Biocon Limited

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SPEAKER 1: Good morning, everyone. My name is Yury Prilutsky. I work with Christopher Schott, the Pharmaceuticals Analyst at JP Morgan. We're very pleased this morning to have Biocon with us today. This is the first we've invited a biopharma company from India to present at the conference and we're happy to introduce Kiram Mazumdar-Shaw, Chairman and Managing Director of Biocon, who started the company in 1978.

SPEAKER 2: Thank Yury. Good morning everying. It's a real pleasure for me to present Biocon's credentials for the very first time at the JP Morgan Healthcare Conference here today. I guess for those of you who are not familiar with Biocon, we are India's first biotech company and Asia's largest publicly-listed biopharma company. Our current market cap is a little over $1.2 billion. Let me, you know, start by briefly commenting on the very challenging times that the global biopharma industry is going through. And this is despite the fact that the demand for pharmaceuticals continues to grow unabated. Billions of potential customers across both the developed and emerging markets are creating this demand. But I guess the moot question being asked is under the current circumstances, can we generate meaningful economic returns in addressing these globally expanding opportunities? You know, I'd like to use the analogy of designing a car for a long distance cross country rally. And, you know, the current model worked very well for several legs but suddenly showed up design faults. It breaks down frequently, guzzles gas, costs too much to operate, and is unable to navigate certain rough terrain. So I guess we're really looking for redesigning a new car which can basically manage rough roads and get us to the finishing line without breaking the bank. So I'd like you to think of Biocon as one of these redesigned cars. You know, we spent the last 10 years developing a very interesting and new economic model for drug innovation, leveraging the India advantage and this is what I'd like to share with you over the next 25 minutes. I'm confident that you will find Biocon to be a very differentiated story worth tracking and worth investing in. So let me start with the mandatory safe harbor statement. I guess there will be a few forward-looking statements. And to begin with, I'd like to give you a quick snapshot of Biocon. The company was established in 1978 as an industrial enzymes company which actually pioneered the Indian biotech sector. Over the last 10 years we have undergone a complete business transformation into an integrated biopharma company. We chose to go for an IPO and a very successful IPO in 2004 and saw us listed in the Indian stock exchanges. And like I mentioned a little while ago, our current market cap is a little

over $1.2 billion. Our consolidated revenues are in the order of $450 million. These are expressed as 12-month trailing numbers. What we have is a very unique biopharma business model that straddles both products and services. We also have a very strong research-driven ethos in the company and this has enabled us to build a very interesting and robust pipeline of products that are well balanced between biosimilars and novel biologics. And this is, of course, supported by a very strong IP portfolio that has about a thousand patent filings and 200 patent grants. What we've also created is a global scale USFDA compliant biomanufacturing base which really gives us a strong competitive advantage as an integrated biopharma company. And last but not least, in terms of our talent pool we have a head count of a little over 4,000 employees and it's important for me to mention here that 75% of these are scientists and engineers of which 10% are Ph.Ds. So with that introduction, I'd just like to give you the kind of outline of my presentation. I would like to start by really commending on the global biopharma landscape and how the biopharma industry is recalibrating. And against this backdrop, I'd like you to--- I'd like to present Biocon's differentiated business model. Of course, I'll touch upon our strong product pipeline which we are developing for global markets and end a few slides on our financial and operational track records. So let me start by commenting on the way the global biopharma industry is recalibrating in response to present day challenges of declining drug approvals, poor research productivity, stagnating top line growth, and above all, the risks and increasing risks and costs associated with drug innovation. There are clear trends that companies are pursuing some very, very new strategies. One of these is about portfolio diversification and it's interesting to see how this is happening where companies are picking on products with shorter regulatory timelines like diagnostics, devices, new drug delivery systems, vaccines, and interesting to see how global pharma is even looking at generics and biosimilars as one of the diversification strategies. Emerging markets is certainly a strong focus now with many global biopharma companies. Emerging markets are seen to be the highest growth opportunities and this is really about addressing stagnating top line growth amongst companies. Late stage asset acquisition is another very interesting trend. This is, again, to address the declining, you know, pipelines and filling them up with late stage assets that can accelerate time to market. And as I mentioned, one of the biggest risk that the industry is addressing is about the increasing risks and costs associated with drug development. And here, industry is beginning to experiment with new risk sharing models. Co-development is a very interesting strategy. And outsourcing R&D services to reduce cost is another way of looking at cost mitigation in drug innovation. So with this as a backdrop, I'd like to quickly turn to Biocon's differentiated business model. To begin with, I'd like to say that intuitively, we have actually addressed many of these current day challenges and this has helped us to build a biopharma business that is both risk-balanced and cost competitive. We have created a fairly unique and differentiated business model where I'd like to sort of go through some of these differentiators. We have a very balanced portfolio that straddles products and

services. I'd like to also highlight the fact that we have created a self-financed business model that has focused on being loaded and positive in cash flow, which has actually allowed us to finance global scale manufacturing as well as a very interesting high potential R&D pipeline. Partnering has also been a very integral part of our business model where we have forged strong alliances both on the research as well as on the marketing fronts. R&D has also been called to our differentiated strategy where we have leveraged India's cost advantage to afford risk and global partnerships to share risk. And I think this is quite an important part of our differentiated business model. Now starting with our products portfolio, we have actually gone about product development strategy by aiming to move up the regulatory learning curve and this almost mirrors one of the recalibrating strategies that I talked about, where global biopharmas0020trying to focus on products that have shorter regulatory timelines. So when we started evolving our biopharma business, it was very important that we started with products with shorter regulatory timelines and then challenged ourselves with, you know, going up the regulatory curve by trying some more advanced products. So the first off the block, we have small molecule generic APIs like statins and immunosuppressants, and this then allowed us to move up the regulatory curve by developing biosimilars. The first set of biosimilars that we actually developed were recombinant proteins like insulin and insulin analogs, and the way forward was then climbing up to more complex biosimilar monoclonal antibodies. Novel biologics are now a natural way forward as a long-term strategy, clearly understanding that the regulatory path for novel biologics is going to be far more complex and much longer than we have been used to in the past in terms of both generic APIs and the biosimilars. And what I'd like to say is that this approach has actually allowed us to develop a short-, medium-, and long-term market entry strategy. The first to enter the market very quickly were our generic APIs: statins and immunosuppressants. And I'm pleased to say that this, you know, has been a very effective short-term growth strategy for us where we have garnered significant market share, both in the US and European markets. These, as APIs, we have a market share in excess of 20% in both these markets. So it's fair for me to say that, you know, 1 in 5 statin tablet or an immunosuppressant tablet that is being marketed in this part of the world would probably have API derived from one of our USFDA compliant plants. Our medium-term strategy has focused on biosimilar insulins which have begun to perform very well in India and several emerging markets, where we have entered into alliances with several regional partners. Biosimilar mAbs will follow a similar commercialization part of an "India and emerging markets first" strategy, and eventually to the developed markets through strategic partnerships with companies like Mylan and others. We propose to identify strong global partners for our novel programs which we expect will deliver long-term sustainable growth. In terms of our marketing efforts, we intend to develop our India market presence on our own. However, we have opted for marketing tie ups in emerging markets like Latin America, Mexico, Middle East, North Africa, Asia, China, Turkey, etc, with strong regional players. Emerging markets, I'm pleased to

say, already accounts for 40% of our products sales and this will certainly be a very important growth driver for the foreseeable future in the short-term. Now coming to our portfolio of services, it's interesting for me to mention that Biocon's Services Business is a business that grew out of an internal need to support the development needs of our evolving biopharma business. And what could have been expensive cost centers for a company of our size were conceived and developed as profit centers. We setup 2 wholly-owned subsidiaries, Syngene and Clinigene, which together provide end-to-end services from pre-clinical discovery research to human clinical trials. And this is being provided to a very diverse client base that includes global pharma majors, midsize pharma, and biotech companies, as well as start ups. This has enabled Biocon to benefit from world-class R&D infrastructure and high-end development capabilities. And what this model also made us do was to put into place a very strong IP culture within the organization. And this has earned Biocon a very reliable track record both in terms of respecting other people's IP and creating strong IP for itself. Our Research Services Businesses have delivered a robust 36% CGR over the last 5 years. And today, Syngene and Clinigene are preferred service providers for a number of pharma majors, the most notable of these being Bristol-Myers Squibb which carries out integrated drug development at a dedicated facility managed by Syngene. The future prospects for this business all go well given the current trends of increased R&D outsourcing, given the need to address cost very effectively. And data already indicates that 21% of 2009 global R&D spends were outsourced and it's interesting to note that this was less than 1% 10 years ago. India is also poised to be the preferred location for clinical trials given the very attractive cost arbitrage that exists which is not really just about the cost of clinical trials but also about faster patient enrolments in certain sectors, disease sectors, which adds to this arbitrage. I now like to focus on our self-financed business model that has allowed us to actually build a global scale biomanufacturing facility that meets USFDA norms. We are one of the largest producers of statins and immunosuppressants globally. We are Asia's largest insulin producer and we also have global scale monoclonal antibody production capabilities. Most of our facilities are USFDA qualified and this also includes an aseptic fill/finish facility that was recently qualified by USFDA. Why am I really focusing on this slide? Because I really believe that as an integrated biopharma company based out of India, manufacturing is going to give us a very strong competitive edge. Whether it's biosimilars or whether it's novel biologics, cost of goods is going to be key to building that global competitive advantage. And we certainly believe that manufacturing is going to be key in building this global advantage for Biocon. I'd now like to turn to our R&D pipeline. Again, this is something which has been self financed where we have judiciously created an R&D pipeline that's well balanced between biosimilars and generics, and as well as novel biologics. Biosimilars and novel programs that are both in early stage and late stage of development are shown on this slide. And the strategy that we have adopted is to maximize development in India to take advantage of the lower R&D costs and faster clinical development

timelines. And this has actually enabled us to commercialize these products quite rapidly into India and some of the emerging markets and then allowed us to pursue more expensive global development once the risk is reduced. And this strategy has really worked extremely well for us because we've seen many of our markets enter several markets in the emerging market space in a very short time line. Biocon has also leveraged the R&D and clinical development advantage to take novel programs to a proof of concept before licensing. This has been a very strong strategy for ourselves where it has enabled us to take 2 of our novel programs, through self funding, to a phase 3 proof of concept clinical trial in India. I'm gonna talk about 2 of these programs that are fairly advanced and both these programs have potential blockbuster profiles. IN-105 potentially is an oral insulin program that potentially address 300 million diabetes patients worldwide while T1h or anti-CD6 monoclonal antibody is entering phase 3 clinical trials for psoriasis, and this is an indication where 3% of the global population suffer from this autoimmune disease. The strategy is to enter and obtain regulatory approval in India and several emerging markets and then pursue more expensive global development once the risk is reduced in terms of attaining proof of concept. I believe that this approach will unlock maximum value for Biocon and its shareholders whilst reducing the development risk for the licensee. So let me turn to the first of these programs. This is a program which we have called IN-105. It's an oral insulin program which is, if I may say so, the most advanced program in the oral insulin space globally. It's a new entity. It's a new molecular entity. It's a conjugated peptide. In terms of its pharmacological profile, it is metabolically active to insulin. It shows lower immunogenicity and mitogenicity when compared to insulin. It has a very good safety and clearance profile. What we have done so far is established oral delivery through a number of phase 1 and phase 2 studies. We have a very stable tablet formulation and a very interesting phase 2 study that showed that absorption of IN-105 is proportional to the dose administered. And this is the study that actually allowed us to now enter into phase 3 development. This is an ongoing trial which involves a 6-month double-blinded, placebo-controlled trial in type 2 diabetes patients who are poorly controlled on metformin, where the primary endpoint is HbA1c control. What is interesting about IN-105 is its product profile in terms of how it can be positioned in terms of monotherapy, in terms of combining it with various oral antidiabetic tablets like metformin, sulfonylureas, PPAR agonists, DDP-IV inhibitors, etc. And there's another way of product positioning this particular oral insulin which is as a premeal insulin in combination with basal insulins. We have submitted a US IND which was filed in December 2009 and we believe that we are now approaching a situation where we can actually progress with many more global development trials. The next program that I'd really like to touch upon is a very interesting program which is anti-CD6 monoclonal antibody. The target is a type 1 cell membrane glycoprotein which is predominantly expressed by T cells and a B cell subset. It has a very unique ALCAM binding profile where it binds to activated T cells, B cells, and monocytes. And it has a very ideal setting in many autoimmune conditions. We have, again, pursued clinical

trials in both psoriasis and rheumatoid arthritis, and we are about to enter an important pivotal phase 3 clinical trial for psoriasis. You can see from these images that the product looks extremely promising. We have seen extremely good remission rates coming from, you know, injecting just once a month and, you know, we've done monthly injections and weekly injections, and this now allowing us to design a very important phase 3 clinical trial. Apart from this, we will be starting a phase 3 trial in RA and we also intend to look at some of the preclinical data that we have generated in animal models which seems to suggest that this will also do quite well in multiple sclerosis and type 1 diabetes. So there's a lot of work to be done in 2010 and it's a very exciting time for all of us at Biocon. The way we've gone about our novel programs and our whole biologics research approach is also about building strategic research partnerships. We have forged interesting partnerships to share risks and costs associated with drug development and we have sort to partner with companies that bring complementary capabilities. These are companies that have also bought into the India story. And I'd like to really just quickly touch upon 4 of our important strategic partners. I'd like to start with Mylan with whom we have a very interesting partnered program for a bunch of biosimilars. Amylin is a very interesting strategic partnership for us in research where we are jointly developing a novel peptide for diabetes. Amylin, of course, is very well recognized as a leading discovery researcher in the diabetes space. They've been extremely successful with many of their diabetes and obesity molecules. The third company that I'd like to touch upon is Vaccinex. We have a very interesting research partnership with Vaccinex to develop biobetter monoclonal antibodies based on Vaccinex's proprietory technology. The first of these molecules is a biobetter anti-CD20 monoclonal antibody. And the last partnership that I'd like to talk about is with Iatrica. This is a small start up company which is a spin-off of Johns Hopkins with whom we are developing immunoconjugated monoclonal antibodies that actually evoke T cell response, and this is a therapeutic vaccine approach to cancer. So now, to sort of wrap up quickly, I'd like to go through our financials. As you can see from the slide we have maintained robust operating and net margins whilst increasing investment in our manufacturing and R&D. And we have a 5-year average EBITDA of 30%, a 20% PAT, and a very low debt equity of 1 is to 10. R&D is now approaching 8% of revenues which again reflects on the way we are focusing on R&D investment. And in terms of our research services, this is also something that's really, really, you know, delivering handsome returns for us. So these are the growth drivers I'd like to leave you with and I hope that I've been able to present to you a very differentiated model that Biocon is in terms of being risk balanced, cost competitive, and a very unique model that has self-financed both research and marketing, as well as manufacturing. Thank you very much.

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