



Biocon Limited presentation delivered at the 29th Annual J.P. Morgan Healthcare Conference on 01/10/2011.

SPEAKER 1: Good morning, everybody. My name is Jessica Fye on the pharmaceuticals team at J.P. Morgan. We are very pleased to be introducing Biocon. From Biocon, we have Kiran Mazumdar-Shaw, the Chairman and Managing Director.

SPEAKER 2: Thanks, Jessica. Before we start, I'd like everyone to observe a minute of silence because President Obama has asked the nation to observe a minute of silence for the tragedy in Arizona, so may I ask everyone to stand up for this? Thank you. Good morning, everyone. I'm Kiran Mazumdar Shaw, chairman and managing director of Biocon and it's a pleasure for me to speak about key developments at our company since my introductory presentation at last year's J.P. Morgan conference. I'd like to start with a very important key growth driver that we had identified last year, which are the emerging markets. Emerging markets, as you know, are forecast to have double-digit growth for the foreseeable future. Given the fact that two-thirds of the world's patient population reside in these regions, it is certainly very logical why these estimates are the way they are. Having said that, we must recognize that although emerging markets are large and offer great opportunities for growth, these are complex and very price-sensitive markets as well. So what you are seeing today is that 70% of drugs being marketed in these regions are generics. It is interesting to also note the impact of rising affluence and medical advancements that are taking place in these markets which are creating unprecedented demand for newer drugs and therapies at international price points. Also, changing lifestyles and improving life expectancy is leading to a greater incidence of chronic diseases. Therefore, it is a very dynamic evolving space which is why the whole pharmaceutical industry is backing emerging markets as the next growth potential and growth driver for the sector. Compare this with what is happening to the mature markets of the developed economies and it is a slightly different story. Growth in these markets is sub 5 percent levels. These markets are challenged with spiraling healthcare costs and there is a strong demand for reducing healthcare spends and, obviously, there's a lot of pricing pressure on drugs as well. If you look at what's happening in these developed economies, prescription rates of the generics is going up, but as a value proposition, it is a much smaller part of the whole market. Nevertheless, I think both the developed and the emerging economies are rooted in a philosophy of affordable healthcare. So that's something which, we as a company based in India, are very cognizant of, and it is against this backdrop that we have set ourselves a mission of being a global biopharmaceutical enterprise committed to delivering affordable

products and services for patients, our partners and healthcare systems across the world. And our strategic intent in achieving this mission is to reduce therapy costs of chronic diseases with generics and biosimilars. We seek research and marketing partnerships that provide global access, and we are also leveraging India's cost and clinical base to deliver a high potential research pipeline of high value, licensable R&D assets. So, over the next 20 minutes or so, I'd like to focus on some key highlights, especially with reference to our partnerships and our research pipeline that we believe are our catalysts of strong growth for the year ahead.

I'd like to start with our product pipeline. It is important to mention here that our approach to developing products has been a portfolio approach. I must remind people that, although Biocon is 30 years old, our biopharmaceutical history is only about a decade old. And over the past 10 years, we have successfully developed comprehensive portfolios of statins and immunosuppressants as generic APIs in the small molecule space and this, I'm pleased to say, has contributed to 75% of our revenues and delivered a very good and sustainable 5-year CAGR of 24%. The path ahead in 2011 is to expand our small molecule portfolio to prostaglandins and peptides. We are very selective about the portfolios that we choose, and we hope to move up the value curve from APIs to dossiers, especially in ANDAs as we believe that this approach will drive much higher value growth for us in the year ahead. Our approach in large molecules has been, again, a portfolio approach where we have focused on 2 broad portfolios; the first of them being insulins, which includes recombinant human insulin and insulin analogs, the second portfolio is around monoclonal antibodies. In the large molecule space, however, we have chosen to straddle both biosimilars as well as novel programs as a risk-balanced strategy, where we believe that the novel programs have the potential of giving us pretty large upsides, if successful. Our portfolio approach, I'm pleased to say has yielded good financial returns and has allowed us to forge very strong partnerships.

Moving to partnerships, we have always believed that partnering is very strategic to our business philosophy and in fact, I believe that we are entering a decade of strategic partnering. Today, I think it is resource sharing and risk sharing models that are the only way forward to fix Big Pharma's broken innovation engine, and I believe that Biocon is very pleased to be in this particular space. We have sought both research and marketing partnerships as a way to access global markets and as you can see from the slide, we have some very key strategic partnerships, which I would like to briefly allude to. The most visible and high-profile partnership that we recently announced was with Pfizer to commercialize our insulins portfolio which, to us, is going to be a very important growth driver in the foreseeable future. Similarly, a year ago, we announced a partnership with Mylan for the development and commercialization of a basket of monoclonal antibodies as biosimilars. In addition, we have some very key strategic research partnerships with Amylin, Vaccinex, the Center for Immunology in Havana, and IATRICa, and

these include a hybrid peptide, which is a molecule that we are developing with Amylin for diabetes and some very interesting monoclonal antibody programs as well as fusion monoclonal antibodies with the others. What really makes this whole partnering opportunity very special for us is the fact that we can develop all these programs using and leveraging India's cost and clinical base in a very cost-effective manner, and we are then able to take them first to the emerging markets and then on to the more regulated markets as the programs advance.

Now I'd now like to spend some time on our insulins business which is a very important partnership with Pfizer. Industry reports indicate that the insulin market is currently valued at about 13 billion dollars and is estimated to grow to a size of 20 billion dollars by 2020. The insulins account for 46% of the diabetes drug segment with a historic growth of 14% per annum. Going forward, this segment is forecast to grow at about 6% per annum, factoring in the advent of biosimilar insulins as we go along. Of course, it is well-recognized that insulin analogs are rapidly outpacing recombinant human insulin and it is also well-accepted that biosimilar insulins are inevitable. The Biocon-Pfizer partnership aims at addressing this very large opportunity first in the emerging markets which are huge markets by themselves, and then address the U.S. and European markets beginning with recombinant human insulin in 2013.

In terms of Biocon's business in India, Biocon's insulin business in India is also beginning to gain traction and although our insulins business is just 5 years old, we have steadily gained market share. In volume terms, we have a 10.8% share in the insulin vial segment and a 13.2% market share in the Glargine vial segment. We expect to roll out devices in the second half of 2011 and this, we believe, will enable us to increase market share. At a growth level, we have outpaced both the market and the market leader in the insulins vial segment. As you can see from the slide, the market has grown 10.6%; the market leader has grown 9.3%; and Biocon has grown 12.7%. We are also going to share the Indian market with Pfizer starting this year, and our co-exclusive marketing arrangement with Pfizer is expected to garner greater market share from the market leaders going forward.

I'd now like to shift gears and talk about our novel pipeline. This is a pipeline which we have filled with products for diabetes, oncology, and autoimmune diseases, and what is important for me to emphasize in this research pipeline is the fact that we have programs at different stages of development. The most advanced programs are our Oral Insulin or IN-105 Program and our Itolizumab or our anti-CD6 Monoclonal Antibody Program. Other programs that are advancing are BVX-20, our humanized anti-CD20 monoclonal antibody that we are co-developing with Vaccinex, and 2 other programs that are in early stages of development- our hybrid peptide program with Amylin and the fusion monoclonal antibodies designed to be immuno-stimulatory monoclonal antibodies designed as tumor vaccines with a small start up firm from Johns Hopkins. We expect to initiate discussions for partnering many of these programs in 2011 and again, this is

going to be a very important phase for us.

I'd now like to turn to some of these programs and share progress updates with you. Starting with our IN-105, the Oral Insulin Program, where the data has been much awaited. What is important for me to mention here is that this was a proof of concept, phase 3 study, with about 260 patients where we compared patients on metformin who are not doing too well and with add-on of oral insulin with a placebo-control arm. We have got some very interesting initial data. Data analysis is ongoing as we speak, but what is important to highlight here is that although we did not meet the defined end point of a placebo-corrected HbA1c drop of 0.7%, largely because we have seen a much higher than expected placebo effect, we have seen very good proof of concept in terms of other aspects of efficacy and safety where we have met several secondary end points. We believe that frequent glucose monitoring has basically led to lifestyle modifications and this is why we have seen a much higher placebo effect than what we expected, and we have data to basically corroborate this particular assumption where we have seen fasting glucose levels drop across the study in the placebo arm. Having said that, what we have seen are statistically significant reductions in postprandial glucose levels throughout the trial. We've also seen significant drug effect in several subsets and up to a 0.8% placebo-corrected HbA1c drop in many of these subsets. In terms of safety, we have seen a very good safety profile; no clinically relevant hypoglycemia was observed; no serious adverse events; the drug appears to be non-immunogenic and weight neutral. We do plan to initiate partnering discussions very soon and we propose to conduct further studies after we partner.

Moving on to our next product Itolizumab; this is an immune-modulating anti-CD6 antibody. I think immune-modulating antibodies are a very exciting new approach to autoimmune diseases and we are presently evaluating this particular drug for 2 indications: psoriasis and rheumatoid arthritis. What is also important to mention here is that early pre-clinical studies are also showing that this particular antibody is very important in certain other indications like psoriatic arthritis, multiple sclerosis, lupus and type 1 diabetes, and therefore, we very aptly refer to this as a pipeline within a product. Initially, we are going to be looking at RA and psoriasis and very soon, multiple sclerosis. With these 3 indications alone addressing a market size of over 20 billion dollars by 2015, it is a very good space to be in.

I would now like to share some data on psoriasis. We have seen some very good PASI scores; we have seen mean PASI improved by 50% in 4 weeks and 75% by 12 weeks; we have seen good PASI scores: 50%, 75%, 90% and 100% PASI scores. We have seen significant changes in the quality of life parameters.

Moving on to RA, again, this is a study that has seen good ACR 50 and ACR 70 scores which we have not been seen in the methotrexate control arm. This was an add-on therapy to methotrexate

-patients on methotrexate and not doing too well. Again, we have seen some very important improvements in both quality of life and disability parameters, as well as tender and swollen joint counts which have substantially reduced and have sustained over a 24-week period. In this slide, what is very important for me is to really show you a comparison of Itolizumab with other biologics targeting rheumatoid arthritis and in this particular slide, you can see that there are 2 strong differentiators: Whilst it is very comparable in most aspects of the data, what is important here is to show you that there are much lower infection rates in our particular antibody and the dose rate that we're using is much lower than other antibodies and these, we believe, are going to be strong differentiators. It is, therefore, these differentiators that we will focus on when we evaluate these drugs in future studies. The clinical plan, therefore, is to continue with psoriasis and rheumatoid arthritis. We have completed patient enrollment in the psoriasis trial and we plan to obtain primary end point data by Q1 of this year and hope to apply for an Indian registration by Q3 of 2011 and have Pre-IND advice from USFDA at the same time. The other RA study is about to start and we expect to complete the study next year and apply for a U.S. IND in Q3 of 2012.

Moving on to our third program - an enhanced antibody BVX-20 - a humanized monoclonal antibody we are co-developing with Vaccinex's platform technology. What we have seen in pre-clinical data, which includes primate studies, is that this particular antibody is comparable with Rituximab in most respects, but it does have a differentiated off-rate when it comes to CDC activity which is higher than what is observed for Rituximab. Once again, this potentially indicates that a lower dose is possible and it could have a higher efficacy in CLL. These are the aspects that we will evaluate over time. But what this also means is that if this is so, then BVX-20 can compete very effectively even with biosimilar Rituxan. The clinical plan, therefore, is to conduct a phase 1/2 trial on refractory-NHL patients or relapsed-NHL patients, roughly 50 patients is what we have considered for this trial with a primary end point being safety and a follow-up for 2 years. We will look at PK on first and last doses and we hope to file a U.S. IND in Q3 of this year.

I'd now like to just briefly speak about emerging markets that I started with in my introductory comments. We believe that emerging markets are going to be high growth, high-return markets for us. We have already delivered a 40% growth in our emerging markets this year and we expect to do so in the year ahead. Biosimilar insulins are certainly going to be very important for these emerging market strategies. The current emerging market estimate for this insulin business is about 1.5 billion dollars with a 5-year CAGR of 15%. Estimated to be a 5 billion dollar insulins market by 2020, and considering the fact that the emerging markets account for 70% of the world's diabetic population, we believe that these are very important markets for us and with lower regulatory barriers they, obviously, offer us very fast market entry. Biosimilar Mabs in the emerging markets are also a very important opportunity for us. The current market size is estimated at 1.5 billion growing to 2.6 billion. Generics, again, are going to be extremely important

for this as APAC alone accounts for 16% of the 124 billion dollar generics market with the fastest growth rate.

Some quick comments on our financials - we have delivered a 5-year CAGR of 24% with a 5-year average EBITDA of 27% and a 5-year average PAT of 20%. As you can see, we have a very robust balance sheet with a net debt of just about 4 million dollars and equity of 426 million, and this is the reason why we have been able to self-finance our very expensive R&D programs. We are amongst the top 10 R&D spenders in India. We are at roughly 8% levels in terms of our R&D spends and we expected to be around 8% to 10% going forward as we continue to invest in our very high potential innovation pipeline.

Another growth driver for us has been our research services business where we have delivered revenue CAGR of 21%. There are some very interesting global trends in terms of externalization of R&D where big Pharma is investing and externalizing over 22% of its R&D. We are also seeing that risk sharing and resource sharing models are becoming the order of the day, and what we are also seeing is that there is a move from component to integrated discovery programs, from chemistry to biologics, and what big Pharma is now looking for are strategic development partners. It is no longer about cost, time and productivity arbitrage that used to be the rational and the reason for externalizing research. The biologics opportunity is very interesting because in-licensing from small biotechs and filling up research pipelines with biologics programs are becoming very important for big Pharma. What is relevant for us is that biologics programs far exceed internal capacity, so this is one of the main reasons why externalizing this aspect of biologics development is becoming a big opportunity for our research services companies. Syngene and Clinigene, are very well-positioned to offer this integrated platform and end-to-end solution, both for NCEs and NBEs. A very important partnership that we have developed in this risk sharing integrated research services model is BBRC, which is the Bristol-Myers Squibb partnership where we have a dedicated, integrated R&D hub customized for BMS to pursue pipeline development. This facility has over 450 scientists and it works in a seamless way with its labs back in the U.S.

To summarize, I'd like to focus on the key growth drivers that we have set ourselves for 2011 - emerging markets, biosimilar insulins, MAbs, licensing of our novel programs, research services and of course our historic small molecule APIs which we see are going to be very key to us.

Thank you very much.



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