



# **BIOCON'S 33RD ANNUAL GENERAL MEETING**

# CHAIRMAN'S ADDRESS BANGALORE JULY 21, 2011

Dear Shareholders,

Welcome to the 33rd Annual General Meeting of Biocon.

The past decade has been a transformational ten years for our company, in which we have built a strong foundation to support a soaring corporate structure. We now enter a new decade, where the engine of biopharmaceutical growth has moved east. This shift in the world order will enable us to validate our vision as a global biopharmaceutical enterprise that helps change lives for the better – one that delivers innovative and affordable products and services to patients, partners and healthcare providers.

In our growth journey, we have judiciously operated in accordance with a differentiated model that is risk-balanced and cost-competitive, establishing a robust portfolio of biopharmaceutical products and services that spans disease areas. We have taken deliberate steps to ramp up our presence across products and around the world through strategically important and valuable research and marketing partnerships.

This forward-looking growth strategy has allowed us to become global suppliers of drug substances like statins and immunosuppressants. We have pursued a portfolio approach in developing our research pipeline which is well balanced between novel and biosimilar programs whose value we will periodically unlock through licensing or via market access at the opportune time. As we stride onward, we will build Brand Biocon through products that make a difference to the treatment of chronic conditions like diabetes, cancer, cardiovascular, renal, and autoimmune disorders.

The journey ahead is therefore one of value-added transition as we sustain and grow our brand presence. We are focused on moving up the value curve from drug substances to branded drug products and from Drug Master Files (DMFs) to Product Dossiers. Over the past decade, Biocon has reinforced its brand equity across our customer and partner base. We must now work toward extending that brand recognition to our products in the retail market. This, we believe, will propel us along a high-growth track and allow us to differentiate ourselves in a crowded marketplace. It is these brands that will help us build the Biocon of the future.

While building Brand Biocon, we must look beyond the market and engage with healthcare professionals and patients to deliver medical education. Not only will this create greater awareness of disease management, but it will also enable better outcomes, deepen brand equity, and create higher value. Brand Biocon is committed to the ethos of making a difference to patients through affordable drug innovation. I am very happy to share with you the progress we have made in creating this brand recognition.

#### BrandBuilding through Differentiation and Specialization

Over the years, our well-orchestrated business and research strategy has helped us develop products that address chronic therapies in select disease segments. As part of our approach to brand building, we have identified anchor products to spearhead the launch of our brands into the Indian market.

#### DIABETOLOGY

The first such key product was recombinant human insulin, branded Insugen®, which launched our Diabetology division in 2004. Entering at the lowest rung, we have worked our way up the anti-diabetic value chain to be ranked 12th in the large Diabetes segment last fiscal. Insugen® is a leading brand in the country today, rapidly narrowing the gap with its innovator counterparts.

Biocon Diabetology has set new standards in the way diabetes therapy is marketed and managed in India. We are perceived as a front-runner in the Indian Diabetes market. With a differentiated range of diabetes products, this division has provided diabetics with high quality, innovative and affordable diabetes management options. Our first

insulin analog Glargine, branded BASALOG®, was introduced into the market in 2010 and is already the No. 2 brand. We have innovatively supported this division through a successful patient engagement program, Winning with Diabetes, and are now creating a medical education forum, ABIDE. This forum will enable a strong doctor-patient interface through a network of clinics, supported on an IT platform. ABIDE also aims to disseminate medical information and training modules to diabetics and physicians in remote corners of the country.

Spurred by the success of our Insulins, we have entered into a path-breaking agreement with Pfizer to address a large and lucrative global opportunity for Biosimilar Insulins. Having posted impressive growth in FY 2010-11, the recent launch of Insugen® 100 IU has reiterated Biocon's commitment to introducing WHO-recommended international standards for rh-Insulin. We will also be shortly launching our much-awaited Insulin pen, INSUPEN®.

#### NEPHROLOGY

Since its launch in 2007, Biocon Nephrology has come a long way in offering the most comprehensive and wellbalanced portfolio of products for dialysis and transplantation. Biocon has also developed a very strong portfolio around Chronic Kidney Disease. Our Nephrology division has performed exceedingly well, with its flagship brands TACROGRAF™ (tacrolimus) – now occupying the No. 2 position in the market – and RENODAPT® (mycophenolatemofetil) – the third-largest brand in its category. Impressive branding, high visibility in the market and a differentiated safety device have propelled the success of our ERYPRO<sup>™</sup> group of erythropoietin-based therapies for the dialysis segment.

# **ONCOTHERAPEUTICS**

In Oncology, our brand portfolio has garnered impressive market share. Anchored by our proprietary anti-cancer MAb, BIOMAb EGFR®, supported by Abraxane®, an albumin fusion nanoparticle taxane, and our biosimilar Granulocyte Stimulating Factor (GCSF), NUFIL<sup>™</sup>, the division is gaining good traction in the market. The current financial year was marked with the launch of various marketing initiatives which served to differentiate BIOMAb EGFR® in the targeted therapies market and boost Abraxane®'s brand equity. A robust clinical development program is now underway to further analyze and explore the possible benefits of these molecules to treat various types of cancers.

# CARDIOLOGY

Launched in 2008, the fourth division, Cardiology, has been propelled by our flagship brand STATIX®. Q3 2011 saw the launch of PRASACT<sup>TM</sup> (prasugrel) and TIROZEST<sup>TM</sup> (tirofiban) to consolidate our interventional cardiology portfolio. Recent introductions like BESTOR® (rosuvastatin) and ACTIBLOK<sup>TM</sup> (metoprolol) continue to follow a high-growth trajectory. We have launched several patient awareness drives and institutional initiatives for enhanced management of cardiovascular disease. Our portfolio of Cardiology products is receiving nationwide appreciation from medical and patient communities.

#### **IMMUNOTHERAPY**

In FY 2011, we added a new division: Immunotherapy. In Phase I this division will roll out molecules for the treatment of immune-related dermatological disorders. It launched with two differentiated molecules in its armory – TBIS® (tacrolimus) and PICON® (pimecrolimus), for the treatment of atopic dermatitis and vitiligo. Both drugs have been well accepted and are performing exceedingly well in the market. The division will leverage its strong research capabilities and technology platform to develop a robust pipeline of innovative molecules. Among the division's most promising pipeline therapies is a humanized monoclonalantibody, iltolizumab.

#### **COMPREHENSIVE CARE**

To cater to the critical care segment, Biocon launched a Comprehensive Care Division to provide affordable and quality medicines for illnesses including nosocomial infections, post-surgical complications, trauma, and medical emergencies. The division's robust portfolio of products includes CELRIM®, CELRIM TZ®, Biopiper TZ™, IMICELUM™, PENMER®, ENTAVAR™, MEEZAT™, and GENPIROME®. I am proud to declare that within just six months from launch, this division has gained entry to the country's best corporate hospitals with its high-quality portfolio of specialty products.

#### **Research & Development**

Biocon's R&D has had a highly successful, decade-long track record of innovation. Our research efforts have generated a robust pipeline of generic small molecules, biosimilars and novel biologics with the potential of unleashing high-value growth in a sustained manner over the foreseeable future.

Our portfolio of generic molecules has enabled us to garner a dominant position as a supplier of generic APIs, viz. statins and immunosuppressants, to US, European and Latin American markets. This, I am pleased to say, has yielded good financial returns and has allowed us to forge very strong partnerships with global generics companies. One such partner, Mylan, has extended this relationship in 2009 to a portfolio of biosimilar monoclonal antibodies. In October 2010, we announced a global commercialization partnership with Pfizer for our portfolio of recombinant human insulin analogs.

Our novel pipeline is also rapidly advancing into the clinic. The most advanced programs are IN-105 (oral insulin) and T1h (itolizumab), an anti-CD6 targeting MAb, both of which have completed Phase II/III proof of efficacy clinical studies. Oral Insulin met all secondary end-points, indicative of proof of action. Another program, BVX-20, a humanized anti-CD20 monoclonal antibody being co-developed with Vaccinex, is about to enter the clinic. Two more in early stages of development are: a hybrid peptide with dual pharmacology for type II diabetes being co-developed with Amylin; and immunoconjugated Mabs which will function as tumor vaccines. The latter are being developed with latriCa, a start-up which originated from a discovery made at the Johns Hopkins University. We expect to initiate discussions for partnering a few of these programs in the coming fiscal.

# Patents

Biocon was granted 40 patents in FY 2010-11. Our total IP asset stands at 1,075 patent applications, of which 148 are PCT applications and 245 are granted patents.

#### **Strategic Partnerships**

Forging symbiotic partnerships has always been at the heart of Biocon's business philosophy and we will continue to build value through strategic partnering. We have sought both research and marketing partnerships as a way to make a global impact.

#### Pfizer

The most visible and high-profile partnership that we recently announced was with the world's leading pharmaceutical company, Pfizer, to commercializeour insulins portfolio. Pfizer will have exclusive and a few coexclusive rights to commercialize these products globally, while Biocon will be responsible for the clinical development, manufacture and supply of these biosimilar insulin products. We firmly believe this landmark partnership will drive considerable growth in the foreseeable future. By 2015, a number of insulin analogs are expected to lose patent protection, resulting in a significant opportunity for the biosimilars market. With this alliance, Pfizer and Biocon expect to be well positioned to be the first movers in this potentially large market opportunity.

# Optimer

FY 2011 also saw Biocon and Optimer Pharmaceuticals Inc. enter into a long-term supply agreement for the commercial manufacturing of the API, fidaxomicin, Optimer's new drug for the treatment of C. difficile. I believe our partnership with Optimer is an emphatic recognition of Biocon's capabilities as an R&D partner as well as an acknowledgment of our global biomanufacturing strength. I am delighted to inform you that Optimer has just received US FDA approval for this molecule. Biocon is the sole supplier of this drug substance for their global markets.

#### **Strategic Foreign Direct Investment**

World-class infrastructure and attractive tax incentives make Malaysia a compelling destination for biotechnology. Investing in Malaysia provides us with an international location with strategic geographical proximity to India. Biocon is pleased to be an early mover in this emerging opportunity and has agreed to invest in establishing a biomanufacturing facility at Bio-XCell, a custom-built Biotechnology Park in Iskandar Malaysia, Johor. This investment is the largest for the Malaysian biotechnology sector thus far. In the first phase, Biocon proposes to invest around USD 160 million to create an insulin manufacturing facility targeted to be operational by 2014.

#### **Research Services**

Our research services business supported by Syngene and Clinigene continues to be a key growth driver, delivering a CAGR of 13%. Clinigene has completed a decade of excellence in offering quality clinical research solutions and its major achievement this year has been the successful completion of a first-time US FDA inspection of the Human Pharmacology Unit (HPU) and the Bioanalytical Research Laboratory.

We are well positioned to take advantage of the increasing trend in big pharma to externalize R&D. Additionally, there is a perceptible drift from fee for service and component services to integrated R&D and partnered codevelopment on a risk-sharing platform. Syngene and Clinigene are uniquely placed to offer end-to-end integrated services in both small and large molecules.

Our partnership with Bristol-Myers Squibb is a forerunner of this integrated service model. The customized R&D hub, BBRC, that has been created at Syngene, is enabling BMS to pursue pipeline development through a team of over 450 scientists working seamlessly with BMS labs in the US.

# **Beyond Borders**

#### NeoBiocon

After the successful launch of Abraxane® in the UAE region, this year NeoBiocon has introduced a range of branded generic products in therapy areas of cardiology, diabetology and infection management. NeoBiocon has posted substantial growth in revenues and profits and we are pleased with the progress of this JV and look forward to greater access to this high-growth region.

# AxiCorp

Pursuant to our global insulins partnership with Pfizer, I would like to announce that Biocon is divesting its stake in its German subsidiary, AxiCorp GmbH, to the existing group of promoter shareholders. We believe that this is in the best interests of the shareholders of both companies.

Axicorp has done an admirable job in sustaining profitability under difficult external circumstances, triggered by German healthcare reforms. Biocon wishes AxiCorp's management and employees the very best in their future endeavors.

# **Corporate Social Responsibility**

The year gone by saw Biocon Foundation focusing on integrating its health initiatives to maximize their impact and relevance to the communities it works with. By bringing together the Foundation's programs in preventive healthcare, primary healthcare and health insurance for surgery and other hospital care, we aim to make our healthcare interventions more effective, sustainable and scalable.

In FY 2011 we concentrated on preventive health, particularly addressing problems related to the paucity of doctors. Keeping this in mind, we train community health workers to be peer educators and helpers who administer our programs, ranging from a unique mobile phone-based cancer screening program to preventive health education.

We are excited about the potential of this mobile oral cancer screening program to detect oral cancer in the early or pre-cancerous stages, thereby enabling the possibility to make lifestyle changes that can provide better outcomes or even eliminate the onset of cancer altogether.

Biocon and Biocon Foundation have also assisted the Government of Karnataka in building hundreds of homes for displaced families in the Bagalkot district of Karnataka that was severely affected by floods.

# FINANCIAL PERFORMANCE

Consolidated revenues (including AxiCorp) increased 17% from Rs. 2,405 crore to Rs 2,814 crore. Sales revenue from research services grew 13% from 281 crore to 318 crore. Consolidated EBITDA grew 24% from Rs 509 crore to Rs 630 crore. Operating margins (excluding AxiCorp) were maintained at a healthy 24%. Consolidated PAT increased to Rs 368 crore against Rs 293 crore in FY 2010

#### **Looking Ahead**

The organization we have built this far provides us with a strong foundation for a new era of growth. We are now Asia's largest biopharma company and the only Asian company among the top 25 in global biopharma. The critical mass we have garnered in our journey in the domestic formulations space gives us the confidence to pursue an enhanced brand position in the market. These branded formulations, coupled with our strong R&D pipeline, integrated portfolio of research services, and strategic partnering, will ensure that Biocon's growth trajectory sustains its momentum for years to come. I would like to see Brand Biocon build on its core values of quality, affordability, reliability, and innovation to become a global biopharma leader which makes a difference to millions of lives across the world. That to me is the true and enduring test of a successful brand in the global pharmaceutical arena.

I would like to take this opportunity on behalf of the Board of Directors to thank our esteemed shareholders for their belief in our innovation-led entrepreneurial spirit. Inspired by the tremendous possibilities of science and working with commitment, teamwork and integrity, Team Biocon has remained admirably focused on advancing novel therapies, driving our businesses and supporting patient health, the world over. I look forward to the year ahead with a sense of confidence to deliver even greater value to all our stakeholders.

Thank you,

Kiran Mazumdar-Shaw Chairman & Managing Director

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Bangalore Thursday, July 21, 2011