

# FORTITUDE

## Four Decades of Pioneering Excellence

### CHAIRPERSON'S REVIEW

Kiran Mazumdar-Shaw  
Chairperson & Managing Director

Dear Shareholders,

Forty years ago, I started Biocon with the vision of creating a business that would leverage science for the benefit of society.

With just two employees, Biocon started making industrial enzymes in a 3,000 square feet shed in Bengaluru. Our beginning was small, but our aspirations were big.

In the next 40 years, we balanced scientific risks, capability risks, regulatory risks, financial risks and business risks to emerge as India's premier biopharmaceutical enterprise. Today, we are known for our world-class products, our talented human capital, our marquee partners and our pioneering role in building a biotechnology-led business in India.

Our fortitude led us to brave the odds in building a business model around the then nascent field of biotechnology. We were driven by a business purpose to replace polluting chemical technologies with eco-friendly enzyme based technologies, an idea ahead of its times. It was a big challenge to convince industry leaders to invest in clean, eco-friendly biotechnology-based solutions at a time when environmental sustainability was not a global priority. We persisted and finally succeeded in getting many companies across different industries to make the switch to environmentally responsible enzyme based technologies as early as 1980.

We were an enzymes-led biotechnology enterprise until 2007 when we divested this founding business to fuel our ambition of making a difference to patients through our biopharmaceuticals business. That said, over nearly three decades, Biocon had emerged as India's largest enzymes company which led to a rich value being ascribed for the acquisition.

The new focus on biopharmaceuticals drew its mission from the huge unmet need that patients in India and the developing world suffered on account of lack of access and affordability. Moreover, we truly believed that we could drive exponential growth through this new strategic intent. Thus Biocon moved from revenues of ₹318 million in 1999 to over ₹5 billion in 2004, a milestone that provided us the confidence to go for an Initial Public Offering (IPO).

### Statins: Risk-Taking Pays Off

Our foray into biopharmaceuticals started with statins, a class of small molecules that lower cholesterol levels in the blood by reducing its production in the liver. We had to negotiate a host of scientific capability and regulatory risks to go from manufacturing enzymes to making fermentation-derived statins for global markets. Our ability to take this kind of a risk paid off when in 2001 Biocon became the first Indian company to be approved by the U.S. FDA to manufacture Lovastatin using solid state fermentation technology.

We subsequently became one of the biggest statins producers worldwide. Today, our Active Pharmaceutical Ingredients (APIs) or drug substances are used to produce billions of statin pills globally.

### 40 Journey of FORTITUDE

Our revenue stood at over ₹5 billion in 2004 at the time of our IPO, growing from ₹318 million in 1999.





## 40 Journey of FORTITUDE

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### Insulins: Making a Difference by Being Different

We took another calculated risk when we chose to expand our strategic options from small molecules like statins to recombinant proteins like insulins to address the growing healthcare challenges associated with diabetes. We did not hesitate to exploit differentiated technologies, such as a proprietary yeast platform based on *Pichia pastoris* to make recombinant human Insulin (rh-Insulin) at a time when other insulin makers were using the 'tried and tested' *Escherichia coli* bacterial expression system. We continue to be the only company in the world that is producing rh-Insulin and insulin analogs on a *Pichia* platform. Taking this risk has enabled Biocon to emerge as a leading insulins player globally. Biocon today has the science, scale, scope, technology and over 15 years of experience in addressing the needs of patients with diabetes, having provided over 2 billion doses worldwide.

In India, we built on the impact we created through our branded insulin, Insugen®, to develop a Branded Formulations portfolio aimed at patients suffering from life-threatening conditions such as cancer and renal illnesses.

### Novel Biologics: Upping the Ante

We did not limit ourselves to generic insulins but decided to push scientific boundaries and create new knowledge that was breakthrough in its impact to human existence through novel biologics and novel targets in the area of large molecules. At a time when the prevailing business ethos of the Indian pharma industry centred on manufacturing generic medicines, we decided to embark on an IP-driven strategy of differentiation to build credibility while enabling a first mover advantage in many cases.

It was a huge scientific risk because we decided to start our novel molecules journey with a complex entity: a monoclonal antibody. It paid off and Biocon earned the distinction of launching India's first indigenously produced novel monoclonal antibody for head & neck cancer, Nimotuzumab, in 2006. The effectiveness of our molecule was endorsed last year as an outcome of an investigator-initiated study on head & neck cancer patients at the prestigious Tata Memorial Hospital, Mumbai, which demonstrated that Biocon's Nimotuzumab in combination with chemo-radiation showed statistically significant improvement in progression-free survival over the standard of care, which is chemo-radiation alone.

Our work on first-in-class drugs, including oral insulin (Insulin Tregopil) and anti-CD6 antibody (Itolizumab), allowed us to push the boundaries of science to invest in developing affordable therapies that can impact global health.

Through Itolizumab we were able to offer an affordable biologic therapy, which involved a less aggressive dosing regimen and a longer treatment free period, to psoriasis patients in India when we launched it as ALZUMAb™ in 2013.

While Itolizumab was indicated for chronic plaque psoriasis in India, this unique molecule is potentially a 'pipeline in a product'. In FY19, a Phase I b / II trial in acute graft-versus-host disease (aGVHD) using Itolizumab was initiated by our partner Equillium, who has licensed the molecule for development in U.S. and Canada. Equillium has been awarded 'fast track' and 'orphan drug' designations for the molecule in both prevention and treatment of aGVHD by the U.S. FDA.

### Taking Our Novels Play to the Next Stage

Translating great laboratory discoveries into clinical success is a major challenge for the global biopharma industry. To lower the risk of failure and translate our new molecule discoveries to the clinic more effectively, we have strengthened our already existing translational sciences capabilities by

building a dedicated and experienced scientific team within R&D and entered into key collaborations.

In FY19, we incorporated Bicara Therapeutics based in Boston, U.S., as a wholly owned subsidiary of Biocon to focus on developing a pipeline of bifunctional antibodies that exploit the recent advances in immuno-oncology. We believe bi-specific antibodies are the next big opportunity as they offer an advanced therapy option against cancer.

In doing so, Biocon has today emerged as a strong innovation-driven biopharma company operating out of Asia, which has put India on the global innovation map.

### Riding the Biosimilars Opportunity

Biocon was among the early movers in industry to pursue a high risk strategy of developing biosimilars for global markets. This was a key strategic decision taken by the management to further advance our commitment for providing affordable access to life-saving biologics. In hindsight, it was an enormous financial and business risk with a number of unknown regulatory risks. It was sheer fortitude that has enabled us to take a lead in this very coveted new business segment.

Through our 'Made in India' biosimilars business, we seek to pursue a humanitarian path that will provide affordable access to high quality generic biologics to make a difference to diabetes, cancer and autoimmune diseases.

Our long-standing global biosimilars strategy of 'emerging markets first' and 'developed markets later' is paying off well. We have succeeded in bringing the benefit of high quality biosimilars to patients in India, other emerging market countries in Latin America, Africa, Middle East & Turkey, Asia-Pacific regions and also now in developed markets of U.S., EU and Japan.

As our biosimilars business has reached a new inflection point, we are consolidating the development, manufacturing and commercialization operations under an independent entity, Biocon Biologics with its own dedicated management. We have recently appointed Dr Christiane Hamacher as the CEO of Biocon Biologics. I am confident that with her depth of knowledge and experience of global markets, she will successfully lead the company to its next milepost of benefiting millions of patients across world markets.

### End-to-end Integrated Discovery & Development Services

Our trust with innovation started with Syngene in 1993, which was set up to spearhead a new concept of providing scientific research services to global innovator companies. We took on the challenge to position India as a 'destination of choice' for outsourcing scientific research activities. Today, Syngene offers 'end-to-end' integrated discovery and development services to leading life sciences companies like Bristol-Myers Squibb, Amgen and Baxter.

### Sustainability Programs and Corporate Social Responsibility

Our underlying ethos of access and affordability goes beyond our business. We had set up Biocon Foundation in 2004 as part of our Corporate Social Responsibility (CSR) to address gaps in essential healthcare services, basic education, sanitation and hygiene in underserved urban and rural areas of India. We undertook various CSR initiatives with the aim of promoting socio-economic inclusion through innovation and sustainable models that deliver scalable solutions.

## 40 Journey of FORTITUDE

Biocon was among the early movers from India to pursue a high-risk strategy of developing biosimilars for the global markets. Through this business, we seek to pursue a humanitarian path to provide access to high quality affordable biologics.



## 40 Journey of FORTITUDE

We brought effective primary healthcare services to the doorsteps of the less privileged in rural and urban India through our unique technology enabled eLAJ Smart Clinics operational at the PHCs in collaboration with the government.



As a pharmaceutical company working in the space of chronic diseases, we were painfully aware of the struggle that the poor and marginalized in India face in accessing even basic healthcare services. To address this situation, we brought effective primary healthcare services to the doorsteps of the less privileged in rural and urban India by establishing Primary Healthcare Centers (PHCs), actively creating awareness about disease prevention, public health and nutrition. We took this a step forward through our unique, technology-enabled eLAJ Smart Clinics, which are providing prevention, early diagnosis and better treatment outcomes, as well as, reducing out-of-pocket expenditure for communities with poor healthcare access. eLAJ Smart Clinics were operational at 18 PHCs which recorded nearly 167,000 patient visits in FY19.

Given that a third of oral cancer cases in the world are reported in India, Biocon Foundation initiated formation of an Oral Cancer Task Force comprising seven eminent oncologists from all over India. This Task Force has developed guidelines for the management of head & neck cancer in India. During the year, nearly 11,000 people were screened for oral, breast and cervical cancers by the Foundation which helped in early diagnosis and treatment.

As a company that has worked on cleaner and greener biotechnologies based on enzymes, we have taken a novel approach to revive some of Bengaluru's polluted lakes. We have implemented a three-step bioremediation process using technology which is unique and cost effective in comparison to conventional draining and cleaning processes and have succeeded in restoring the ecosystem of the dying 35-acre Hebbagodi Lake, located in the outskirts of Bengaluru. This project has won several awards including a place in the Limca Book of Records for introducing the largest artificial floating wetlands in India. The 'proof of concept' established at Hebbagodi Lake has opened the path for Biocon Foundation to initiate other lake rejuvenation projects.

The evolving science in the biotech sector is leading to a demand for high-skilled jobs in India. We realized that a wide gap exists between the quality of human capital available in India and the growing needs of the industry. In order to address this huge talent deficit we established the Biocon Academy in partnership with Keck Graduate Institute, U.S., in 2013. The Academy currently runs four specialized programs in collaboration with leading institutes from India including its flagship Biocon KGI Certificate Program in Biosciences. Over 500 students who have graduated from the Academy, have been placed across 50 leading biotech and pharma companies in India.

### Financial Highlights: FY19

Biocon has scaled up its size manifold in terms of revenue and profits during its 40-year journey. In FY19, we reported a robust growth of 31% with a Consolidated Revenue of ₹56,588 million. Our Net Profit for the year soared 143% to ₹9,053 million. Adjusted for exceptional items and associated tax, our Net Profit almost doubled in FY19 to ₹7,291 million.

During the year, three of our strategic business segments, Small Molecules, Biologics and Research Services, crossed the ₹15 billion revenue milestone. FY19 was a landmark year for the Biologics business, which reported a growth of 97% to ₹15,169 million, thus emerging as a key driver for Biocon's incremental growth. Our annual revenue performance was also supported by a 28% growth in the Research Services segment to ₹18,256 million and 18% growth in Small Molecules to ₹17,728 million. Branded Formulations revenue grew a modest 7% to ₹6,564 million.

A higher share of Biologics revenue in FY19, boosted profitability as reflected in the consolidated EBITDA margin of 27% for the full year despite a 34% increase in Net R&D expenses on account of higher spends on biosimilars as well as the Generic Formulations programs. We continue to invest heavily in R&D as we believe it is the fuel that will spur our future growth. At a gross level, we spent ₹4,796 million on R&D this year, corresponding to 13% of revenues excluding Syngene.

## Looking Ahead

In the next few years, we aim to make our R&D engine extremely efficient. Having successfully delivered several biosimilars to patients in U.S., EU and Japan, we have gained rich experience in managing the risks entailed in taking advanced therapies from 'bench to bedside' even in the most stringently regulated markets.

We aim to develop the next wave of biosimilars through a faster and far more predictable process supported by high-end computing and data analytics. Biocon, with Mylan, Sandoz and its other partners, will certainly focus on maximizing the efficiencies that we enjoy as a fully integrated biosimilars company.

Currently, some of our partners have taken the onus of commercializing Biocon-manufactured biosimilars in global markets. Going forward, Biocon aspires to front-end the commercialization of some of its biosimilar assets in global markets. We believe that to succeed in an increasingly competitive market place we will need to be disruptive in the way we serve patients, prescribers and payers. We are investing in digital technologies that can help us differentiate our products in global markets to deliver sustained success.

FY20 promises to be an exciting year for Biocon as all our growth verticals including Biologics, Small Molecules, Branded Formulations and Research Services, build on their performances of FY19, opening up immense growth opportunities for the Company.

In conclusion, I would like to state that our strategy of being a differentiated biopharmaceuticals company, leveraging innovation for affordable access has been fraught with risks and challenges. We have succeeded in making a difference to millions of patients, enduring the complexity of the ecosystem through our courage of conviction and commitment to address global health challenges.

I would like to thank our shareholders for traversing this arduous journey along with us and reposing their trust in the Company's management. We look forward to their encouragement and contribution, as we pursue the next phase of our journey.

Thank You.  
Yours sincerely,



**Kiran Mazumdar-Shaw**  
Chairperson & Managing Director  
May 29, 2019

## 40 Journey of FORTITUDE

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