Biocon Limited

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Jessica Fye: Good morning everyone. My name is Jessica Fye. I am on the pharmaceuticals team at JP Morgan. I am very excited to be introducing Biocon this morning. Just a couple of quick housekeeping reminders: please silence your cellphones and the breakout session after this will be in the Sussex room down the hall. So with that, excited to introduce Kiran Shaw, Biocon's chairman and managing director.

Kiran Mazumdar Shaw: Thank you. Good morning, ladies and gentlemen. I am Kiran Mazumdar-Shaw, CEO of Biocon and over the next 25 minutes, I would like to take you through a presentation that will basically touch upon the global trends in the pharmaceutical industry, how Biocon's business is aligned with these trends, an update on the progress that we have made thus far, and I will end with our half-year financials and the road ahead.

The year gone by has seen some key developments which include the amicable parting of ways with Pfizer with respect to our biosimilar insulins, a stake investment by GE Capital in our research services subsidiary- Syngene, our exit from the partnered research program with Amylin post its acquisition by BMS and a very important development in terms of an option agreement that we have signed with BMS for our oral insulin program, IN-105. I am also pleased to announce that we have just received approval from the Indian Drug Regulatory Authority for our novel anti-CD6 Monoclonal Antibody- Itolizumab for psoriasis. This is a very significant milestone that enhances the value of this late-stage asset.

So let me start with a perspective of the growth trends in the pharmaceutical industry and as you can see from the slide, it is estimated that the global pharma industry will grow from about 950 billion dollars that were registered in 2011 to about 1.2 trillion dollars by 2016. What is very important to note here is that emerging markets are expected to deliver 75% of this growth. In fact, growth from emerging markets will be more than double that of developed markets where emerging markets are expected to generate 180 billion dollars of growth compared to 70 billion in the developed markets. This strong growth in emerging markets is reflective of 2 distinct trends: One is increased government spending on healthcare which is creating sizable tender markets, and two, the growing affluence in these regions which is also expanding the retail markets. Going further, it is also very important to note that generics are really driving growth both in developed

and developing markets as governments try to contain spiraling healthcare costs.

As you can see from the slide, generics are expected to outpace branded drugs by a factor of 10 where generics are expected to grow from a 240 billion dollar level that they registered in 2011 to around 430 billion dollars by 2016, a nearly 80% growth compared to a mere 8% growth in branded drugs which are expected to grow from 713 billion to about 775 billion. What is also important for me to highlight, is that biosimilars are expected to grow five-fold from a little less than 1 billion dollars today to about 5 billion dollars by 2016, Once again, emerging markets are really going to be where most of this growth is going to take place and Asia alone is expected to account for 40% of this growth.

So with that introduction, let me then dwell upon Biocon's business model which has a growth strategy of moving up the value chain along 5 clearly identified growth segments, and our near term growth drivers mirror what is happening in the world: which is about a focus on generics, biosimilars, as well as emerging markets.

Our small molecules segment which is presently focused on generic APIs is keen to move into branded generics for emerging markets and ANDAs for the US. Biosimilar insulin and monoclonal antibodies will address growth, first in emerging markets and later in developed markets. Our branded formulations will focus on expanded branded generics in India and select India-like RoW markets. Our novel molecules will leverage the India cost advantage and talent base to address the challenge of high cost innovation as does our research services segment which also aims to leverage the India advantage to help our customers develop drugs more cost effectively.

Let me take you through each one of our growth segments in more detail. So starting with our small molecules segment- here our strategy for ANDAs is based on vertical integration right down to APIs. We have a differentiation strategy based on fermentation-derived molecules as well as based on complexity of synthesis. We have selected a portfolio of approximately 25 molecules which addresses a combined current market size of 30 billion dollars. We expect to file our first 2 ANDAs by the end of 2013, and the 25 molecule portfolio is expected to address opportunities starting 2015 onwards. Our API portfolio of statins, Immuno-suppressants and now the proprietary product, Fidaxomicin, continues to grow. Our small molecule segment remains a large part of our current business; improved manufacturing efficiencies have delivered higher margins for this business this fiscal. And we are targeting a top line of 300 million dollars by fiscal year 2018 with a focus on an improved product mix with higher margins.

Moving on to biosimilars, I would like to highlight the fact that our biosimilar insulins portfolio comprising of recombinant human insulin and insulin analogues addresses a potential market size of 17 billion dollars and a biosimilar monoclonal antibody and biologics portfolio that addresses a market size of 33 billion dollars. Collectively they address a potential market size of

50 billion dollars. Coming to biosimilar insulin and insulin analogues, this is a portfolio that is focused presently on emerging markets where our recombinant human insulin has been registered in over 40 countries and Glargine in over 5 countries. Post Pfizer, we have also entered into several regional partnerships in Russia, Eastern Europe, Latin America, Southeast Asia, and China. Our Malaysian facility is on track for operational readiness by the end of 2014 and I am also pleased to state that we have doubled our Indian operations, where we have increased our capacity by a factor of 2. We have also successfully introduced our insulin delivery device, INSUPen, in India and several emerging markets which are now expected to garner a greater market share. In terms of clinical update, recombinant human insulin has completed a phase 3 study in Europe. Results from the first part of the study have established the efficacy endpoint: non-inferiority to the innovator product. Immunogenicity and safety data at the 6-month time interval also reflect a similarity to the innovator, and we are now awaiting immunogenicity and safety data which was evaluated over a 12-month period. We expect to file for market authorization in the EU later in fiscal year 2014. We have also successfully completed a global phase 1 PK/PD comparability study for insulin Glargine and are now preparing for a phase 3 global clinical trial. We expect to file for market authorization in 2015. Post Pfizer we are also in partnership discussions for commercialization rights in US and Europe. Now coming to our biosimilar MABs and biologics that have partnered with Mylan, this portfolio continues to make good progress. I can share with you a clinical update for our first monoclonal antibody that has moved into the clinic, which is biosimilar Trastuzumab. The India trial, which is a pivotal phase 3 registration trial, is in progress and we expect to complete this trial by the end of 2013. We have also commenced patient enrolment of a phase 3 global trial for biosimilar Trastuzumab and to the best of our knowledge; this is the second biosimilar Trastuzumab that has entered the clinic in global trials. We also expect to move 2 more programs into the clinic by fiscal year 2014.

Coming to our novel molecules segment, as you can see from the slide, we have a very robust pipeline of novel molecules. I will also like to repeat that we have, since the last presentation, terminated the partnered program with Amylin for AC-165198, a hybrid peptide molecule targeting diabetes and obesity. This is post the acquisition of Amylin by BMS. This decision was arrived at keeping in mind, that it was always the intention of the 2 partners to out-license this program to a large pharma. I would also like to point out here that our novel anti-CD-20 program has also entered the clinic, and I will now update you on the progress made in 2 of our lead programs, IN-105 or oral insulin and the anti-CD-6 or Itolizumab program. In terms of the IN-105 program, we are pleased to announce that we have entered into an option agreement with Bristol-Myers Squibb. I would like to briefly remind you that we had encountered a placebo effect in our India-centric phase 3 clinical trials. However, I must emphasize that proof of principle was demonstrated in these trials. BMS will now help Biocon redesign phase 2 trials to address some of the questions around the placebo effect. These phase 2 trials will be done as global trials

under an already filed US IND and we will also include sites outside India. Coming to the most exciting part of this presentation which is the anti-CD-6 antibody Itolizumab, I am pleased to announce that we have received marketing authorization for Itolizumab from the Indian Drugs Controller for psoriasis. We plan to launch the product later this year under the brand name Alzumab as an infusion treatment for patients with moderate to severe psoriasis. We now intend to file an IND in the US to commence global clinical trials with a sub-Q formulation for RA where we have some good phase 2 data generated in India, and this will be done on patients who have failed treatment with cytokine inhibitors. This successful outcome strengthens our licensing discussions for global development and commercialization. But going beyond this, we believe that this is a very important aspect of our novel molecule pipeline because Itolizumab is a first in class molecule, and it is extremely important milestone wherein we have clearly demonstrated safety and efficacy of this compound, which has been extensively reviewed by an eminent group of Indian medical experts. This approval will also allow real world experience with the drug and we expect to further establish the very low incidence of opportunistic infections, which we have seen for this particular drug during the clinical trials, which we believe is a major differentiator for Itolizumab. Post marketing safety data will be tracked comprehensively to add value to global development, and we also believe that the India development strategy will allow for a more comprehensive approach in global development that we believe will also provide a greater probability of success. We also believe that the novel mechanism of action of Itolizumab, allows for therapy options for non-responders to currently approved biologics.

Coming to our branded formulations segment, this segment has shown a consistent 40% year on year growth for the last 3 fiscals. Biocon's 7 therapy divisions have realized good brand value with many products currently ranked amongst the top 3 selling brands in India. Biocon is now the fastest growing insulin company in India growing at 33% per annum outpacing well-entrenched players who are growing at 15-20% per annum. The launch of our delivery device, INSUPen, has also augmented growth through the sale of cartridges and we expect to garner much greater market share going forward. We believe that Biocon is very well differentiated in this space, as we have a unique mix of novel products, biosimilars, as well as branded generics which have helped us build a very good profile in the Indian market. Our growth rate of over 30% is twice that of the Indian market which is at 15%, and we are now recognized as a leading oncology company in India. Moving ahead we are targeting a top line of 200 million dollars over the next 5 fiscals on a robust path that will deliver a 20% growth.

Coming to research services, Syngene along with its CRO subsidiary Clinigene continues to differentiate on a number of platforms. Syngene's capabilities in both small molecules as well as biologics are unique differentiator and in addition, the Syngene-Clinigene axis provides end-to-end discovery to clinic approach in drug development. In terms of niche service offerings,

Syngene is well positioned to offer biologics capabilities including antibody drug conjugates. It has developed unique in vivo xenograft models and has created a commercial scale production facility of NCEs for its customers. It also offers very high end Bioanalytical services, cytotoxic APIs manufacturing, formulation development, and thanks to the recent partnership with GE, we have created novel platform technologies which allow for early and rapid toxicology evaluation exampled by the use of cardiomyocytes. At the business level, Syngene offers a number of models. One is the customized dedicated infrastructure like it has done for BMS and more recently for Abbott; end-to-end programs based on project-based fee for service models; risk sharing, milestone-based research models and then the IP sharing incubation-based model is something that we have introduced very recently. Two very important announcements in our research services division is the stake investment by GE Capital, where they have picked up a 7.7% stake in Syngene for a post money valuation of 325 million. This is not just a financial transaction, but one of value addition where GE's leading cutting-edge expertise in Life Science technologies will enable Syngene to further enhance its service offerings. Additionally, the GE investment establishes a base valuation which is an important milestone towards the proposed future public offering. A key milestone was also the establishment of a dedicated Abbott Nutrition R&D Center along the lines of the Integrated Research Center established for BMS in 2008 and this paves the way for expanding this model to broaden the customer base in a much more sustainable manner. Thanks to these various efforts of the research services division continues to deliver robust growth, 40% at the top line and a commensurate growth at the profit line where it has increased from 5 million to 7 million in the first half of this fiscal.

Now moving on to our financials, as you can see from the slide, we have delivered a strong top line growth with a 3-year CAGR of 22% where we ended last fiscal and close to 450 million dollars. The first half of this year has also delivered good growth where we have seen a 23% year on year growth at the top line to deliver about 250 million dollars at the half-year basis. R&D expenditure has grown significantly. It has grown 54% to touch 16 million dollars as many of our programs move into the clinic. Both at an EBITDA & PAT level the growth has been 8% to about 60 million and 34 million dollars respectively. Key growth drivers for the first half have been our APIs and biosimilar insulins which have grown 21% from 115 million to 140 million dollars. Branded formulations have yielded 45% growth from 24 million to 35 million and research services have also delivered robust growth of 40% from 36 to 50 million for the first half.

In terms of the path ahead, we are looking at delivering a billion dollar top line by fiscal year 2018. Our current business has an overreliance, as you can see, on small molecules and we expect that by FY 18, the small molecules business segment will actually contribute 300 million dollars in terms of our overall business, and we expect to have a much better product mix with higher margins, which is what we are focused on today in our new value addition strategy. Branded

formulations, which today account for about 10% of our business, is well poised to reach a size of 200 million by FY 18 in India and India-like markets. Biosimilars, largely insulins, are also expected to grow to a size of 200 million dollars by FY 18, but emerging markets will provide the main growth opportunities. We do expect to enter US and European markets by this time with modest sales but with significant growth prospects thereafter. Research services are also likely to see robust growth and we expect to attain a size of 250 million by FY 18. And here we see Syngene as being one of the significant players in Asia in the research services space.

In the near term, our eyes are focused on achieving 700 million dollars by fiscal year 2015 where our small molecules segment is expected to attain a size of 280 million dollars where the focus is going to be on improved product mix and improved margins. Our research services business is expected to continue with the sustained growth momentum and deliver 175 million dollars for us. Branded formulations, based on our differentiated offerings, are expected to realize 140 million dollars in terms of our top line business. Biosimilars, as I mentioned earlier- largely insulins, is also expected to seek very good geographical expansion and deliver 70 million dollars in terms of top line growth. And our novel molecules, in terms of out-licensing and global development, are being estimated at the modest 35 million by FY 15. There are many upsides that are likely to exist in the form of many of our licensing opportunities and many of our ANDAs, but we do believe that we are very confident in attaining our growth projections in 2015 and in fiscal year 2018. So I will stop my presentation and look forward to taking on a Q&A in the next room. Thank you.