.



*Harish Swaminathan:* Okay, but would you be indicating to us that it has been broadly successful?

Kiran Mazumdar-Shaw: Yes, we will do that.

**Harish Swaminathan:** Okay and on the T1H - would we be thinking of out-licensing it after Phase III or is it going to happen before the start of Phase III or how is it going to happen?

*Kiran Mazumdar-Shaw:* Phase III has already started and therefore we will be looking at licensing it after Phase III is over because it is very difficult to unlock good value unless you get some good data.

**Harish Swaminathan:** Okay and my last question is on Atorvastatin - we are approaching Europe through Spain?

Kiran Mazumdar-Shaw: Can you repeat the question?

*Harish Swaminathan:* Are we using Spain as a window to address the entire European market for Atorvastatin or is it that we are confined to Spain? Also, when can we see the real impact of Atorvastatin in the books?

**Rakesh Bamzai:** The product patent has not yet expired but this is an opportunity ahead of the product patent expiry in Spain.

Harish Swaminathan: Okay, thank you very much.

**Moderator:** Next question comes from Mr. Ravi Agarwal from Edelweiss Capitals.

**Ravi Agarwal:** Yes, good afternoon, thanks for taking my call, actually just on the Oral Insulin bit again, the earlier impression we used to get was that the India launch would actually happen much before you take it to the US and some of the other regulated markets. Has that changed?

*Kiran Mazumdar-Shaw:* Yes. Your perception is correct. We have begun to understand what licensing and specifically what global licensing is all about. We realize that it is difficult to have a separate strategy for India and another for global. They have to be aligned and that is why I think it is not in our hands alone to decide whether the India launch should take place or not. Theoretically you may be able to launch in India but I think it will become a global strategy to align with our potential partner- would they rather do it as a global launch or do India first.

Ravi Agarwal: So, now essentially it would be a global launch if and when it happens...

*Kiran Mazumdar-Shaw:* We will decide that jointly with a partner when we finalize one.

**Ravi Agarwal:** The second question is again on oral insulin. I was reading some time ago that Oramed is also pretty much in an advanced stage and they have actually tied up very recently with Sanofi for some clinical supplies for their bulk at least for the oral



insulin project. Do you see a race between yourself and a company like Oramed as to who would be the first to launch this product?

**Kiran Mazumdar-Shaw:** I think their whole approach is very different relative to ours. I don't want to comment on the race bit but all I can say is that our approach is very different to Oramed's because theirs is a formulation approach whereas ours is a molecule approach. Ours is like an analog approach and therefore very different from Oramed.

**Ravi Agarwal:** But the end result I guess would be still that both of you would be competing to launch an oral insulin product. Is that right or is that...?

Kiran Mazumdar-Shaw: I don't think that Oramed is really ahead in the game.

Ravi Agarwal: Okay, thank you so much.

Moderator: Next question comes from Mr. Balasubramaniam of PCS Securities.

**Balasubramaniam:** Yes, hi. Congratulations on a very good set of numbers and recently Natco also came out saying that DCGI which stopped them from marketing Albupax is reentering marketing. Would that be a dent to your product Abraxane which the last time when we spoke you said is almost a Rs 200 crore potential market?

**Kiran Mazumdar-Shaw:** Abraxane is clearly a product that has been recognized and received very well by the market. I don't want to comment on Natco or its product. All we can say is that Abraxane has got a leadership profile. It has got a huge quality profile and I think it has got the potential of being a very strong brand for us.

**Bala Subramaniam:** Okay, so what could be the total market size approximately?

**Rakesh Bamzai:** I would like to correct you slightly. The market potential of that segment is Rs 200 crores. Abraxane is not a Rs 200 crore brand. We have 1000 patients on Abraxane which is a record in any Onco therapy type product. Abraxane has been approved recently as the first line therapy for metastatic breast cancer. There are three clinical trials ongoing for three more indications. So it is a very big brand.

*Kiran Mazumdar-Shaw:* One of the things that is important when you start developing these kind of novel drugs is that the clinical trials are going to be extremely important. Therefore whatever drug, even a follow on, clinical trials to look at safety and efficacy data is necessary. Doctors in India are very clear about that.

**Bala Subramaniam:** One more question - recently we read a newspaper report and it was on the TV that a group of Indian scientists have developed an insulin which is a one dosage per month sort of a thing. Would that really change the landscape of insulin in India or the world over or are there already any drugs available in the market such as this?

*Harish lyer:* I think that it is very early stage to talk about that as a possibility. Certainly I think they have shown some data in animal models but when you look at it, you realize that there may be some issues with this that have to be overcome. For example, how do



you dose an insulin like that for one month? You have to give one dose and predict what is going to happen over an entire month. It is a bit complex so there are potential risks around that. I think it has to be evaluated carefully to see if that can really have a huge impact.

Bala Subramaniam: Okay and the human trials have not taken place on this, right?

Harish lyer: Correct, it is purely a lab science right now.

**Bala Subramaniam:** Okay, thanks a lot and all the best for the future.

Kiran Mazumdar-Shaw: Thank you.

*Moderator:* Next question comes from Mr. Rajesh Ranganathan from Doric Capital.

**Rajesh Ranganathan:** Hi, good afternoon. Thanks a lot for the call. A few questions one is with regard to the Mylan program. You had indicated in an earlier call that sometime this year you should be able to go into the clinical trial stage for some of the products. Can you please give us an update on what the current thinking on the time line is?

*Harish lyer:* We are still on target to do this. We hope to start clinical trials sometime in this financial year.

**Rajesh Ranganathan:** And is there any indication of which products or how many products?

*Harish Iyer:* No, we cannot reveal that.

**Rajesh Ranganathan:** Okay and there are some numbers thrown around on the gross or net R&D expenditure for this year that is confusing. Can you clarify again? If I remember right last time around you said Rs 300 crores gross expense for this year and maybe Rs 150 crores net. Is that correct?

*Murali Krishnan:* Yes, ~ Rs 150 crores will be the net figure.

Rajesh Ranganathan: And Rs 300 crores would be the gross?

*Kiran Mazumdar-Shaw:* We never talked about a gross number. We said Rs 150 crores will be the net R&D.

**Rajesh Ranganathan:** And with respect to the opportunity in biosimilars - in the rest of the world market, which is non Europe, non US, what is your assessment of the potential? If you look at Mylan and their program, as of now it seems it is focused on the developed market and even if you look at Teva they have also focused on developed markets. Do you have an independent assessment of whether there is a substantially larger opportunity in the rest of the world market?



**Rakesh Bamzai:** yes, we have done that. Emerging markets are important markets for us and with the monoclonal antibodies or other biosimilars that we are developing with partners or alone, we are going to focus a lot on the emerging markets as well.

**Rajesh Ranganathan:** The reason I am asking is because there are no patents in the emerging markets and so you are not restricted by the timeline in terms of when the products go off patent in the developed markets. You could look at developing products, which are more sort of easily marketable in developing markets even though they may be the last to go off patent, so I was wondering what is the direction of your strategy?

**Rakesh Bamzai:** I think there are regulations in the emerging markets. There are clinical studies needed, some countries have patents and some don't. But as an IP abiding company, we will go after those markets when they are available to us.

**Rajesh Ranganathan:** Any numbers you can share with us in terms of potential with say one illustrated example?

**Rakesh Bamzai:** We cannot give you numbers but we can tell you that we are focusing very aggressively on the emerging markets with all the biosimilars and other molecules that we have.

Rajesh Ranganathan: Thank you and best of luck.

Rakesh Bamzai: Thank you.

Moderator: Last question comes from Mr. Sunit Mehrotra from Vardan Investment.

**Sunit Malhotra:** Good afternoon, ma'am. This is Sunit Mehrotra from Vardan Securities. I would like to ask one question about our oral insulin program. We filed for a US IND somewhere around last December and the approval came in January. What has taken us so long to start these trials there? Isn't time of essence to us?

*Kiran Mazumdar-Shaw:* Yes it is but it takes time to get regulatory approval to start any trial which is why clinical development takes so long.

**Sunit Malhotra:** May I ask another question regarding IN 105 – Are you reasonably sure by now whether it is effective or not?

**Kiran Mazumdar-Shaw:** Yes we are and that is why we are doing all these trials. We have certainly demonstrated that it works but you cannot just simply launch something because you think it works. We have to prove it through lot of trials and that it is doing what it is supposed to do.

**Sunit Malhotra:** Thank you so much, ma'am.

*Moderator:* There are no further questions, now I hand over the floor to Ms. Kiran Mazumdar-Shaw for her closing comments.



**Kiran Mazumdar-Shaw:** Thank you very much for participating in this particular investor conference call and I really look forward to sharing good news with you even in the next quarter and hopefully that we continue to meet your expectations. 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 and have a pleasant day.

Note: This document has been edited to improve readability.

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