



# 35<sup>th</sup> Annual General Meeting

Chairman's Speech  
July 26, 2013

## PARADIGM CHANGED

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AGM Venue: Tyler Jacks Auditorium, Biocon Research Centre  
Biocon Park, Plot No. 2, Bommasandra-Jigani Link Road, Bangalore 560 099

### Dear Shareholders,

Welcome to the 35th Annual General Meeting of Biocon.

I am extremely happy to share with you that FY13 has been an extremely important year for us. With the approval of Itolizumab, a novel molecule for the treatment of Psoriasis, Biocon has changed the healthcare paradigm in India. An outcome of transformative innovation, this novel biologic drug has the imminent potential to alter the course of autoimmune diseases and the lives of patients all over the world.

The year gone by has been extremely gratifying for Biocon as we delivered on our commitment of affordable innovation, through successful development of 'first in class' novel Biologic Itolizumab to be introduced in India as ALZUMAb™. This is the first anti-CD6 monoclonal antibody in the world to be commercialized, which makes it a path breaking innovation to come out of an Indian laboratory. While large pharma innovators are now pursuing molecules that play in the Th17 pathway, Biocon is a recognized front-runner. This is a recognition of the quality of research done at Biocon.

During the year we also made significant strides towards effecting organizational change that can deliver the required growth to meet the aspirational goal of achieving a US\$ 1 billion top line by 2018. In consultation with McKinsey & Co. we arrived at an optimal paradigm that can drive robust and sustainable growth.

### Paradigm Change – Organizational Structure

After careful deliberation, we decided to move from a function-led to a business-led structure by carving out Strategic Business Units (SBUs), where businesses own core functions and share support functions.

Accordingly, five key Business Units have been created:

- **Small Molecules:** APIs and Generic Finished Dosages
- **Biosimilars:** Insulins, Monoclonal Antibodies & Biologics
- **Branded Formulations (India)**
- **Novel Molecules**
- **Research Services**

These changes, we believe, will help us create an optimal matrix, where business heads will have greater clarity on business needs and a better understanding of deliverables. We also expect that this will enable shorter response times and faster decision making thereby enabling better execution of strategy. A key expectation is that each SBU head will have greater autonomy and greater accountability for the financial performance of their respective businesses.

### Paradigm Change – Business Strategy

#### SBU: Small Molecules - APIs & Generic Finished Dosages

##### Added Value

Up until now, our Biopharma business was led by fermentation-based small molecule APIs viz. Statins and Immunosuppressants. The strategy ahead is to lower the threat of commoditization by moving up the value chain to Generic Finished Dosages for global markets.

Our ANDA sub business unit aims to build a robust pipeline of difficult-to-make, technology intensive molecules which can be commercialized primarily in the U.S. as well as other global markets.

The focus is on key therapeutic segments like oncology, diabetology, cardiology, dermatology, ophthalmology and inflammatory diseases. We currently have over 20 ANDA programs under development. We expect to file our first ANDA in the U.S. by FY15.

#### SBU: Biosimilars - Insulins & Monoclonal Antibodies

##### The Next Wave of Growth

Biosimilars are expected to provide the next wave of growth for Biocon as global consensus builds around regulatory guidelines. Patents protecting some of the biggest-selling biologic products will expire soon, heralding that global markets are getting ready for the entry of Biosimilars. The latest available IMS forecast for Biosimilar products indicates a global market size of US\$ 5 billion by 2016.

Aligning with this opportunity, we expect that revenues from Biosimilar Insulins & Monoclonal Antibodies (MAbs) will contribute approximately 20% to our overall business revenues by 2018.

We have allied with Mylan as a strategic partner for our Biosimilar programs. This partnership has seen two phases of collaboration. The first phase was initiated in 2009 with a portfolio of five Biosimilar Biologics viz. Trastuzumab, Bevacizumab, Etanercept, Adalimumab and Pegfilgrastim. Phase two in 2013 saw the extension of this partnership to include three Biosimilar Insulin Analogs viz. Glargine, Lispro and Aspart.

The Biosimilar Insulin Analogs deal executed with Mylan this year, is significant as it endorses the high value of Biocon's Insulins portfolio, following the amicable dissolution of our global partnership with Pfizer in FY12. Unlike the erstwhile Pfizer deal, which was based on development milestone payments and royalties, the Mylan deal involves co-development and profit sharing upon commercialization. This means that Mylan will bear a significant portion of the development costs required to take these Insulin Analogs to the U.S. and European markets.

Significant progress is being made in our Biosimilar MAbs programs. A global Phase III trial for Biosimilar Trastuzumab for treating metastatic breast cancer (MBC) continues to recruit patients with trial approvals in major European countries. We have also completed patient recruitment in a separate Phase III trial for Biosimilar Trastuzumab in India and expect to file for regulatory approval with the Drugs Controller General of India (DCGI) in 2014.

#### SBU: Branded Formulations (India)

##### Premium Niche through Branded Biologics

Over the years, Biocon has been able to differentiate itself as a biologics-led healthcare company and has thereby created a premium niche in a crowded Indian pharma market. Today, Biocon stands apart as the largest domestic Branded Biologics Company in the country.

Our India-centric Branded Formulations business has a portfolio of over 80 brands across seven therapy segments. What makes us unique is the fact that approximately 50% of our business accrues from Biologics. Biologics are expensive to develop, but by offering these world-class products at affordable prices, we have been able to make a huge difference to millions of patients in India. Biocon's contribution to bringing affordable medicines to the market is making significant impact in cancer care, where our wide portfolio of drugs is gaining us recognition as a leading Oncology Company in India.

Nimotuzumab, sold under our brand BIOMAb EGFR®, is a humanized anti-EGFR MAb which has revolutionized the treatment of head and neck cancer in India. It is considered the best available treatment in its class of drugs given its efficacy and superior safety profile in terms of minimal skin toxicity. BIOMAb EGFR® also provides reduced cost of therapy which is at least 50% lower than other comparable therapeutics. Over 5,500 patients have been treated with BIOMAb EGFR® thus far. Significantly, over 1,500 patients have been able to access this life-saving drug through our compassionate use program for underprivileged patients.

Another key treatment is Evertor™, the first generic Everolimus (an mTOR inhibitor) to be introduced to several global markets. Launched two years ago, Evertor™ has been used to treat over 1,100 renal cancer patients. The drug has been offered at a therapy cost that is at least 60% lower compared to the innovator brand.

Our leading division, Diabetology continues to grow in stature as the largest Indian Insulins Company. In keeping with our mission to deliver affordable healthcare, our Insulin products marketed under our brands Insugen®, BASALOG® and INSUPen® have made an enormous difference to diabetics not only in India but to patients across developing and emerging markets.

#### SBU: Novel Molecules

##### From 'Lab to Market'

ALZUMAb™ (Itolizumab), our novel anti-CD6 MAb, ready to be introduced in India, will offer a new line of treatment that is set to usher in a paradigm shift in the management of psoriasis. In addition, ALZUMAb™ (Itolizumab) has shown promise in several other indications including rheumatoid arthritis (RA), multiple sclerosis (MS) and other autoimmune conditions. Emerging data shows that Th17 cells – a subset of T-cells – play a critical role in autoimmunity and there is a new focus within the biotech/pharma industry to design ongoing research around the Th17 pathway.

ALZUMAb™ (Itolizumab) has taken the lead in this area. It targets CD6, a cell surface receptor expressed by T-cells, shown to reduce proliferation of Th1 and Th17 cells. Biocon is one of the few companies to have a novel MAb with a mechanism of action (MOA) and clinical data involving the Th17 pathway.

Leading Indian dermatologists who participated in the pivotal clinical trial are encouraged with the long remission of psoriasis in patients treated with

ALZUMAb™ (Itolizumab). For Biocon, we see this novel drug as an important beginning in our quest for recognition as a global innovator and we have made a big statement with ALZUMAb™ (Itolizumab). We are proud that this will be the first instance of a breakthrough innovation that will be taken from India to the developed world.

Our Oral Insulin candidate IN-105 is also a novel molecule that we believe holds great promise. The ongoing effort is to redesign a protocol that will correct the inadvertent flaws of a previous trial and bring out the efficacy of this exciting molecule. Bristol-Myers Squibb (BMS) has seen the merit of this approach and has entered into an Option Agreement for IN-105. This agreement provides for financial and developmental assistance from BMS to establish efficacy through a number of Phase I & II clinical trials. On the completion of these studies, BMS will have an exclusive option to further develop and commercialize the asset worldwide.

### SBU: Research Services

#### Differentiation through Specialized & Integrated Services

This business unit comprising Syngene and Clinigene platforms, celebrated a big milestone this year when it crossed the US\$ 100 million revenue threshold. This validates the strategy of moving from a commoditizing 'fee-for-service' model to integrated and value-added services that span from early discovery to late stage clinical development. The robust growth delivered by this business reflects a strong mix of retained and expanded clientele as well as the addition of important new customers across diverse platforms that go beyond biopharma to include nutrition, consumer health, agrochemicals, food science and electronics sectors. Today, we have approximately 90 life sciences customers including 16 of the Top 20 biopharma companies of the world. The current growth momentum and strong order book indicates that we are moving in the right direction.

In fact, Syngene has emerged as India's largest and Asia's second largest Research Services Company.

Syngene's growing stature has also attracted a valuable investor GE Capital to take an approximately 7.7% stake at a post investment valuation of Rs 16,250 million. This clearly validates the scale, the value, the quality and the differentiation of Syngene as a leading Research Services Company.



### Biocon in Malaysia

The construction of Biocon's biopharmaceutical manufacturing and R&D facility in Malaysia is progressing rapidly as per plan and is on track to come on stream by FY15.

This new state-of-the-art facility will provide additional capacities to cater to Biocon's increasing demand for insulin and insulin analogs for emerging and developed markets. A small dedicated HR team at Malaysia has already started the recruitment process for the upcoming facility.

## Paradigm Change – Corporate Social Responsibility

### Building Sustainable Solutions

We see Corporate Social Responsibility (CSR) as a very important part of our business. As a Company, we are conscientious about investing in our community and will strive to comply with the new Companies Bill recommendation to allocate 2% of corporate profits in the realm of CSR.

The Biocon Foundation was created in 2005 to redefine Corporate Social Responsibility, the Biocon way. Our approach has been to make enduring social impact through programs that build sustainability.

### Healthcare

Our comprehensive healthcare efforts span preventive, primary, secondary and tertiary healthcare programs. Our micro-health Insurance program, Arogya Raksha, now serves nearly 2,00,000 people across nine primary health centers in rural Karnataka.

This year, we increased our focus on chronic illnesses through tobacco cessation and oral cancer screening programs. Our oral cancer screening program in collaboration with the State Government and ASHA workers (Accredited Social Health Activist) has conducted screenings in high risk groups in three pilot villages this year. Mobile phones equipped with specially developed software were used to screen over 5,000 people, of which over 300 individuals were detected with positive lesions, who were taken to the nearest diagnostic center for a biopsy. This helped in early intervention and potential cancer cure. This program also aims to drive the cessation of tobacco products usage, which is the root cause of oral cancers.

Biocon Foundation, in partnership with the local administration at Bagalkot, also initiated a pilot program to address the issue of child malnutrition after a survey conducted in the district which revealed that over 3,000 children under the age of five were malnourished.

### Education

Starting with one district and 11,000 Chinnara Ganitha maths work books in 2006, we now print 1,00,000 books which are distributed in 8 districts in Karnataka. Recent data indicates that children have significantly benefited from these books as their computational skills are way above those who have not had access to these books.

### Infrastructure

Biocon Foundation has been involved in the reconstruction of Mangalgudda village, where many families were rendered homeless by devastating floods that hit North Karnataka in 2009. At the request of the Government of Karnataka, Biocon has built over 400 new houses in Mangalgudda and handed over to the government for further allocation. Each house has been provided with a toilet and solar lighting. We have been requested to build additional 100 homes which we have agreed to do this fiscal.

We want to build a model village with good sewage and sanitation, rain water collection, a primary health care center, a computer aided school and a community center to conduct workshops on skills and adult education.

## Financial Performance

FY13 has been a very significant year for us at Biocon. At a Group level, revenue grew 18% to Rs 25,380 million driven primarily by stellar performances in Research Services and Branded Formulations. Our Research Services business showed a robust revenue growth of 36% from Rs 4,101 million to Rs 5,572 million this year. Our Branded Formulations business grew 34% from Rs 2,594 million to Rs 3,474 million in FY13. Overall, our EBITDA and PAT margins have been delivered at 23% and 20% respectively.

Exceptional income realized from the partnering of our Biosimilar Insulin Analogs portfolio with Mylan saw the Group net profit surge 50% to a record Rs 5,088 million. Excluding exceptional items, Group net profit was at Rs 3,430 million. It must be highlighted though, that PAT has been significantly impacted by tax which has increased from Rs 541 million in FY12 to Rs 975 million this fiscal. This is on account of a partial loss of SEZ and EOU tax benefits for various manufacturing facilities.

### Looking Ahead

FY14 promises to be an exciting year for Biocon as we will launch ALZUMAb™, our second novel biologic after BIOMAb EGFR®. To sustain our growth momentum we will continue to augment our Branded Formulations and Research Services businesses. We also expect to expand our Insulin footprint in emerging markets which will add to this growth. Our focus this fiscal will be to optimize our product mix in our APIs business and drive down cost across all businesses through higher productivity and better cost containment. I would like to commend Team Biocon for delivering strong growth under challenging circumstances in FY13.

Finally, I am proud that our strong commitment to research and innovation has enabled us to bring to the market a 'first-in-class' biologic drug that has the potential to change the treatment paradigm of psoriasis and other autoimmune diseases. This lends credibility to our strategy of building a rich pipeline of innovative programs that has today made Biocon one of the highest R&D spenders in this country. I have no doubt that innovation and intellectual property are hallmarks that will create exponential and enduring value for Biocon's stakeholders in the coming future.

Kiran Mazumdar-Shaw  
Chairman

## Paradigm Changed : 2013

**ALZUMAb™**  
A novel biologic

'FIRST-IN-CLASS'  
NOVEL BIOLOGIC FOR PSORIASIS

With the approval of Itolizumab, a novel anti-CD6 antibody, for the treatment of *Psoriasis*, Biocon has changed the healthcare paradigm in India. An outcome of transformative innovation, this novel biologic drug has the imminent potential to alter the course of autoimmune diseases and the lives of patients all over the world.

- **Excellent Safety and Efficacy Profile**
- **Longer Remission Periods and Low Infection Rates.**



### Psoriasis Clinical Study with Itolizumab

#### Patient 1



Before

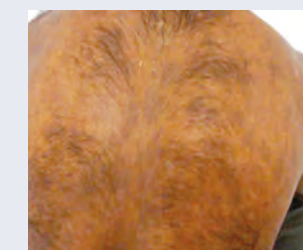


After

#### Patient 2



Before



After