Chairperson's **Review**

Kiran Mazumdar-Shaw
Chairperson & Managing Director

Our Journey of **Endurance**

Dear Shareholders,

2018 marks 40 years of Biocon's journey of endurance during which we have pushed many challenging boundaries to provide us with a leading edge as India's premier biopharmaceutical enterprise.

Developing biologics for global markets takes patience, deep pockets and an unwavering focus. Navigating the research, development, manufacturing and regulatory pathways for these cutting-edge therapies are akin to endurance races. Many competitors dropped out of the race when faced with the grueling obstacles of regulatory and investment risks. Skeptics told us that a small biotech company out of India would find it difficult to meet the quality and manufacturing standards demanded in developed markets. We ensured that we thwarted such concerns with a deep commitment to quality and regulatory compliance. And it is this never-say-die spirit that has given us an 'enduring edge.'

We demonstrated our competitive edge this fiscal when we became the first Company from India to get its biosimilar Trastuzumab approved by the U.S. Food and Drug Administration (FDA) in December 2017.

Biosimilars market is expected to grow rapidly, exceeding USD 28 billion by 2020 from the present USD 5 billion.*

In the U.S., healthcare savings arising from biosimilars are projected in the range of USD 24 billion to USD 150 billion between 2018 and 2027.

**Source: Genetic Engineering & Biotechnology News*

We demonstrated our competitive edge when we became the first Company from India to get its biosimilar Trastuzumab and Pegfilgrastim approved by the U.S. Food and Drug Administration.

This product has been co-developed with our partner Mylan and will be launched in the U.S. market under the brand name Ogivri™.

We crossed another landmark this year when Semglee™, our Mylan-partnered biosimilar Insulin Glargine, was approved in EU and then in Australia.

In June 2018, Biocon and its partner Mylan became the first to receive approval for biosimilar Pegfilgrastim from the U.S. FDA.

These approvals have propelled us into an exclusive league of global biosimilars players.

Biocon: At the Right Place at the Right Time

These achievements will enable us to deliver on our stated promise of providing affordable access to life saving biologic drugs which represent a large and increasing portion of the overall prescription drug market. In 2017, biologics accounted for 11 of Top 15 drugs by value. *(Source: Genetic Engineering & Biotechnology News).* As these drugs are complex to develop, they are exponentially more expensive than conventional prescription drugs. The advent of biosimilars, or biogenerics, provide relatively lower cost access to these advanced therapeutics and thereby an opportunity for significant savings for patients, insurers and the healthcare system overall. As patents expire on novel biologics, the biosimilars market is expected to grow rapidly, exceeding USD 28 billion by 2020 from the present USD 5 billion. *(Source: Genetic Engineering & Biotechnology News).* Biocon is today well poised to enter the developed markets of U.S. and Europe at a time of increasing acceptance of biosimilars. The European Union has over 40 biosimilar drugs approved since 2006. The U.S. is catching up fast with 11 biosimilar approvals over the last three years. There is greater clarity now on "interchangeability" of biosimilars, extrapolation of clinical data to other indications, and the ability to launch upon approval, subject to patent expiry, in the U.S. Encouragingly, U.S. pharmacy benefit managers (PBMs) are giving preference to biosimilars.

It is equally reassuring to see the regulatory willingness to abbreviate the approval pathway for biosimilars based on advancements in the understanding of biologic molecules. These developments are helping to ensure that safe, effective, and affordable biosimilars reach patients faster, as payors and prescribers gain greater confidence in increasing their adoption.

Over a span of a decade, we have developed a rich pipeline of approved and in-development biosimilars that have concurrently built high end R&D and regulatory expertise.

Differentiating to Lead

At a time when the prevailing business ethos favored predictable and attractive ROCE (Return On Capital Employed) ventures based on chemically synthesized generic drugs, Biocon chose to invest in developing biologic drugs based on recombinant DNA led bio-processing technologies. This called for a combination of specialized talent, state-of-the-art research and manufacturing infrastructure and a culture of deep science and regulatory compliance. The ability to comprehensively deliver on these have given us the 'edge' to produce innovative and affordable biologics at a scale that can address global market needs.

Our core values of quality, affordability, reliability and innovation have differentiated us in the marketplace and given us a distinct competitive edge. We have earned the distinction of being one of the Top 3 global players of biosimilar insulins in volume terms, which enables us to pursue our goal of supporting 'one in five' insulin-dependent people with diabetes the world over.

Climbing the Learning Curve

Over a span of a decade, we have developed a rich pipeline of approved and in-development biosimilars that have concurrently built high end R&D and regulatory expertise.

Our 'lab to market' journey for biologics started with two novel monoclonal antibodies, Nimotuzumab for cancer and Itolizumab for autoimmune diseases. It is this approach that has enabled us to acquire deep insight into immunology and antibody technology. Additionally, we have leveraged this knowledge to develop a wide portfolio of biosimilar drugs to address a large and evolving worldwide demand.

While the opportunity was vast, we realized that the investment and regulatory challenges posed grave risks. We therefore chose to partner with Mylan, a global leader in generic medicines, who was willing to share the risks and co-develop a mutually selected portfolio of biosimilars for worldwide marketing.

We also recognized the additional risks of developing biosimilars against a backdrop of evolving regulatory pathways in different global jurisdictions. To this end, Biocon and Mylan have worked closely to play a key role in the knowledge exchange with regulators, payors and other stakeholders in order to enable the evolving regulatory pathway for biosimilars.

Pursuant to our growing stature in the biosimilars arena, we have entered into another global partnership this fiscal with Sandoz, a Novartis division, for a set of next-generation biosimilars.

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Both our partnerships have been forged on cost and profit sharing. Whilst our partnered program with Mylan addresses market opportunities that emanate over the next five years, our partnership with Sandoz will address patent expiration opportunities thereafter.

Path-breaking Novel Innovation

Apart from biosimilars, our biologics strategy has had a keen focus on developing a pipeline of innovative drugs. We continue to progress on our novel programs that encompass fusion antibodies and cutting-edge antibodies; which have generated encouraging and exciting data, garnering a great deal of licensing and partnering interest from leading pharma and biotech companies.

In FY18, JDRF extended their support to our R&D efforts aimed at developing our first-in-class oral insulin molecule, Insulin Tregopil, to treat Type 1 diabetes. Recently, a large investigator-led study with Nimotuzumab in head and neck cancer patients in India established the molecule's 'best-in-class' status for the treatment of one of the most common forms of cancer in the country.

Managing Risks

Running India's largest biopharmaceutical company in a risk-averse investment environment has been a constant balancing act. Our biopharmaceutical strategy entails a high risk-high reward model. In order to balance the risk profile, we have adopted a hybrid business model that generates predictable earnings which help to support the investment needs of our biosimilars portfolio. Additionally, our collaboration with Mylan has provided a risk sharing platform that is now at a stage of delivering commensurate returns to both partners.

Scale-Up

Biocon's mission of making a difference to global healthcare calls for sizable capital intensive investments in research and manufacturing infrastructure to deliver economies of scale. Over the last decade, Biocon has built India's largest bio-manufacturing facilities in Bengaluru and Asia's largest Insulins manufacturing complex in Malaysia. We have also invested in creating one of the largest fermentation based bulk drug capacities for Statins and Immuno-suppressants globally. These investments have and will enable us to have a significant global footprint to serve patient needs.

Over the past year, we initiated the construction of our second antibodies facility in Bengaluru, to support our projected biosimilars business for the next decade. The year gone by has also seen capacity expansion of our

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Malaysia insulins facility. Our biopharmaceutical facilities have received drug substance and drug product approvals from several regulators globally.

Regulatory Challenges

In FY18, our manufacturing sites in India and Malaysia underwent several inspections by various regulatory agencies as a part of the drug product approval process. Some of these audits led to regulatory observations that were largely procedural and aimed at continuous improvement but some also required remedial measures, including plant modifications in order to be fully compliant. We have also proactively engaged qualified third party consultants and external experts to assess the effectiveness of the corrective and preventive actions undertaken by us and evaluate our quality systems and manufacturing operations in order to be on par with global best practices.

Financial Highlights

FY18 delivered revenue of ₹43,359 million and a YoY growth of 6%. Net profit for the year stood at ₹3,724 million. The revenue growth in FY18 was driven primarily by a 19% increase in our Research Services business, a strong turnaround post the fire incident in December 2016. Our Biologics segment revenue delivered a modest 10% growth on account of a plant shutdown that was required for modifications and requalification post regulatory audits. Branded Formulations sales increased 11% YoY whilst our APIs business de-grew marginally due to pricing pressure exerted by a commoditizing market. Significantly lower licensing income also muted earnings. Our Group EBITDA at ₹10,353 million for the year represented an EBITDA margin of 24%.

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We ended the year with a strong fourth quarter wherein Biologics and Research Services businesses grew 47% and 45%, respectively, and the Small Molecules and Branded Formulations businesses turned in a positive performance, indicating a normalized business trend.

Sustainability Programs and Social Responsibility

At Biocon, we are intensely conscious of our role as a responsible corporate citizen. Our business philosophy that aligns with the importance of sustainable healthcare solutions, finds resonance in our engagement with our employees, the environment and society at large. We are constantly investing in adopting best practices for a safe and healthy environment. Our CSR efforts through Biocon Foundation are directed at addressing critical national and state level gaps in primary healthcare, education, environmental sustainability and rural development.

The Foundation has developed a unique eLAJ Smart Clinic model to deliver diagnosis-based primary healthcare to communities with poor access to quality healthcare. The eLAJ network has been further expanded this year with the addition of 10 new clinics in various districts of Karnataka. The 21 eLAJ smart clinics run by the Foundation have provided healthcare services and recorded nearly 2,30,000 patient visits in FY18. In Rajasthan, the Jhalawar primary healthcare centre (PHC) run by the Foundation was declared a 'model' PHC by the Rajasthan government.

We have also conducted a number of health camps of which our flagship cancer detection program has screened over 53,000 men and women for oral, breast and cervical cancers till date. Patients with potential risk have been supported to undergo further evaluation.

As a part of our efforts aimed at ensuring environmental sustainability, Biocon has taken an ambitious initiative to contribute to the lake revival mission of Bengaluru. Biocon Foundation has embarked on saving two large lakes in the vicinity of our facilities. Bioremediation has resulted in significant improvement in the water quality of these lakes. Steps are now being taken to ensure that these water bodies are spared from sewage, debris and garbage dumping.

On the education front, Biocon Academy has continued its mission of training biotech students into industry ready talent. The Academy has an unblemished 100% placement record where its students have been hired by leading Indian biotech and pharma companies. Building on the success of the current programs, we have rolled out two new programs for Clinical Development and Faculty Development in FY18. So far, over 400 students have graduated from Biocon Academy.

Today, Biocon is at an inflection point and looks set for sustainable long term growth led by its various businesses.

Looking Ahead

The year gone by has witnessed the significant progress made by our biosimilars pipeline in gaining approvals from the U.S. FDA, European Medicines Agency (EMA) and regulators of emerging markets.

These approvals are expected to translate into accelerated revenues in the years ahead starting with FY19. Syngene is poised to do well on the back of a vibrant outsourcing market and robust long term demand. We are also moving up the value chain from APIs to generic finished dosages which we anticipate will drive strong growth in the Small Molecules business and help us recover from the headwinds that we have faced in the year gone by.

Today, Biocon is at an inflection point and looks set for sustainable long term growth led by its various businesses.

It is sheer endurance that has brought us here. We have stayed the course and believed in our business model. We have successfully managed both failures and risks in a fast changing world that brings new and disruptive ideas every day. We have constantly raised the bar by benchmarking ourselves against the global best. Through a combination of high technology, talent, and a culture rooted in deep science we have proved that as an organization, we have what it takes to make world-class, cutting-edge biologics. We are proud of the fact that we have put India among the frontrunners in the global biosimilars race. Our ability to endure has ensured the biosimilars business is no longer perceived as a high-risk bet with a low probability of success, but a high-value market opportunity.

Finally, I would like to thank our esteemed shareholders, partners and other stakeholders for believing in our story and reposing their confidence in our capability and extending their support in our long journey of endurance.

Thank You.

Yours sincerely,

Kiran Mazumdar-Shaw
Chairperson & Managing Director

June 6, 2018