Biocon Limited

Q2 & H1 FY13 Earnings Conference Call Transcript
October 31, 2012

Participants from Biocon Group's Senior Management Team

- Kiran Mazumdar Shaw: Chairman and Managing Director
- John Shaw: Vice Chairman
- Murali Krishnan K N : President, Group Finance
- Arun Chandavarkar: Chief Operating Officer
- Rakesh Bamzai: President, Marketing
- Kiran Kumar: Deputy General Manager, Finance
- Sandeep Athalye: Vice President, R&D; Clinical Lead for Insulins Program
- Peter Bains: Director, Syngene International
- M.B. Chinappa: President, Finance, Syngene International
- Manoj Nerurkar: Chief Operating Officer, Syngene International

Presentation Session

Moderator: Ladies and gentlemen, good day and welcome to Biocon Limited H1 FY13 Earnings conference call. As a reminder, all participant lines will be in listen-only mode. There will be an opportunity for you to ask questions at the end of today's presentation. If you need any assistance during this conference call, please signal the operator by pressing * and 0 on your touch-tone telephone. Please note that this conference is being recorded. I would now like to hand the conference over to Ms. Urvashi Butani from CDR India.

Urvashi Butani: Thank you. Good afternoon everybody and thank you for joining us on Biocon Limited's Q2 & H1 FY13 conference call. We have with us on the call today Ms. Kiran Mazumdar Shaw, Biocon's Chairman and Managing Director and her colleagues from the senior management team. We will begin this call with opening remarks from Biocon's Management followed by an interactive question and answer session. I would like to add that some of the statements made in this Concall may be forward-looking in nature and a note to that effect is 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 period ended 30th September 2012.

Kiran Mazumdar Shaw: Thank you Urvashi. Good afternoon and welcome to Biocon's investor conference call for the first half year of FY13 ended 30th September 2012. I am pleased to report that we have ended the first half of the fiscal with good performances across all verticals. At a group level we have registered revenues of 1,235 Crores which is a 23% year-on-year growth

attributable to both increase in volumes as well as better export realization on account of a weak rupee.

Now to provide greater granularity I would like to look at our business segment-wise: APIs and biosimilar insulins have grown by 21% for this first half from 586 Crores last year to 714 Crores this year and this growth has largely come from business expansion of APIs and Insulins in the emerging markets and Tacrolimus & Fidaxomicin sales to the US. Branded formulations have also sustained its growth momentum and have grown at 45% from 122 Crores last year to 177 Crores this year. Research Services continue to deliver a strong growth with 40% YoY increase from 180 Crores last fiscal to 252 Crores for the first half of this fiscal. At the profit level, research services have grown 42% from 26 Crores last fiscal to 37 Crores this fiscal reflecting greatly improved earnings.

Now coming to expenditure, R&D expenditure has risen significantly this fiscal and stands at 79 Crores for H1FY13 which is a 54% increase over the same period last fiscal. This reflects the progress that is being made by our various biosimilars and novel molecule program in the clinic including a European Phase III trial for recombinant human insulin which has generated positive interim data.

Now, I would like to spend a few moments talking about our research spends which is integral to our business. I would say Biocon is an outlier when it comes to research investments. I call this an investment and not expenditure deliberately, because investing in research and development for Biocon will drive exponential growth in the future. It is very important for us to recognize that R&D is a gestational investment. The time to realize returns on such investments is much longer than for the generics business model. I think this is very important for all of us to understand and recognize because it is these investments that will deliver strong and sustainable growth for Biocon going forward.

I would also like to state that raw materials, power and personnel costs have also increased by 27% during the comparable period this fiscal. What is commendable, in my perspective, is that despite these; EBITDA has grown 8% from 281 Crores to 305 Crores and we have seen commensurate PAT growth from 156 Crores to 169 Crores for H1 this fiscal. This reflects the robustness of our business model. We have self-financed our R&D as well as our expansion and yet delivered growth along with good profitability.

If you look at our business, you will see that R&D constitutes around 10% of biopharma revenues. This is the highest in the Indian pharmaceutical space and this is what makes us an outlier. I am very confident that in the years ahead it is this investment, this differentiation that will set Biocon apart from our peers.

In terms of human resources – I am also pleased to report that the prestigious Science magazine ranked Biocon amongst the top 20 best biopharma employers in the world. We are the only Asian company to feature on the list and this once again reflects the quality of our human resources and the enabling ecosystem at Biocon that we have created over the years.

I am now very pleased to make an important announcement that pertains to the investment made by GE Capital in our subsidiary Syngene. As per the terms of the agreement, GE Capital will

invest 125 Crores for a 7.69% equity share valuing Syngene at a post money equity valuation of 1,625 Crores. This, we believe, establishes a base valuation which is an important milestone towards the proposed public offering. I would like to highlight at this stage that the market conditions at this point in time are not conducive to listing. We believe there are political, economic and global uncertainties which do not make it the right time for listing Syngene. We will certainly look at an opportune time to list Syngene once all these externalities stabilize.

This base valuation is also about unlocking Syngene's and Biocon's value. We recognize that the last time when we were looking to list Syngene, we were not in a position to capture its true value given that the Biocon group's stock, in our view, was undervalued and it would have commensurately undervalued Syngene's valuations. GE Capital's investment is not merely a financial investment but it is also about value addition. There were several interested parties and investors wanting to take a stake in Syngene and we finally opted for GE because GE has a leading edge expertise in life science technologies, which we believe will enable Syngene to benefit and further enhance its service offerings through innovative services.

Our net cash position is a robust 625 Crores post the dividend payout that we made in July. Now, on the R&D front I would like to share information on our various research programs. To begin with, I am pleased to report positive interim data on our European Phase III clinical trials for recombinant human insulin. The said data has demonstrated comparable efficacy and safety between our products and the innovator products. The trial has met its efficacy endpoint with a comparable immunogenicity and safety profile. The second part of the study which requires us to evaluate additional safety and immunogenicity parameters over 12 months is ongoing but these encouraging results will be pivotal in our regulatory and market authorization submissions to European agencies which will also allow us to commercialize these products in many other markets.

Our novel molecules continue to make progress during the reported period. We are in advance stages of finalizing our licensing agreement for our oral insulin program the IN-105 program. We have initiated engagement with potential partners for out-licensing Itolizumab which is our Anti-CD6 monoclonal antibody program for the global markets. We have recently reported positive data for Itolizumab from a Phase-III India centric trial for Psoriasis and this has enabled us to file with the DCGI for marketing authorization in India. We intend to initiate further clinical trials for Itolizumab for other promising indication namely Multiple Sclerosis, Vitiligo and Rheumatoid Arthritis.

An important development during this quarter is our decision to exit from our partnered program with Amylin Pharmaceuticals following its acquisition by BMS. Amylin's proprietary molecule was being jointly developed as a novel diabetes treatment agent by the two partners. A change in control at Amylin provides Biocon with an exit option, which we have chosen to exercise. This we believe will enable Biocon to focus its resources to other advancing programs. I would like to elucidate that Amylin and Biocon had always intended to out license this program to Big Pharma at an opportune time and the acquisition of Amylin by BMS, provides us with that opportune moment to exit from the program.

Our Malaysia project is making good progress and is on track to deliver additional insulin capacity by fiscal year 15. In terms of outlook I would like to state that we see this growth momentum

continuing for the remaining two quarters and we expect to comfortably meet our internal forecast. I will stop at this point and open it up to question and answers.

Question and Answer Session

.**Moderator**: Thank you very much. Ladies and gentlemen we will now begin the question and answer session. Anyone who wishes to ask a question may press * and then 1 on your touch-tone telephone. Participants are requested to use only handsets while asking a question. The first question is from Mr. Ravi Agarwal from Standard Chartered, please go ahead.

Ravi Agarwal: The first question is related to the EU studies on your human insulin program. I am very curious about two things: one is that the trial was done for type-one diabetes so I was wondering why you chose type-one where presumably type-two would be the more prominent indication to look at. And secondly, why have we not chosen Human Mixtard as the reference drug.

Kiran Mazumdar Shaw: I will let my colleague, Sandeep Athalye who is the Clinical lead for our Insulins program, answer this question.

Sandeep Athalye: Hi, this is Sandeep. I will begin with your first question and if I correctly recall the question was why we chose type one patients and not type two. We know for ourselves and through our discussion with the regulators, that type one patients are more sensitive to do trials with and doing the trial in type one patients would enable us to get approvals both in type one as well as type two diabetes..

Ravi Agarwal Do we get also approvals for the mixed combinations, assuming the long term studies also are successful or…

Sandeep Athalye: I think you are right. Our understanding with the regulators is that we will automatically get approval for the mixed combinations as well upon completion of the Phase-III study using our formulations.

Ravi Agarwal: My next question is a housekeeping question. The notes to accounts mentioned a figure of around 31 Crores in other operating income, which is a one-time fee from some clients. Just wondering what that was and will it be a recurring feature going forward.

Kiran Mazumdar Shaw: This includes a number of fees received from various parties, which also includes a small compensation from our Amylin program where we have chosen to exit from this program and we have been partly compensated for our spend on this program.

Ravi Agarwal So, if I understand correctly we have not received any licensing income or fee.

Kiran Mazumdar Shaw: No, it does not include any licensing income, this only include a few payments from various parties for various services that we have rendered.

Murali Krishnan: We normally show the licensing income under biopharmaceuticals income line.

Ravi Agarwal: Any FOREX gain or loss this quarter.

Kiran Kumar: During the first half, we have a FOREX loss of about 24 Crores which is a part of other expenses.

Ravi Agarwal: So, the last quarter the forex loss was around five Crores another 19…

Kiran Kumar: Yes, It is 19 Crores for Q2 FY13.

Murali Krishnan: It is largely coming from the BMS contract.

Ravi Agarwal: Okay thank you so much.

Moderator: Thank you. The next question is from Bhavin Shah from Dolat Capital, please go ahead.

Bhavin Shah: Will the Phase-III recombinant Human insulin get filed by the end of this fiscal?

Kiran Mazumdar Shaw: As I mentioned earlier, we are still awaiting the second part of our study data which is about immunogenicity over a 12-month period. We are expecting all the data to come in by sometime next year, so we will not be able to file our market authorization application till probably the end of next fiscal.

Bhavin Shah: Even if you assume October to be a time line to get the filing and everything done, it will be 18 months from thereon to finally get the product in the market.

Kiran Mazumdar Shaw: Your understanding is right.

Bhavin Shah: I was wondering as to why there is no receipt of any licensing fee for the quarter. So, are the insulin registrations not happening in other emerging markets and no further penetration is going on? I just wanted to get some sense over the other businesses where we could get some fee here.

Kiran Mazumdar Shaw: On the contrary, our sales in emerging markets for insulins have done extremely well. We are continuing to register these products in many markets. We have not received any new licensing income in other areas.

Bhavin Shah: What would the constant currency growth in Syngene be for the quarter?

Kiran Mazumdar Shaw: I would say about 25%.

Bhavin Shah: And lastly is the Fidaxomicin ramp up in Europe getting reflected in this quarter or will we see something more meaningful happening in the quarters to come.

Rakesh Bamzai: Fidaxomicin has been one of the best launches in the US for anti-infective drug. It is getting launched in ten more countries. We have pretty robust growth plans for the future

and we have very good indications from the partner that they are going to do very well in this molecule.

Bhavin Shah: I wanted more clarity on the European market. How does that supply...

Rakesh Bamzai: Supplies are going on and the partner is about to launch the product in a few more geographies.

Bhavin Shah Okay so that would probably make the second half more prominent.

Rakesh Bamzai: Yes.

Bhavin Shah: Alright thanks, I will be in the queue, thank you.

Moderator: Thank you. The next question is from Amit Shah from Prabhudas Lilladher, please go ahead.

Amit Shah: Just a couple of questions. I am carrying forward from the earlier question. There was no licensing income in this quarter and there was some 13 – 14 odd Crores licensing income which you reported in the last quarter, so I am just trying to get a sense for the full year. What number one should look at for the licensing income?

Kiran Mazumdar Shaw: We cannot give you any indication at this point in time.

Amit Shah: Okay sure ma'am. Congrats on the GE investment, so it values Syngene at ~1,600 crore. I am just trying to get a sense on what kind of valuation GE has paid in terms of may be PE ratio or EBIT to EBITDA ratio.

Kiran Mazumdar Shaw: Well, we are unable to disclose this at the point in time but all I can say is that it is valued much better than what the markets are valuing Biocon.

Amit Shah: And just one last question from my side. Last quarter, you mentioned in the con call that roughly 13 odd crore of licensing income from Pfizer has been adjusted to R&D. Could you just give the figure for this quarter?

Kiran Kumar: For the first half of this year it is 21 Crores.

Amit Shah: 21 Crores, okay perfect. Thank you so much, that's it from my side all the best.

Moderator: Thank you. The next question is from Nimesh Mehta from MP Advisors, please go ahead.

Nimesh Mehta: Can you highlight how the money received from GE will be used.

Peter Bains: We look to build on the momentum that we have seen in the last two and a half years. We have seen the research services division grow 13% in 2011, 29% in 2012 and 40% with the half way mark this year and this includes expanding in a fundamental capability where we

have been building to deliver integrated services in discovery and development to our clients. So, we will further expand these fundamental building blocks in enhancing chemistry, biology, biologics and clinical development capabilities.

Nimesh Mehta: Are we likely to set up any new research facility with the new money that has come into Syngene?

Peter Bains: Yes, I think it is very likely that we will continue to expand capacity which would include additional laboratory capabilities to provide the infrastructure to expand in chemistry and biology, biologics and formulation development.

Nimesh Mehta: And just as a matter of housekeeping, how many projects do we have currently which are on an FTE basis and other non-FTE basis.

Peter Bains: I think I will answer that question in this way. The research services division serves a universe of about 90 clients and that universe includes 16 of the world's top 20 biopharmaceutical companies, many mid-sized biopharmaceutical and pharmaceutical companies with a mix of the small, virtual and start up biotechs. The universe extends beyond biopharmaceuticals to adjacent sectors which include agrochemicals, animal health, nutritional companies and consumer companies, petrochemical and specialty chemical companies which utilize Syngene and Clinigene's underlying scientific and technical capabilities. We employ a range of models and those include both Fees for Service and FTE models with the balance between them at about 30:70.

Nimesh Mehta: Sorry I did not get that.

Peter Bains: We could revert to you with the specific numbers later but I think it is a balance of both models. The trend is more towards FTE based models which will become more integrated in nature in the longer term.

Nimesh Mehta: And last question is on the recombinant insulin. We have seen good positive results. Can you just let us know the current size of the insulin market with which it is referenced? I think they are Actrapid and Insulatard, and the total sales that these two.

Rakesh Bamzai: The reference product is the European reference product. It is under a billion dollar all over Europe.

Nimesh Mehta: You mean to say these two products are generating less than a billion dollar all over the world.

Rakesh Bamzai: We are talking about Europe, in Europe the classical insulins like recombinant human insulin is around $700 million.

Nimesh Mehta: And what would be the share of these two brands in that, any ballpark number would be helpful?

Rakesh Bamzai: There are three brands, there is regular insulin, long acting and mixed, and so all three put together is $700 million in Europe.

Nimesh Mehta: And there are how many players in Europe currently, which would account for 700 million.

Rakesh Bamzai: There are three players Novo, Lilly and Sanofi Aventis.

Kiran Mazumdar Shaw: If you look up any report, it will give you all the details that you are looking for.

Nimesh Mehta: Okay, fair enough, thank you.

Moderator: Thank you. The next question is from Ranjit Kapadia from Centrum Broking, please go ahead.

Ranjit Kapadia: My question refers to the tax rate. The tax rate has gone up from 18% to 25% despite the high R&D spend, so what is the reason for this?

Murali Krishnan: The one-off income which we received in the current quarter has been taxed at the full rate. Hence the effective tax rate has gone up.

Ranjit Kapadia: Thank you.

Moderator: Thank you. The next question is from Girish Bakhru from HSBC, please go ahead.

Girish Bakhru: Can you share the margin wise profitability in the contract research business. I see in the quarter particularly margins have improved significantly.

Peter Bains: At the EBIT level the margins in the contract research services are around 30-35%, being maintained consistently over two years and at the PAT level there are at high teens.

Girish Bakhru On the biosimilars front, given that Mylan has recently commented that they have started Phase-III for Herceptin in the global markets, what is the outlook there? I mean if you can give an idea of the filing timeline in the EMEA and the possible launch in Indian markets?

Kiran Mazumdar Shaw: Well, I think that these are just early days. I mean we have just started the global trials so it is too early for us to give you any comments and as per our agreement with Mylan, they will be able to comment on their commercialization timelines.

Girish Bakhru: Lastly on the Fidaxomicin front, there were some issues on the reimbursement of that product in the US market…

Kiran Mazumdar Shaw: No, there are no issues on reimbursement. I think what they have done is that they have decided to offer discounts to expand the market.

Girish Bakhru On the brand you mean to say…

Rakesh Bamzai: They have offered hospital discounts. Hospitals amounts to 25% of their overall market, so to get a higher penetration they have offered some discounts in the hospitals which are very small.

Girish Bakhru Alright thank you so much.

Moderator: The next question is from Sudarshan Padmanabhan from HDFC Securities, please go ahead.

Sudarshan Padmanabhan: There has been a 45% growth in your branded formulations business on not a relatively smaller base. Can you give a sense as to what is going to be the strategy going forward over the next two to three years., I mean even beyond the company reaching a certain level of base, how do we see the product launches on an annual basis and what kind of therapies are we looking at targeting going forward.

Rakesh Bamzai: I think we have stated in our previous calls as well, that branded formulations are going to be very strategic to Biocon's growth. We will continue growing aggressively in India and other emerging markets. Our strategy is to bring brands not only in India but also in other markets. We are expecting this growth to continue in years to come.

Sudarshan Padmanabhan: Thank you I will join back the queue.

Moderator: Thank you. The next question is from Bino Pathiparampil from IIFL, please go ahead.

Bino Pathiparampil: Just a follow up on the insulin data. When you continue the trial for the next six months, would you be looking at HbA1c also at the end of one year? Or would we be looking at only the safety end points?

Sandeep Athalye: The HbA1c end point was six months. The second part of the trial is solely linked to immunogenicity and safety, which are largely hypoglycemic events.

Bino Pathiparampil: So now the way it looks is, by mid-2014 we might file and by late 2015 or early 2016 we can potentially expect the launch. Is that correct?

Rakesh Bamzai: That is correct.

Bino Pathiparampil: And regarding this GE investment- is there any commitment in terms of time or return etc of an IPO or is it just like any other PE investment? Is it like a pre-IPO placement or is it just like a PE investment?

Kiran Mazumdar Shaw: Yes, there is a broad understanding that we will have an IPO in a certain timeframe.

Moderator: Thank you. The next question is from Surya Patra from Systematics Shares & Stocks, please go ahead.

Surya Patra: I wanted to know something more on the formulation front. Currently most of our efforts on the branded formulation front are in India. What is our thought process regarding the emerging markets and what initiatives have we already taken for the emerging markets. Are we generating any revenue out of the emerging market and what is the share of these markets in the current formulation business?

Rakesh Bamzai: As I said earlier, India is very important for us, currently growing at 45%. The next important market is UAE. We launched NeoBiocon in 2009 in UAE aimed at building brands. It is growing very well and we are going to scale it up to many markets in future. Today the share of the pie for the international bit is very small, but going forward you will see us reporting the international sales from branded formulations quite regularly.

Surya Patra: Okay are we going to do this via the partnership route in the emerging markets or will we be going through with our own teams there? What is the strategy going ahead and it seems that if we capture the emerging market well, then possibly the growth momentum in branded formulation would continue for a few years.

Rakesh Bamzai: Yes, we will have different strategies depending on the markets in concern. Our primary objective will be to capture value through our own teams but we also will have partnerships in few markets.

Surya Patra: Can you tell us that as far as branded formulations are concerned, which are the markets where we would be doing some activities in the very near term?

Rakesh Bamzai: We will launch products in markets such as Malaysia where we now we have a local presence. We will launch in other Asian, African, Latin American markets going forward.

Surya Patra: We have earlier talked about China and Brazil, so any progress in there sir?

Rakesh Bamzai: We will be in China through partnerships and in Latin America, we will have mixed strategies.

Surya Patra: Okay, Could you give some time line visibility on the completion of Glargine global Phase III trial?

Sandeep Athalye: Based on our current assumptions, we are targeting mid to late 2015.

Surya Patra: What is the CAPEX plan for the full year and next year and what portion of that would be related to R&D and how much would be on **i**nfrastructure?

Kiran Mazumdar Shaw: There are two aspects to capital investments. Our normal CAPEX is going to be around 150 Crores and we expect the Malaysian facility to also be accruing spends, so we will be spending close to another $100 million over a the next fiscal.

Surya Patra: Out of the 150 crore, what would be the mix between the R&D led CAPEX and the normal infrastructure led CAPEX.

Kiran Mazumdar Shaw: This is all infrastructure related CAPEX.

Surya Patra: Okay anything extra that we are doing on the R&D CAPEX?

Kiran Mazumdar Shaw: Well, Biocon Research Centre was the only CAPEX spend that we incurred in R&D, which is complete. There might be some small spends in buying equipment and in related areas but these are the annual kinds. The 150 Crores outlay will cover that.

Surya Patra: What is the investment plan for the MAbs? What is the kind of investment that we are targeting for the global clinical development per MAb or what is estimated for each MAb product?

Kiran Mazumdar Shaw: Please address this question to Mylan.

Moderator: Thank you. The next question is from Sachin Kasera from Lucky Securities, please go ahead.

Sachin Kasera On the domestic formulation, could you give some more insights on performance in key segments: what was the market growth, what is the type of market share we have gained, the number of MRs that we currently have, our productivity and plans on additional MRs going ahead.

Rakesh Bamzai: We have about 1650 people and we are still recruiting. The growth is happening across all the therapy areas within branded formulations. Majority of the growth is driven by Diabetology, oncology, immunotherapy and Comprehensive care divisions. We have a pretty decent market share in segments like Diabetology which has grown from 12% to 17% in insulin. In Glargine**,** it has grown very significantly. In certain oncology product segments, we have grown close to 40%. Further details are available in our IR presentation.

Sachin Kasera So does it mean that since we have got 40% in the category, it would be more likely be 20-25 with gains across the board, is that a right way of inferring it?.

Rakesh Bamzai: Yes.

Sachin Kasera Secondly, I think you mentioned in the previous call that you see the current growth sustaining this year, so we should be somewhere close to around 400 Crores. So do you think for the next two three years this type of growth is sustainable or now that we are on a higher base you would come and align more to the segment growth?

Rakesh Bamzai: We are putting strategies in place to see that this growth is sustainable and the key management of this company is very committed to this growth.

Sachin Kasera: This business has been in the investment phase in the last few years. In the last five – six quarters it has started to gain some critical size. So, what is the type of profitability we are seeing in this division? Has it started to contribute significantly to the overall profits of the company or is that still a year or two away?

Murali Krishnan: It is certainly contributing to the profits of the company. All the divisions have been profitable for the last two years.

Sachin Kasera Right but is it really closer to the company averages or it is still in…

Murali Krishnan: It is getting closer. Profit percentage is in double digits.

Sachin Kasera: Okay, but over a period of two – three years once you sustain this momentum, do you see those profitability improving and getting very close to the company average?

Rakesh Bamzai: I think it should cross the company's average.

Moderator: Thank you. The next question is from Sunil Rao from Sushil Finance. Please go ahead.

Sunil Rao: Could you elaborate on atorvastatin and Simvastatin market in the US as of now. Have you seen any price erosion on Simvastatin because of atorvastatin going off patent?

Rakesh Bamzai: The recently published reports indicate that the Simvastatin market has dipped a bit, but given the type of partnerships we have, we have a small growth in Simvastatin and we have maintained our market of atorvastatin. So, the atorvastatin market is growing and Simvastatin is also growing in single digits. We do not see de-growth in our portfolio in either of these two statins thanks to our partners who are doing a good job.

Sunil Rao: In the last con call, you had said that five of your US customers are awaiting approval. So, would that see any incremental atorvastatin supply going forward in the US market?

Rakesh Bamzai: Yes, we now have seven customers and these customers have not received approvals as of date.

Sunil Rao: Okay so you could see that coming in the due time?

Rakesh Bamzai: Yes that is correct.

Moderator: Thank you. The next question is from Nitin Agarwal from IDFC Securities, please go ahead.

Nitin Agarwal: Kiran, Given that the launch of recombinant insulin in Europe is pretty much like an FY16 possibility, what do you see as the primary drivers for the biopharma business over the next couple of years?

Kiran Mazumdar Shaw: I see insulins as a huge global opportunity where emerging markets are going to be a very important market for us. We believe that emerging markets could be a much larger opportunity than even Europe and US. It is a low hanging fruit for us. We are already gaining a lot of traction in many of these markets. We believe that at least for the next two years till the Malaysian facility comes on stream, we will actually be constrained in terms of addressing these large market opportunities. However, once Malaysia comes on stream we believe that we will have a very large upside in terms of further penetrating this market. So, overall I think insulin

is going to be a business where U.S. and Europe are going to be important from a regulatory approval point of view but the real market opportunity for us is going to lie elsewhere.

Nitin Agarwal: And when do you see the tipping point coming as far as scale up in these emerging markets are concerned, because the emerging markets story clearly has been there for a while for most of the players including ourselves, but it hasn't quite been tapped by anyone as such.

Kiran Mazumdar Shaw: I think we are making good progress in some of these markets. Today we enjoy a very good market share in many of the key emerging markets. In fact our insulin sales have more than doubled since last year and I think this actually has given us a lot of confidence that our product is very well accepted in these markets. We have recently introduced cartridges and pens in some of these markets so that's also going to grow our business in these markets. And we think that the real opportunity for us is going to kick in when our Malaysian facility is ready because we are constrained by our capacity in India.

Nitin Agarwal: Right. The insulin formulation sales would be 10% - 15% of our biopharma sales or would that be like a higher number.

Kiran Mazumdar Shaw: It will be over 10% of our biopharma business.

Moderator: Thank you. The next question is from Kartik Mehta from ICICI Securities, please go ahead.

Kartik Mehta: I just wanted some update on the competitive scenario on the insulin portfolio in India in terms of the market share and pricing. How do you think it would actually shape up over the next two years?

Rakesh Bamzai: In the Indian space, we have Wockhardt, Biocon, Novo, Lilly, and Sanofi Aventis. I can say that we are the fastest growing insulin company in India. Biocon has registered a growth of 33% against our competitors, who have grown in range of 5% to 29%, so that is a good news and we continue to grow with this and our overall ranking is fourth in the insulin market.

Kartik Mehta: And third in insulin.

Rakesh Bamzai: Third in 40 IU insulins.

Kartik Mehta: In terms of the pricing, do you see any action by the Indian competitors which can realign some of the market shares in insulin.

Rakesh Bamzai: Pricing is a matter of discussion. We want one price for this country. Biocon's insulins are under price control (DPCO) thereby we get lesser price from the NPPA than our competition, so we have always supported the argument of one price for one country.

Moderator: Thank you. The next question is from Bharat Sheth from Quest Investment, please go ahead.

Bharat Sheth: Madam, you were talking about capacity constraints that we are facing, so how much growth are we losing because of that capacity constraint.

Kiran Mazumdar Shaw: Well, we are not losing the opportunities right now. Currently we are supplying all that we can to these markets but I think as we grow further, there could be a shortage in terms of the ability to supply by the next year or the year after. We are therefore making sure that our Malaysian facility will actually allow us to address those increasing demands.

Bharat Sheth: We have spoken earlier about the benefits that will be available to our Malaysian facilities. So how will that change our profitability landscape once that facility is on stream and how much it will be cost competitive compared to what we have in India?

Kiran Mazumdar Shaw: It is quite comparable. We will get some advantage and it will reflect in our profitability.

Bharat Sheth: So, on a scale of 100, I mean how much…

Kiran Mazumdar Shaw: We can't be disclosing this kind of information as it is competitively sensitive.

Bharat Sheth: When are we likely to see that facility up for production?

Kiran Mazumdar Shaw: 2014 is when we expect to get the operations up and running.

Bharat Sheth: 2014 calendar year FY14?

Kiran Mazumdar Shaw: Calendar year.

Bharat Sheth: Okay so it will be effectively be our FY15

Kiran Mazumdar Shaw: Yes.

Moderator: Thank you. The next question is from Krishnendu Saha from Quantum AMC, please go ahead.

Krishnendu Saha: How do we see Material and R&D spends going ahead; because as a percentage of revenue, material is at 63% and R&D is around 7%?

Kiran Mazumdar Shaw: R&D is a reflection of how well our programs are advancing and, as you know unlike the generic sector which does not have to invest in clinical development, we are a business that has to necessarily invest in clinical development. We are an outlier there and the more we spend on clinical development, the more it reflects the advances in our program. So, I think you should take it as a positive and not as a negative. If we decrease our R&D spend, I think that would be a cause for concern.

Krishnendu Saha: That is where I am looking at. Just to get a flavor, should we see the current quarter run rate as of something which is like free run rate for the next two years or one year.

Kiran Mazumdar Shaw: If you understand clinical development, I think Phase-III is the most expensive part of clinical development. Right now, the only program in Phase-III clinical trials is the recombinant human insulin. Now, once we start the phase III trials for Glargine and other products, you can imagine the investments will go up, but you have to basically see this as a positive.

Krishnendu Saha: Yes, I get that part. I am just trying to figure out how much cost should we associate …

Kiran Mazumdar Shaw: It will increase and I think what is important for me to point out is that Biocon's business is growing in such a way that we can actually sustain and afford this increasing spend in R&D. I think that is how you should be viewing Biocon- this is a company that has a strong balance sheet, capable of internally financing its key R&D spends, creating licensable assets in the process and then growing its business in the future.

Krishnendu Saha: You will be able to fund your R&D via internal only right.

Kiran Mazumdar Shaw: Yes, we have been doing it all these years and we will continue to do it.

Krishnendu Saha: And the last question is on your study which was done in Europe. It shows non-inferiority of HbA1c, so in a layman's point of view non-inferiority means as equal or even better?

Kiran Mazumdar Shaw: You cannot say it is better. In bio similarity you only want to make it comparable which means that if the innovator product reduces HbA1c by x, our product has also reduced it by x and that's what we call is comparable; which means that the product is the same or similar to what innovator product is.

Krishnendu Saha: what I want to understand is could the results have been better or it is just the same.

Kiran Mazumdar Shaw: The trial is about comparability. You just want to meet the comparable data and that is what it is required by the regulators. There are products called Biobetters and then there are biosimilars. So, it is only when you are trying to develop a Biobetter product that you want to demonstrate superiority.

Krishnendu Saha: Okay fair enough. I was trying to understand the HbA1c was supposed to reduce about 6.5 or 6 for your product and innovator was around the same mark or have you done better than that, just trying to understand that part.

Kiran Mazumdar Shaw: What we want to show is, statistically on an average, what the innovator's HbA1c was and what our HbA1c are. The trial is being done on Type-I patients who are very sensitive to insulin therapy and I think if you can show comparability on Type-I patient it is very, very good data to showcase.

Krishnendu Saha: And these trials were done in controlled form and everything.

Kiran Mazumdar Shaw: When you do clinical trials it has to be done in controlled conditions otherwise it is not called a clinical trial. This was done in Europe at leading investigation sites under very controlled conditions especially given that we were working with Type-I patients.

Moderator: Thank you. The next question is from Monica Joshi from Avendus Securities, please go ahead.

Monica Joshi: Just one follow-up question on the Simvastatin market. You had mentioned earlier in your comment that the market has shrunk but you are seeing a small increase in revenues is that correct?

Rakesh Bamzai: Yes, that is correct. We continued doing well because our partners have good market share.

Monica Joshi: Are you seeing the end product volumes actually shrinking or not?

Rakesh Bamzai: See this is the generic market. When a new drug like Atorvastatin is launched, it will have some impact on the existing product which was Simvastatin in this case. However, the drop in Simvastatin is not drastic- this is small drop; and in the last six months, we have gradually grown on Simvastatin.

Monica Joshi: So, you have increased your market share.

Rakesh Bamzai: That is true.

Monica Joshi: Can you give us a ballpark number on your share in Simvastatin API currently?

Rakesh Bamzai: Because of competitive reasons we cannot share it here, but we have a very good market share in all the statins, wherever we represented in US and Europe.

Moderator: Thank you. The next question is from Harish Swaminathan an individual investor, please go ahead.

Harish Swaminathan: I just have one question on our two novel drugs which are ready for out licensing: IN-105 and T1h. So, I think in January 2011 we had the data on IN-105, so it is now about 18 months to 20 months and in T1h, my understanding is that we had the data for about 10 months or so. So, if you can help me to understand as to what are the specific challenges that you are facing in out licensing it? Is it that some work is happening on the data front, so that a layman like me can get an understanding as to what is it that is delaying us from out-licensing. We have already spent about 20 months post the data has come in.

Arun Chandavarkar: I think the challenges are the challenges that relate to out licensing of any novel program. If you look at what we have out licensed successfully so far has been largely our biosimilars: we had out licensed our biosimilar insulins to Pfizer, we had out licensed MAbs to Mylan. We also have out-licensed biosimilars in certain regional markets. When it comes to novel

molecules, the out-licensing depends on the risk appetite that the partner wishes to take, the stage of clinical development, the disease segment you are trying to address, the competitive space in that disease segment, the price points at which the therapy would make sense to patients depending on whether there is an unmet need and how significant that unmet need is. So, when you look at unmet needs, diabetes is well addressed in terms of anti-diabetic injectable insulins. However if you view the oral insulin program as merely another anti-diabetic program then it might be perceived as been challenging but if you view it as revolutionizing diabetes treatment in terms of a liver targeting insulin and which is a concept that needs to be explained at length to potential partners it takes time. So, repositioning of diabetes is one thing. If you look at T1h or anti-CD6, anti-CD6 is not just novel molecule; it is a novel target so when you are talking about discussions on novel targets not just novel molecules it does take time. Hence out licensing of novel program is very different from out licensing of biosimilars because in biosimilars the out licensing model is largely upon finding a commercial partner whereas in out licensing of a novel program, it is not just finding a commercial partner but a partner who is going to take on the responsibility and do justice to several multiple pivotal trials. Unlike biosimilars, where you might do just one pivotal trial, for a novel molecule you might do three or four pivotal trials to get approvals.

Moderator: Thank you. The next question is from Purvi Shah from Dalal & Broacha, please go ahead.

Purvi Shah: I needed a clarification on the tax rate going forward and also if you could repeat the reason for increase in the tax rate.

Kiran Kumar: On an annual basis, it should be somewhere around the MAT rate or marginally above that at 19-20% .As explained earlier, in the current quarter the tax has marginally gone up due to a one-off income which was recognized and taxed at the 30% rate, but on an annualized basis we should be around MAT levels.

Purvi Shah: I understand that Sanofi has also come up with its reusable pen. So how are we seeing the competition in this segment?

Rakesh Bamzai: We are aware that Sanofi has launched a new pen. Our pen is the best in class and very patient friendly. Physicians have appreciated the use of INSUPen in the market. We feel that the quality of our pen is much better and the patient care, support and services that we give to the patient and to diabetes as a disease in India is enormous. So we feel that we have a competitive edge there and the overall therapy cost to the patient is lowest in the country.

Moderator: Thank you. The next question is from Meeta Shetty from Asia Market. Please go ahead.

Meeta Shetty: Just wanted some clarification. You mentioned that the CAPEX for the year would be at 150 Crores.

Kiran Kumar: That's right.

Meeta Shetty: And how much of that would be going towards the Malaysian plant.

Kiran Kumar: No that is all for India and excludes Malaysia.

Meeta Shetty: What is the CAPEX that will be incurring for Malaysia this year?

Murali Krishnan: Nothing substantial during this fiscal, but in the coming fiscal it will go up.

Meeta Shetty: So, this year we are not having any major CAPEX for Malaysia is that right.

Murali Krishnan: Being the 1st year of the project, there will be some capex spend, may be about 20% of the estimated amount.

Meeta Shetty: Just a bookkeeping question. The reported cash has gone down by about 180 Crores and our other non-current assets has gone up so I just wanted to understand what nature of that non-current assets are.

Kiran Kumar: The cash has gone down because of 116 Crores of the dividend payout that happened in July and the non-current assets constitute certain investments made for a slightly longer tenure...

Meeta Shetty: Lastly, the branded formulation basket of around 350 Crores that we will have by this year, how much of that is contributed by insulins?

Rakesh Bamzai: Close to 50% would be the insulin franchise.

Meeta Shetty: That is 50%?

Rakesh Bamzai: That's correct.

Moderator: Thank you. The next question is from Bhavin Shah from Dolat Capital, please go ahead.

Bhavin Shah: Thanks for taking my question again. Just to recheck will there be any dent in the momentum in branded formulation, if the pricing policy goes through? It is probably premature for me to ask this, but just wanted to check over it.

Kiran Mazumdar Shaw: I think the government had created a lot of confusion by talking about banning branded formulations. But now I think they have clarified saying that companies can market branded formulations and I think what they are looking at is some kind of market weighted average pricing so I do not think many of our brands will really come under this particular purview.

Moderator: Thank you. The next question is from Ravi Agarwal from Standard Chartered, please go ahead.

Ravi Agarwal: Kiran you were talking of ROW markets for rh insulin, just wondering do you take this data which you are generating out of Europe for the ROW markets and then look at approvals or are these two independent tracks as far as getting approvals are concerned.

Rakesh Bamzai: See, we have the first wave countries which we have reported in last call that we are registered in and there are also lots of markets under registration. In the last call we had mentioned 32 approvals of insulin across the world. Now the number has gone up to 42 and we now have 30 countries under registration. So, all these approvals are based on the clinical data that we generate in India. Then we will have wave two countries where European data will be used and the US data will be used and we will get more approvals. So, the market is going to grow constantly based on the data that we have right now and when we have EU data it is going to further grow.

Ravi Agarwal So, realistically outside India what could be a fair timeframe to expect some meaningful revenues to start coming from the formulation side of insulin?

Rakesh Bamzai: We have plans in place to see that we get approvals. After approvals, it takes around 6 -12 months to launch the product in that country so we have plans in place and in next two to three years you will see this quite significantly in our balance sheet.

Ravi Agarwal: And essentially what I understand is that rh is essentially 2015 roughly in Europe and Glargine is one year after that. Is that the correct understanding for this?

Rakesh Bamzai: Yes that is correct.

Ravi Agarwal: Any plans for rh insulin for US- is there anything we are looking at doing there or it is just not there in our…

Kiran Mazumdar Shaw: We are planning to address that market as well.

Ravi Agarwal: But would it be through some 505(b)(2) route or are you waiting for some guidelines to come on this.

Kiran Mazumdar Shaw: We have certain plans but at this point in time we will not be able to share it with you.

Moderator: Thank you. The next question is from Sachin Kasera from Lucky Securities, please go ahead.

Sachin Kasera: Just one question on this private equity deal that we have done. Considering the fact that the company is already generating profits in high-teen on the reserved side, is it that we are looking at accelerating the growth because I would believe that the internal accruals would have been sufficient to fund the type of growth that we are doing. So, are we looking at accelerating the growth on the Syngene and Clinigene?

Kiran Mazumdar Shaw: Well, there were many objectives to this investment. One was to establish a benchmark valuation, by unlocking the base line value of Syngene which was getting masked by the overall group valuation under Biocon. It is the first step of preparing for a listing. The second objective was to accelerate some of our expansion with new differentiated services.

Sachin Kasera One broad question ma'am, if we see in 2004, when we had launched the IPO on a 200 – 250 Crores type of gross block we used to report 500 – 600 Crores sales, our gross block has gone up around 10 times in the last eight years, whereas our sales have gone up five times. Our gross block-to-sales ratio has come down. Is it because we have invested significant amount of capital in terms of capacities, and are waiting for certain approvals? So, over a period of two – three years when we start getting all these approvals, this ratio will become much better going ahead?

Kiran Mazumdar Shaw: Well, certainly our gross block has not kept pace with our original ratio largely because some of these investments are gestational in nature unlike the other generic sector. Hence it takes a little longer to payback. As we have already told you, the true kickers will take place around the 2015-2016 timeframe. In the meantime our growth trajectory is improving through some of the businesses where we have been investing like branded formulations and research services, which are beginning to deliver. This was a commoditizing business; it has now really started looking up and beginning to grow very robustly. We have had a similar experience even in Biocon where if you remember we had invested a significant gross block in statins and then the statins commoditized, so we quickly had to re-orient and get into other sectors which were not commoditizing. It is a question of adapting to what happens in the market place and taking corrective actions.

Sachin Kasera:I think what was mentioned on the call earlier is that you believe the emerging market's insulin opportunity could be as large as US and Europe, I think you also mentioned that there are 32 countries where we have already registered and 38-40 is in progress. What is the overall market size for these 65-70 countries and what is the type of growth rates we are experiencing and if you could highlight some two or three key markets which are fairly large amongst these 65-70.

Rakesh Bamzai: So, out of these 65 countries, the key markets for us in LATAM are Brazil and Mexico. We have Russia, Middle East, North Africa & South Africa, Turkey, China, Korea, and Indonesia. We believe that the size of this particular market opportunity for the insulin business alone is around a billion dollar. It's a very attractive opportunity which we believe that we can actually address in a very significant way.

Sachin Kasera: You had mentioned that insulin revenues were around 10% of biopharma revenues and that is excluding the India insulin sales which are approximately…

Kiran Mazumdar Shaw: Yes, excluding India. This is just exports.

Sachin Kasera: On the India insulin market, is it that the new patients form a market share much higher than the overall market share, is that a fair assessment?

Rakesh Bamzai: The new patients' growth rates are much higher and we are also seeing around 15% to 20% of the patients switching from their old prescriptions to the new prescriptions of Biocon.

Moderator: Thank you. As there are no further questions from the participants I now hand the conference over to the management for closing comments.

Kiran Mazumdar Shaw: Thank you for participating in this conference call and if there are any further queries or clarifications, please do not hesitate to contact my colleagues Murali Krishnan, Rakesh Bamzai, Kiran Kumar, Peter Bains and Chinappa. Thank you very much.

Moderator: Thank you. On behalf of Biocon Limited that concludes this conference call. Thank you for joining us and you may now disconnect your lines. Thank you.

Note: This document has been edited to improve readability.