



# BIOCON'S 27<sup>TH</sup> ANNUAL GENERAL MEETING

## CHAIRMAN'S ADDRESS, BANGALORE JULY 20, 2005

### **INNOVATING THE FUTURE**

Dear Shareholders,

Welcome to the 27th Annual General Meeting of Biocon. As we celebrate our first anniversary as a Public Company, we reflect on the year gone by with a newly acquired role of responsibility and a sense of satisfaction that we have delivered growth in all our business segments. Additionally, we have also begun the process of building new growth drivers for the future.

#### INNOVATION LED STRATEGY

The new WTO-TRIPS regime will sharply differentiate companies based on their ability to discover, develop and deliver proprietary products. Biocon is now rapidly transforming into a discovery-led research organization wherein we aim to leverage two decades of learning and skill building to realize our true potential as a global Biopharmaceutical innovator. Your Company has been focused on an innovation strategy that aims to develop a research pipeline of high value, proprietary products in a de-risked manner. The underlying theme of Biocon's innovation strategy is one of *symbiosis*. Internally, the symbiosis between Biocon and its subsidiaries, Syngene, Clinigene and Biocon Biopharmaceuticals has allowed optimization of R&D resources which has brought in both speed and efficiency in delivering on research programs. In the external dimension, Biocon has forged partnerships with unique Biotechnology companies to develop a large spectrum of novel molecules targeting Diabetes, Oncology and Cardiovascular disease.

#### **DIABETES & CARDIO VASCULAR DISEASE**

Our research program for Oral Insulin is making steady progress and we aim to commence Phase I Human clinical studies in early 2006. This is based on an oral peptide delivery technology developed by a US Biotechnology company, NOBEX combined with Biocon's proprietary Insulin process.

The success of this program will open up a large global opportunity that has the potential of addressing both Type I and Type II diabetes which straddles a multi billion dollar market size.

The key challenges being addressed are with respect to bio-availability and cost of goods. Our aim is to develop an oral insulin tablet that will compete effectively with Insulin analogues as well as with other non-injectable forms including inhaled, buccal and nasal Insulins. Several International Pharmaceutical majors have expressed a keen interest to license this product for global marketing and we will share the outcome of these discussions at the appropriate time. It is important to highlight that the further we are on the development curve, the more value we can realize from this program.

Your Company aspires to launch Oral Insulin as India's first proprietary Biotech blockbuster drug where the Indian market will be the first beneficiary.

The same technology is also being used to develop two more programs:

- a. Oral BNP (B-Type Natriuretic Peptide) for Congestive Heart Failure
- b. Basal Insulin, a long acting, injectable insulin for improved glycemic control

Progress reports on both these programs will be made from time to time.

#### ONCOLOGY

Your Company's JV with a leading Cuban research institute CIMAB has made substantial progress wherein the first molecule, **Biomab**<sup>®</sup> a novel Monoclonal Antibody, is undergoing Human Clinical trials in multiple medical centers in India. The clinical trial is being conducted on a number of head and neck cancer patients in the first stage and will be extended to other forms of cancers including Pancreatic, Colo-rectal, Lung, Breast and Brain tumours. It is envisaged that the trial data will be ready for submission to the Indian Regulatory Authorities in Q4 of this fiscal and has the possibility of receiving marketing approval by Q1 of the next fiscal. **Monoclonal antibodies** represent a new class of drugs that are revolutionizing cancer therapy the world over in providing better efficacy and an improved quality of life. However, such drugs are unaffordable and inaccessible to average Indian patients. Your company will be the first in the country to produce a novel monoclonal antibody for cancer therapy that will be both affordable and a comparable alternate to the best products anywhere. The market potential for this antibody in India is enormous given that an estimated 70 to 80,000 new cases of head & neck cancer are detected each year.

Another oncology directed antibody, Anti-CD6 is also under development. This molecule is being developed for treating patients with Chronic Lymphocytic Leukemia which affects 30% of Leukemia patients.

Your Company is also developing three Cancer Vaccines designed to induce the body's immune system to produce specific antibodies that target known cancer factors EGF (Epidermal Growth Factor) TGF (Transforming Growth Factor) and HER1 (Human Epidermal Growth Factor Receptor 1). The most advanced in terms of development is the EGF vaccine which has been tested in humans in Phase II trials for Non-small cell lung cancer in Cuba. The data generated indicates that the vaccine can significantly increase survival rates for such patients. Your Company plans to conduct larger clinical trials in India and jointly develop the manufacturing technology with CIMAB for large scale production of these vaccines. Successful commercialization of these products will make your Company the first to introduce therapeutic cancer vaccines in the country.

Apart from this, your Company is also developing fully human antibodies BVX 10 and BVX 20 with a US antibody technology partner, VACCINEX. BVX 10 targets TNF∞(Tumour Necrosis Factor) which is expressed at high levels in patients suffering from Rheumatoid Arthritis. BVX 20 is an antibody to treat Non Hodgkin's Lymphoma. Both these antibodies will address global market opportunities.

#### **GENERICS & BIOSIMILARS**

Supporting this exciting pipeline of new drug molecules is a robust backbone of generic molecules that include Statins, Immuno-suppressants, Insulin & Biosimilars. Statins have been the main drivers of growth up until now and will continue to do so in the near term. Insulin, Bio-similars and Immuno-suppressants will carry the baton forward thereafter.

Your Company continues to enjoy a significant share of the US and European markets for Lova, Simva and Pravastatin despite intense competition from China and others. Recent developments related to self withdrawal of US Patents for Simvastatin and Pravastatin by Merck and Bristol Myers Squibb will offer large opportunities for your Company in the next fiscal. Some of this growth is expected to be captured in the second half of this fiscal given that customers will start filling their pipelines months ahead of product patent expiry. Your Company continues to be the only USFDA approved producer of Lova, Simva and Pravastatin.

Insulin, GCSF, HGH and other biologics offer large market opportunities in the European markets which up until now were impregnable. The recently announced guidelines by EMEA (European Agency for the Evaluation of Medicinal Products) for Bio-generics or Bio-similars will now enable your Company to introduce these products into the European markets. Your Company is in discussion with several European Pharma companies to commercialize these opportunities.

Recombinant Human Insulin and other branded formulations have gained increased market share in India. Insulin has also been successfully introduced into several overseas markets in Latin America and the Middle East. The registration process is on-going in 20 other countries in Asia, Latin America, Middle East and China and we are confident that your Company will be a significant global player in the Insulin market in the very near future.

#### SYNGENE & CLINIGENE: SERVICE-LED BUSINESSES

Biocon's subsidiaries, Syngene and Clinigene have demonstrated significant growth in their respective businesses. Your Company is now poised to be the preferred partner for both discovery led and clinical research.

Syngene continues to advance its leadership position in research services. Syngene's new facility at Biocon Park has been fully operational since Q3 2004. Important new research contracts have been drawn up with Novartis, Merck and others. Syngene's growth engine continues to deliver robustly which will necessitate further expansion in the near future.

Clinigene, has built its capability base on in-house clinical trials but is now in a strong position to offer a range of clinical services to third parties. These include bio-equivalence and bio-availability studies as well as Phase I to IV human clinical trials. In recent times, Merck has signed up Clinigene to conduct a number of Clinical Trials as a part of its global clinical program.

A noteworthy development is Clinigene's recently announced strategic partnership with SCIREX Corporation, a division of OMNICOM, a Fortune 500 Company. SCIREX is a well recognized global CRO (Clinical Research Organization) with operations in USA & Europe. The emerging relevance of Asia as a clinical development hub has encouraged SCIREX to partner with Clinigene which in turn views Scirex as its window to the world. Clinical Services is projected to be a large business opportunity for CROs in the Asian region and we are confident that this partnership will build global scale for Clinigene.

#### **BIOCON PARK**

The 90 acre new site christened BIOCON PARK is in its final stages of completion. This mammoth project now enables your Company to address leadership opportunities in statins, immuno-suppressants, Recombinant Insulin, monoclonal antibodies and research services through global scale in its operations. The project is expected to be fully operational by Q4 this fiscal. The full impact of this investment will only be realized from the next fiscal.

#### LOOKING AHEAD

The outlook for the year ahead is positive. Sales of Simvastatin and Pravastatin to the US market; revenues from Insulin, Immuno-suppressants and branded formulations, and expansion of our research services will be the key drivers for the year ahead. Our development initiatives in Oral Insulin and h-R3 antibody for various EGFR expressing cancers are making good progress and providing us with a clear direction in our innovation pathway. Our proprietary technologies and global-scale manufacturing that meets the highest levels of global regulatory compliance, adds to this dimension.

#### ADDRESSING CHALLENGES THROUGH DIFFERENTIATED STRATEGIES

Biocon has always addressed market challenges through differentiated strategies which enables your Company to secure its leadership position.

We consider the following as key challenges to address:

- a. **Commoditizing of Statins and generics:** We are addressing this trend through a strategy of working with innovator companies who are developing NDAs based on existing statins. Additionally, continual improvements in our manufacturing technology is helping us to address pressure on margins.
- b. **The emerging opportunity for Bio-similars in Europe:** Biocon is carefully addressing the guidelines announced by EMEA with respect to Insulin, HGH, GCSF and EPO. Biocon's Insulin and GCSF are well positioned to meet these guidelines and we believe that we are well ahead of potential competition for these products.
- c. **Oral Insulin vis a vis other non-injectable insulins under development:** Regulatory concerns relating to Insulin delivered through pulmonary routes have delayed the approval process. We believe that oral delivery has far lower regulatory issues to address. Current data indicates decreased risk of hypoglycemia and higher efficacy through hepatic or liver –regulation that occurs with oral Insulin. Biocon's oral Insulin program therefore has a high probability of success.
- d. **Monoclonal Antibodies is becoming a globally crowded space:** Biocon's two pronged approach of working with an Anti-EGFR antibody and an EGF Cancer vaccine makes for a uniquely, differentiated therapy. Additionally, both products are de-risked given that the Cuban partner has evaluated the antibody through Phase III clinical trials and the vaccine through "proof of concept" Phase II clinical validation. Both safety and efficacy have already been validated through these trials and Biocon has the opportunity to receive fast track approval as a result.

The Human antibody space is fiercely guarded in terms of Intellectual Property which makes the development process both complex and expensive in terms of licensing. Biocon's strategic partnership with Vaccinex, allows access to their proprietary human antibody platform technology, thereby providing a strong IP protection to Biocon's antibody pipeline

I would like to conclude with a sense of confidence and a strong note of optimism that we will be able to deliver enduring growth in all our businesses. Discovery led research is a long term commitment with no guarantees. Biocon's research strategy is based on a de-risked model that balances proprietary molecules with generics on the one plane and Investigational New Drugs based on "proof of concept" pre-clinical data on the other. Biocon's research strategy aims to deliver high value innovation on a low cost base with speed. Your Company's management believes in realizing a high return on investment in all spheres of its activities. R&D is no exception. Finally, we reinforce our commitment to delivering long term and sustainable value to our shareholders.

Thank you,

Yours sincerely,

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(KIRAN MAZUMDAR-SHAW) Chairman