



*Biocon Limited presentation delivered at the 30th Annual J.P. Morgan Healthcare Conference on 01/09/2012.*

Jessica Fye: Good morning everyone. I'm Jessica Fye from the pharmaceuticals team at JP Morgan. We are very excited to be kicking off the conference this morning with Biocon's presentation. Just a reminder, after the presentation, questions will be entertained in the Sussex Room. We have Dr. Kiran Mazumdar-Shaw, Chairman and Managing Director of Biocon presenting for the company. Thank You.

Kiran Mazumdar-Shaw: Thanks, Jessica. Good morning ladies and gentleman. I'm Kiran Mazumdar-Shaw, founder of Biocon. And it's a pleasure for me to speak about the key developments at our company in the year gone by. Let me start with our stated mission of leveraging India's low-cost innovation base to deliver affordable drugs for chronic diseases in the global markets, which we would like to strategically develop through research and marketing partnerships. Today, we are recognized as Asia's largest biopharmaceutical enterprise and amongst the lowest cost producers of Statins, Immunosuppressants, Insulins, and Monoclonal Antibodies. Our track record as a biopharmaceutical company spans little over a decade during which we have carefully shaped our business into five growth verticals, which I will speak about today. We believe that this will collectively help us deliver a sustainable 20% CAGR over the next five years. Over the next 25 minutes, I would like to focus on some of the key highlights of our business that we believe are growth drivers for the future. So let me start by discussing the five growth verticals that I just mentioned. The first of these verticals is what we call our small molecules business vertical, and this encompasses our historic APIs business including Statins, Immunosuppressants and several other APIs. The vulnerability of our APIs business to commoditization as well as shrinking margins is making us strategize to move up the value chain through 505b2 filings and some select ANDAs, which we hope to integrate all the way back to APIs. This, we believe, will help us front end our business with significant value addition.

The second growth vertical is our biosimilars vertical, which essentially encompasses our biosimilar insulins and our biosimilar biologics. These have been partnered, as you know, with Pfizer and Mylan respectively. We believe that 2016 will see the advent of multiple biosimilars in the formularies in the U.S. and Europe, and we expect to be amongst the front runners in both the biosimilar segments. Biosimilars in emerging markets, we believe offers a sizeable opportunity in the near to mid-term and this is what we hope to focus on in the interim until we get into the more

developed markets. When you look at the global opportunity for biosimilars, in the insulin space by 2020, it is estimated to assume a size of \$20 billion. And the opportunity that we are addressing has to be dimensioned in terms how large it would be for biosimilar insulins. In terms of the biologics market, again, we believe that this is going to be a very compelling opportunity, probably comparable to the same size that we are looking at for insulins.

Going back to our growth verticals, the third growth vertical that we are focused on is our branded formulations business. This is, at this point in time, an India-centric business where Biocon's brands are rapidly rising to market leadership positions in key therapeutic segments namely Diabetes, Cardiology, Oncology, Nephrology, Dermatology, and Immunotherapy. As you can see, these reflect our strengths in statins, antibodies, insulins, and Immunosuppressants. The Indian pharmaceutical market is a very exciting market, and I would just like to share some market indicators that have been reported by McKinsey. The market is expected to grow at a CAGR of 15% over the next 10 years and quadruple to a size of \$55 billion by 2020 from a 2010 market size of \$12.6 billion. The chronic therapy segment, which we are focused on, represents only 25% of the market at this point in time but what is interesting is that it is outpacing the acute segment. The growth pace of the chronic segment is 21% versus the acute segment's 16%. The 2020 forecast, of course, is based on the assumption that 650 million people will come under the insurance umbrella in India and an additional 100 million people will be added to the middle and upper income strata in India, but these are very interesting indices that we are watching very carefully.

The fourth vertical is our very exciting novel molecules vertical. Our pipeline continues to advance. Our anti-CD6 Monoclonal Antibody Program that I mentioned last year, has just completed a large phase 3 double-blinded placebo-controlled Psoriasis trial on more than 200 Indian patients, and I will be sharing some first cut data, which looks most promising. I will also be presenting some very exciting early data on a Bispecific fusion antibody in our drug pipeline.

The fifth vertical is our very robust and rapidly growing research services business. This has been delivering a 25% top line growth. We have also seen a very strong improvement in our PAT from a break-even last year to a PAT of \$5 million in the first half of FY12 on a comparative basis. Our integrated approach to our research offerings has seen us enter into several large long-term research contracts. These are large customers and as and when possible, we will be sharing updates on these large partners.

We believe that these five verticals will enable us to deliver on our targeted five-year CAGR of 20%. Moving on to our interim strategy, this is based on how we propel all these growth verticals based on emerging markets. Emerging markets are very important to us. As you can see from the slide, while U.S., Europe, and Japan account for 74% of the current \$850 billion global pharma market, they are being outpaced by the Emerging Markets largely LATAM and BRICTM, which

are growing at 13% to 15% per annum according to IMS. These markets are expected to grow from \$220 billion today to an aggregate market of \$400 billion, representing almost 40% of the global pharma market by 2015. Biocon's business strategy is therefore focused on expanding its presence in these rapidly growing emerging markets through strong regional partnerships. In terms of market segmentation, the lower entry barriers posed by emerging markets have allowed the strong penetration of generics and in recent times, biosimilars. If I look at each one of these segments starting with generics, which is a fiercely competitive segment, it is estimated to double in size from the current \$155 billion to \$320 billion by 2015. This is largely attributed to the increasing purchasing power of developing nations, coupled with greater government and WHO-sponsored health care expense. Biosimilar insulins are estimated to assume a size of \$5 billion by 2020 in these Emerging Markets. Biocon is already a key player in this segment in several emerging markets through strong regional alliances. In India, we continue to remain focused on key branded insulins, which are doing very well for us. Up until now, our brands, Insugen and Basalog were restricted to a vial segment but the recent introduction of our reusable insulin delivery device, INSUPen, has now enabled us to compete across vials and cartridges and thereby enabling us to grow our presence in India. Additionally, Pfizer has recently launched our insulins in the Indian market under its brands and collectively we believe that we will be making a significant impact on the insulins sector in India. In terms of biosimilar biologics, the current size of the biologics pie in the Emerging Markets is about \$5 billion, but is largely dominated by innovator products. Trends indicate that penetration of these markets with biosimilars will accelerate at a rapid pace as will homegrown novel biologics. EPO and GCSF, for example, are already seeing a 60% penetration in several emerging markets, overtaking innovator brands; and we believe that monoclonal antibodies, vaccines, and growth factors are expected to present substantial opportunities by 2020. In terms of our own presence in Emerging Markets, we are present in over 70 countries with a portfolio of more than 100 products. And what is very important for me to mention here is that our emerging markets business now contributes over 50% of our revenues from 37% just a few years ago. And most of our focus is on LATAM, Middle East, North Africa, and South East Asia.

Turning now to our novel programs, I would like to highlight some of the potentially high-value programs that are in various stages of development. As this table indicates, our research pipeline remains robust and continues to advance in the clinic. I'm pleased to announce that since my last presentation at JP Morgan, a U.S. IND has been filed for our partnered program with Amylin, which is a hybrid peptide molecule targeting obesity and diabetes. We remain very committed to our oral insulin, IN-105 Program, and we are in discussion with potential partners to advance this asset to commercialization. Today, I would like to focus on two programs, which have advanced significantly over the last year. The first is Itolizumab. Itolizumab is a first-in-class molecule against a novel target, which is anti-CD6, which is predominantly expressed by T-cells and a

subset of B-cells. So, it is a humanized anti-CD6 monoclonal antibody, which we are evaluating for its indication in autoimmune diseases like psoriasis, RA, MS, etc. The study that we have just completed is a phase 3 study conducted in India with a patient enrollment of 223. The trial duration was 52 weeks and what I will be presenting right now is interim data of 28 weeks. Just to remind you, the study was designed as a double-blinded, placebo-controlled, randomized, multi-centric, multi-dose, parallel arm study. The first arm basically involves a low-dose induction arm followed by a fixed dose medication for 12 weeks. The second arm involved a fixed dose weekly dosing for 12 weeks. And the third arm was a placebo arm. The primary endpoint was assessing PASI 75 scores at the end of 12 weeks. Post the 12-week period, there has been a crossover study in terms of the placebo arm, which was then put on a biweekly fixed dose of Itolizumab while the other two arms received monthly fixed-dose Itolizumab. The 28- to 52-week dosing cycle was a maintenance dosing cycle once every three months. What is very exciting is the fact that we have seen statistically significant data on PASI 75 scores at 12 weeks over placebo. We have seen significant proportion of subjects meet secondary endpoints as well. And what is also very important is that the safety and tolerability profile was extremely good in all patients. In addition to the PASI scores, the PGA scores also provided a separate confirmation of the efficacy of this drug. As you can see from this particular slide, the 12-week data clearly showed statistically significant response compared to the placebo. Further proof of the drug's effectiveness is shown by the continued improvement in efficacy from 12 to 28 weeks in the drug arms. It is also important for me to mention here that the cohort of placebo patients, who received the drug after week 12 showed significant PASI 75 response. And what was also noted during the study was that PASI 75 response was greater in patients with more severe disease with baseline PASI scores of over 20, and this group actually showed a PASI response of 54% at 28 weeks compared to the overall group that had a response of around 44%. I would also like to share images of some of these patients. As you can see, Itolizumab appears to show vast improvement once the patient began treatment. another very key important point I would like to just highlight here is the fact that the opportunistic infection rates in patients who were put on Itolizumab treatment was relatively low around 10% compared to 30% to 40% reported with other biologic agents. This alone, we believe, will provide a significant opportunity for patients suffering from this disease. And considering the fact that this trial was done in India, it is very good data indeed in terms of opportunistic infections. At the present time, we are in the process of analyzing this and other differentiating aspects of our drug from the trial. So, the overall conclusions are that this is a first-in-class therapy with a novel mechanism of action with an excellent safety profile. We have successfully achieved primary endpoint of PASI 75 at 12 weeks and with continued improvement in efficacy over time. Very low infection rates, which are a good differentiator for this product; and the promising preclinical and clinical efficacy data in other autoimmune diseases namely RA and MS is going to see us conducting future clinical trials in these indications.

Moving over to our other very exciting novel program, which is in the area of bi-specific fusion antibodies, these are bi-specific, targeted immuno-stimulatory antibody fusion proteins designed to target the tumor and stimulate antitumor immunity. What it also does is circumvents tumor-induced immune tolerance. A large portfolio is under development to target a wide array of human cancers. What I would now like to show you is some preliminary data on our first molecule that we hope to take into the clinic late this year. What you see in this slide is a graph that depicts tumor volume in three groups. The group of mice on the extreme left is an untreated control. The middle group has been treated with a commercially available antibody. And the group on the right has been treated by our fusion antibody, BISB. As you can see, there is significant effect retarding the growth of the tumor in the experimental mice on BISB. Of course, I must mention that these studies were conducted without the use of chemotherapy or radiation. And we believe that there could be some very interesting synergistic action in combination with BISB using chemo, radio, or both.

In conclusion, I would just say that our novel programs portfolio continues to be robust and shows promise; and we hope to see continued growth and successes in this particular vertical. Now, coming to the research services, this is, as I mentioned, a very important growth driver for us. With R&D productivity continuing to disappoint, companies are being forced to curb research investments. Externalizing R&D to cost-effective research hubs in Asia is allowing companies to curb research spending without shrinking R&D pipelines. And this trend is seeing research services move from a fee-for-service business model to more sophisticated integrated offerings. It's important to mention that Biocon is a pioneer in the research services segment in Asia and is recognized as Asia's longest established contract research services company. Syngene and Clinigene are now entering their 17th year of operations. We have a team of over 1500 scientists with over 300 PhDs being represented in the scientific population. And what's important is that we are India's largest concentration of life science scientists at a single site. We cater to a diverse array of customers from big pharma to virtual biotechs and small startups. We also cater to other sectors such as the consumer products, nutritional, agri, and even electronics. What we have done over the years is really to build an evolving partnership model that basically started from a component and cluster play, which is fee-for-service kind of models that are more tactical to an integrated play offering end-to-end services, which are more strategic such as the one we have with Bristol-Myers Squibb where we have a large dedicated research hub that can actually develop entire programs, and create pipelines for companies like BMS away from their main research centers. And then finally, we have now got into a more innovative research business model, which really looks at an incubative play, which is about sharing and creating IP, which will also potentially give us a higher upside in this particular model. As I mentioned earlier, Syngene and Clinigene have really generated some robust growth. We have a three-year CAGR of 24%,

EBIDTA margin at around 30%, with strong cash flows and a very healthy balance sheet. On the financial highlights of the Biocon Group as a whole, we have delivered a very strong top line growth of 19% three-year CAGR as I mentioned, largely driven by growth in the Emerging Markets. And this, we believe, will continue to enable us to drive a 20% CAGR as we go forward. Our EBIDTA margin has been sustained very effectively at the 30% level by efficient cost management. The PAT margin has been strong at around 20%. We have a very strong balance sheet, not leveraged, and the company is net cash positive. So, all these work very well for us as we go forward especially given the fact that we are investing increasingly in developing novel biologics as well as biosimilars and other 505b2 initiatives in the future.

To conclude, I would like to talk about these near-term growth drivers and remind you once again of the opportunities for Biocon. We will out license our various assets both novel biologics and other innovator programs in the biosimilar space as well as in small molecules to unlock value for the company going forward. We will continue to leverage our research services with differentiated offerings and hope to drive very strong growth as a result. Our focus on Emerging Markets through regional partnerships, we believe, will drive very, good growth for us. We will enhance our brand equity in domestic markets and in select emerging markets as we go forward. And as I mentioned in the small molecules vertical, we are moving up the value chain with 505b2 filings and ANDA filings in a very selective manner. With that, I want to thank you for your attention and to assure you that Biocon is very excited about its growth prospects and the various verticals that we have focused on in terms of helping us drive growth and create much better quality of earnings. Thank you.



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