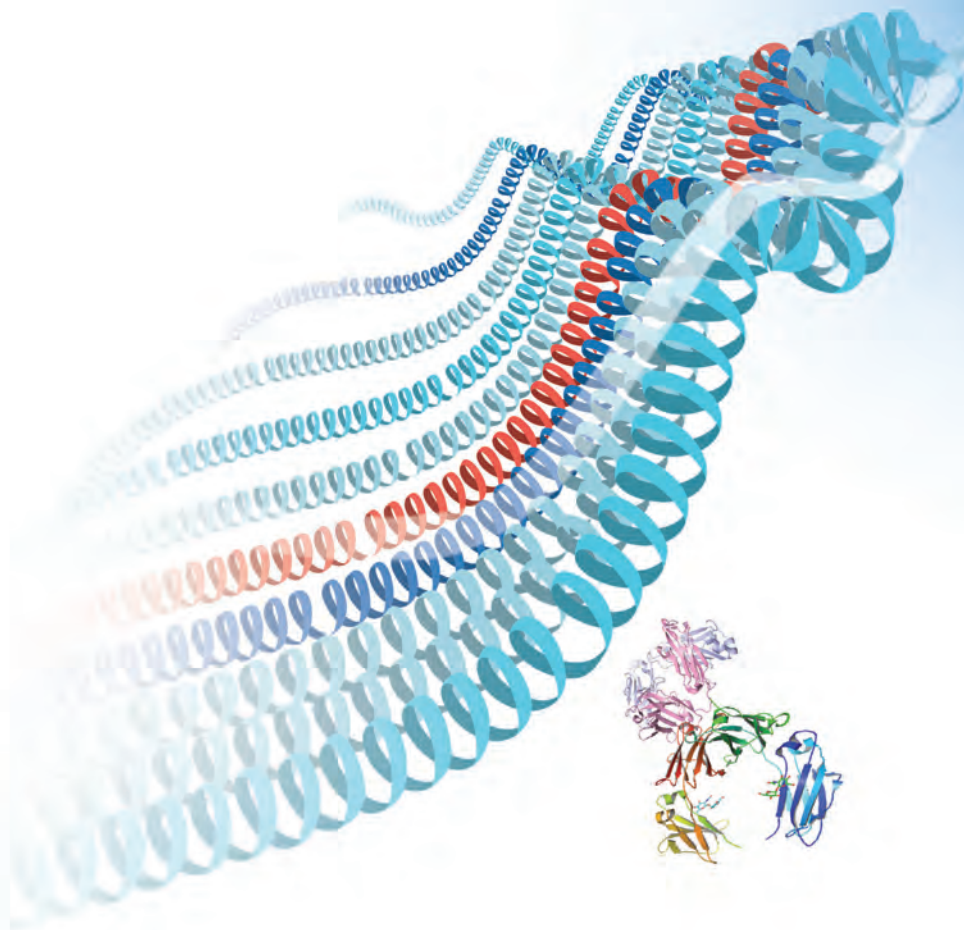




# Enduring Edge

Annual Report **2018**







# Enduring Edge

In a world of complexities, uncertainties and evolving medical paradigms, Biocon's enduring edge leads it to a position of strength in the biosimilars domain.



Biocon has been on a quest to make a difference to global health by developing high quality biopharmaceuticals, and enhancing access by making these products affordable for patients across the world. It has been a journey of endurance over several decades.

We  
have...

**evolved** from manufacturing speciality enzymes, to pharmaceuticals like statins and immunosuppressants, to discovering, developing and producing life-saving biotherapeutics.

**built** capabilities in research & development, manufacturing and commercialization which have taken us from being the 'first Indian company' to win U.S. Food & Drugs Administration approval for manufacturing Lovastatin API in 2001, to becoming the 'first' Company globally to get its biosimilar Trastuzumab and Pegfilgrastim approved in the U.S. in 2017 and 2018, respectively. We are also amongst the first few to receive Insulin Glargine approval from the European Commission in 2018.

**endured** the complexities involved in the global scale-up of a wide range of biologics to attain a strong competitive edge in the marketplace and become one of the leading biosimilars players for insulins, globally.

**established** robust regulatory and quality systems to develop and deliver complex therapeutics spanning insulins to monoclonal antibodies for chronic conditions.

**leveraged** our strengths in innovation, differentiated technologies and scientific talent pool, to create a world-class, agile organization. In doing so, we have succeeded in being recognized as a credible global biopharmaceuticals player.





Our accomplishments during these years, are a reflection of our tenacity, agility and resilience, demonstrating our 'Enduring Edge'.



Key Elements  
of Our  
**Cutting-Edge  
Strategy**



Differentiation



Operational Excellence





Agile Innovation



Smart Risk



Global Scale



Sustainable Quality



Adaptive Learning Organization



Enabling Affordable Access



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# Making Quality Cancer Care Affordable

We created history in December 2017 when biosimilar Trastuzumab co-developed with our partner Mylan won approval from the U.S. Food and Drug Administration (FDA). Ogivri™, a drug for treating aggressive forms of breast and gastric cancers, is the first biosimilar Trastuzumab to be approved in the U.S. It defines an inflection point in Biocon's biosimilars story as Ogivri™ is not only the first biosimilar from our joint portfolio with Mylan to get a regulatory approval from the U.S. FDA but has also made us the first Indian company to have a biosimilar approved in the U.S.



Trastuzumab is a targeted therapy indicated for the treatment of certain HER2-positive early stage and metastatic breast cancers, as well as, metastatic gastric cancer. HER2-positive cancers are those that test positive for the human epidermal growth factor receptor 2 (HER2), which promotes cancer cell growth. About 25% of the nearly 2 million women diagnosed with breast cancer each year worldwide have HER2-positive tumors. Trastuzumab is a monoclonal antibody that binds to the HER2 protein in tumor cells and flags it for destruction by the body's immune system. It has been included in the World Health Organization's list of essential cancer medicines.





## Initial Development

Our Trastuzumab development journey began in 2008 with the cloning of the antibody. The DNA sequence that encodes Trastuzumab antibody was engineered from a very extensive analysis of the protein sequence. This DNA sequence, inserted into the Chinese Hamster Ovary (CHO) cells, helped transcribe the Trastuzumab protein. The protein was purified from the cell culture and formulated. Subsequently, extensive physicochemical and biological characterization involving highly sensitive and orthogonal comparative analytics across a wide range of product attributes and iterative process development were conducted on the expressed protein to ensure that the characteristics of the biosimilar drug and the reference product fell within the same ranges.

## India Launch

In 2011, we initiated a multi-centric Phase III clinical trial in India, administering either the biosimilar or the reference product in patients in a blinded manner. The clinical studies conclusively established the similarity of our Trastuzumab to the reference product in terms of pharmacokinetics (PK), safety, efficacy and immunogenicity. On completion of clinical trials in July 2013, the regulatory submission for biosimilar Trastuzumab was made to the Drug Controller General of India. In November 2013, our product became the first biosimilar Trastuzumab to be approved anywhere in the world and in 2014 it was launched in India as CANMab™.

## Global Clinical Studies

In 2013, we started the global HERITAGE study, a double-blind, randomized clinical trial designed to evaluate comparative efficacy and safety of our biosimilar Trastuzumab versus the reference product. Eligible patients had centrally confirmed, measurable HER2-positive metastatic breast cancer without prior chemotherapy or Trastuzumab for metastatic disease. Patients were randomized to receive either the biosimilar or the reference product with taxanes (docetaxel or paclitaxel) for a minimum of eight cycles. Subsequently, patients with at least stable disease were continued with the biosimilar or reference product until disease progression. The primary endpoint was overall response at week 24 by blinded central evaluation using RECIST 1.1. Secondary endpoints included progression free survival, safety and overall survival at 48 weeks. A sample size of 456 patients was calculated to demonstrate equivalence in overall response at week 24 for biosimilar versus the reference product. This HERITAGE study was the last major step of a multi-phased program to demonstrate that our biosimilar Trastuzumab met the criteria for equivalence in comparison to the reference product. Published study results showed an overall

response rate of 69.6% for biosimilar Trastuzumab compared to 64% for the reference product. There was no statistical difference between the biosimilar and the reference product at week 48 for tumor progression, progression free survival and overall survival.

## Regulatory Journey

Around 600 patients participated across our India Phase III and multi-centric global HERITAGE studies. The robust data package demonstrated that our product was highly similar to the reference product and no clinically meaningful differences existed between them in terms of safety, efficacy and immunogenicity.

In June 2016, we presented 24-week data from the HERITAGE study at the 2016 Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago.

The package was submitted by our partner Mylan to the U.S. FDA as part of the Biologics License Application for biosimilar Trastuzumab in November 2016.

The U.S. FDA's Oncologic Drugs Advisory Committee (ODAC) voted unanimously (16-0) for the approval of our biosimilar Trastuzumab in July 2017. In December 2017, the U.S. FDA

## Biocon's Trastuzumab Journey



Cloning  
Scale up

2008-  
2010

India Phase III Study  
Process & Formulation  
Development

2011-  
2012

approved Ogivri™ (trastuzumab-dkst) for all indications included in the label of the reference product, including for the treatment of HER2-overexpressing breast cancer and metastatic gastric cancer.

Our biosimilar Trastuzumab is currently under regulatory review in Australia, Canada, EU and several other markets.

In 2018, we presented the 48-week data from the HERITAGE study at ASCO's Annual Meeting in Chicago. The 48-week data further demonstrated that Ogivri™ is highly similar to the reference product and no clinically meaningful differences exist between them in terms of safety, purity and potency. We believe this positive data will enable wider adoption of our biosimilar Trastuzumab, thus expanding access to this therapy for cancer patients across the world.

### Expanding Global Footprint

We demonstrated our commitment to enhance access to cutting-edge biologics therapy for cancer patients in emerging markets in 2018 when we became the first to get regulatory approvals for biosimilar Trastuzumab in Brazil and Turkey, two of the Top 4 emerging markets globally for this key breast cancer drug.

The U.S. FDA approval of our biosimilar Trastuzumab was not just a milestone for Biocon, but also for India's pharmaceutical industry. Representing a landmark achievement for the Biocon-Mylan collaboration, it is also an endorsement of our development, regulatory and manufacturing capabilities in the area of monoclonal antibodies. This journey has strengthened our resolve to continue to endure the challenges and stay on the chosen path of enabling access to affordable biotherapeutics.



CANMab™ Approved & Launched in India  
Global HERITAGE Study



Final Similarity Package  
BLA Filing with U.S. FDA



Ogivri™ Approved - Dec 2017  
Post U.S. FDA ODAC's Unanimous (16-0) Vote for Approval in July 2017





# A Commitment to Effective Diabetes Management

Biocon embarked upon the Insulin Glargine development journey after successful launch of Insugen® (recombinant human Insulin) in India. We are driven by our passion to develop affordable biopharmaceuticals and are committed to make insulin-based therapy increasingly accessible for people with diabetes globally.



Insulin Glargine is a long-acting insulin analog that offers better glucose control with the convenience of once daily injection versus the discomfort of multiple daily injections and reduces the possibility of developing hypoglycemia (low blood sugar). It is prescribed for adults with Type 2 diabetes as well as adults and pediatric patients (children 2 years and older) with Type 1 diabetes.





## Initial Development

The biological process of manufacturing Insulin Glargine starts with a yeast cell, *Pichia pastoris*, which is genetically engineered to express the human Insulin Glargine protein, when grown in culture, which is then purified and formulated. The quality of the Insulin Glargine is established and controlled using multiple orthogonal analytical techniques.

The CMC development, non-clinical and clinical studies for Insulin Glargine in India culminated in its approval and subsequent launch under the brand name BASALOG® in 2009.

To take Insulin Glargine to people with diabetes worldwide, Biocon initiated its global CMC development program in 2010. Our comparative pharmacokinetics / pharmacodynamics (PK/PD), Phase I trials demonstrated the bioequivalence

# Biocon's Insulin Glargine Journey

2006-2009

CMC Development  
 India Toxicology & Clinical Studies  
 Approved & Launched in India

2010-2012

Global CMC Development  
 Global Toxicology Study  
 IND/CTA Filed in U.S.  
 Global PK/PD Study  
 RoW Filings Initiated  
 Partnered with FFP in Japan  
 IND Filed in Japan  
 Japan PK/PD Study

of biosimilar Insulin Glargine with the reference product in glucose clamp studies.

## Global Trials

In 2013, we expanded an existing global partnership with U.S.-based Mylan to include insulin analogs, Glargine, Aspart and Lispro. Subsequently, we initiated the global INSTRIDE clinical program to establish the efficacy, safety and immunogenicity of biosimilar Insulin Glargine in comparison to the reference product in patients with Type 1 and Type 2 diabetes. INSTRIDE 1 was a 52-week study in 558 Type 1 diabetes patients, while INSTRIDE 2 was a 24-week study in 560 Type 2 diabetes patients. In both the studies, patients were randomized to receive either biosimilar Insulin Glargine or the reference product once daily and the primary endpoint was change from baseline in HbA1c after 24 weeks. Secondary endpoints included glycemic endpoints such as change from baseline in fasting

plasma glucose and insulin dose, as well as, safety endpoints like systemic reactions, device-related safety issues and immunogenicity.

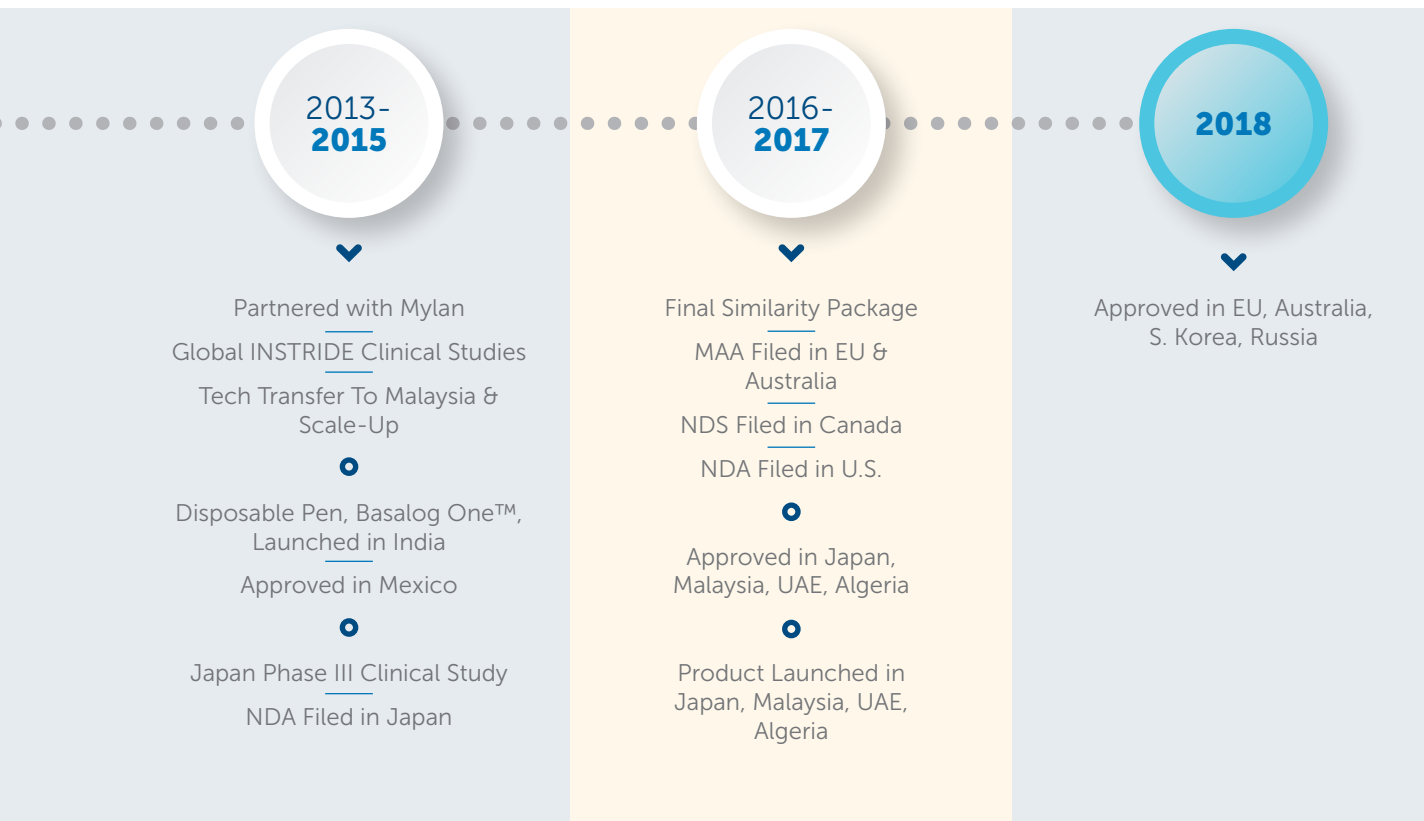
On conclusion of the trials, we made a regulatory submission with the European Medicines Agency (EMA) in 2016, which included analytical, functional and pre-clinical data, as well as results from the PK/PD and confirmatory efficacy/safety global clinical trials for biosimilar Insulin Glargine.

## Approvals Across the Globe

In 2015, our product became the first Insulin Glargine to be approved in Mexico as per the country's biologics approval pathway.

Subsequently, we achieved a major regulatory milestone with approval of our Insulin Glargine in Japan. The approval followed the successful completion of initial development by Biocon and local comparative Phase I followed by Phase III clinical studies in over 250 Type 1 diabetes patients





by our Japanese partner. This was Biocon's first biosimilar approval in a developed market and the first biosimilar from a company in India to be approved in Japan. The approval and launch of our Insulin Glargine disposable pen in Japan in 2016 was an important continuing endorsement of our product quality.

Till date, 1,700 patients and healthy volunteers have been evaluated in comparative clinical studies conducted across the U.S., EU, Japan, India, Canada and other countries for establishing the safety and efficacy of Biocon's Insulin Glargine.

In January 2018, the EMA's Committee for Medicinal Products for Human Use (CHMP) recommended Insulin Glargine co-developed by Biocon and Mylan for approval. After CHMP's positive opinion, the European Commission approved the sale of the biosimilar Insulin Glargine, Semglee™ 100 units/mL 3 mL prefilled disposable pen, in March 2018. It is the first biosimilar from Biocon and Mylan's joint portfolio

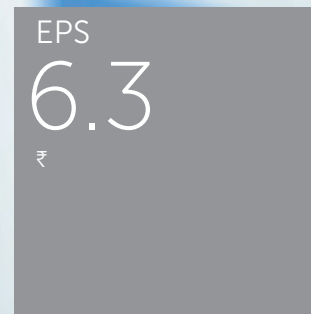
to be approved in Europe.

Our biosimilar Insulin Glargine has also been approved in Australia, Russia, Mexico, South Korea, Malaysia and 28 other countries, enabling us to provide an affordable treatment option to millions of people with diabetes worldwide.

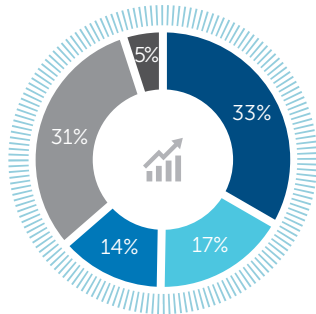
It is a proud achievement for Biocon that takes us closer to realizing our aspiration of reaching 'one in five' insulin dependent people with diabetes worldwide.



# FY18 at a Glance

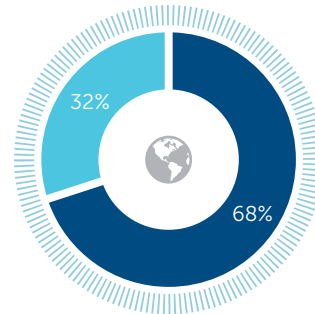


Business Revenue Mix\*



- Small Molecules ₹ 15,077 Million
- Biologics ₹ 7,702 Million
- Branded Formulations ₹ 6,115 Million
- Research Services ₹ 14,231 Million
- Other Income ₹ 2,062 Million

Geographic Distribution



- International
- Domestic

\*Includes inter-segment revenue

## Vision

To enhance global healthcare through innovative and affordable biopharmaceuticals for patients, partners and healthcare systems across the globe.

## Mission

To be an integrated biotechnology enterprise of global distinction

Essential to this mission is excellence in:

- Intellectual asset creation through discovery, research and development
- State-of-the-art manufacturing capabilities
- Internationally benchmarked quality and regulatory systems
- New medical insight through disease specific clinical research
- Customer relationship through outstanding products and services
- Human resource development through training, mentoring and empowering
- Management of research and business partnerships

## Values

- Integrity and Ethical Behaviour
- Performance Driven Work Culture
- Value Creation through Innovation and Differentiation
- Quality through Compliance and Best Practices
- Collaboration, Team Work and Mutual Respect





# 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



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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.





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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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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.

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 Immunosuppressants 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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We proactively evaluate our quality systems and manufacturing operations in order to be on par with global best practices.

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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The 21 eLAJ smart clinics run by Biocon Foundation have provided diagnosis based primary healthcare services and recorded nearly 2,30,000 patient visits in FY18.

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.



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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

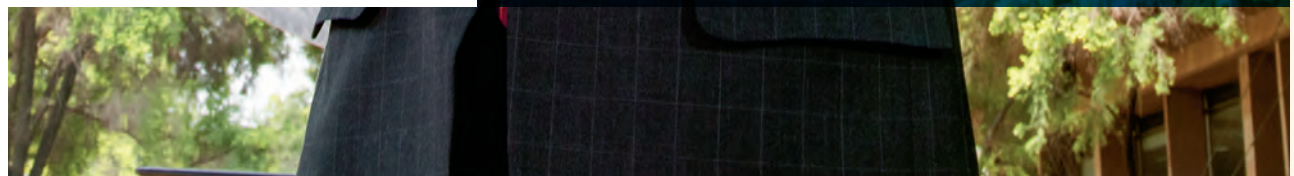


## Q&A with the CEO

Dr. Arun Chandavarkar,  
CEO & Joint Managing Director

Almost 70% of new drug approvals are predicted to be biologics by 2025. As innovator biologics lose patent protection or exclusivity,

it presents a significant opportunity for high quality affordable biosimilars to ease the strain on healthcare budgets.





# The Executive Edge

Sustaining an 'enduring edge' requires a deeply ingrained corporate culture that places a premium on good governance, compliance, integrity and collaboration.

## What are Biocon's core values that help it create an 'enduring edge' ?

Biocon aims to create an 'enduring edge' by a consistent focus on value creation through innovation and differentiation with significant investments in cutting-edge R&D and efficient, compliant operations. Our strategy is aligned to the global imperative of improving access to high quality, affordable biopharmaceuticals and speciality medicines in chronic therapies such as diabetes, oncology and immunology. This has translated into a diversified and differentiated pipeline of fermentation-derived complex generics, biosimilars that include insulins and monoclonal antibodies, and novel biologics.

Sustaining an 'enduring edge' requires a deeply ingrained corporate culture that places a premium on good governance, compliance, integrity and collaboration. We have consistently attracted top talent that shares these core values and believes in making a difference to patients globally.

## Being amongst the few companies globally to have received approvals from developed countries like the U.S., EU and Japan, how does Biocon propose to maintain an 'enduring edge' in biosimilars ?

Our credibility as a serious player in the biosimilars sector was first established with the Japanese approval for Insulin Glargine partnered locally with FUJIFILM Pharma. Our credibility was enhanced by the U.S. FDA approvals for biosimilar Trastuzumab and Pegfilgrastim and the European and Australian approvals for Insulin Glargine, both in partnership with Mylan. We have also established our presence in key emerging markets through safe, effective and high quality biosimilars including recombinant human insulin.

Maintaining an 'enduring edge' in biosimilars entails nurturing internal scientific talent and R&D infrastructure to support existing programs as well as an expanding pipeline; being in constant dialogue with key stakeholders to drive biosimilar adoption; seeking cost advantages through technology and operational excellence; being ever vigilant on quality and compliance through continuous improvement; and striking strategic partnerships to manage risks and bridge near-term experience gaps.

The foundation lies in our strong internal R&D capabilities across the entire development continuum spanning clone generation, process and analytical, pre-clinical and clinical development. Our regulatory strategies have benefited from the experience of navigating an evolving regulatory landscape as agencies gain confidence in delineating abbreviated approval pathways for biosimilars.



Our 'enduring edge' also stems from our strategic choice of not operating as a virtual company. We have made significant investments in commercial scale, globally compliant manufacturing facilities across diverse technology platforms.

Our 'enduring edge' also stems from our strategic choice of not operating as a virtual company. We have made significant investments in commercial scale, globally compliant manufacturing facilities across diverse technology platforms spanning insulin analogs, monoclonal antibodies and other recombinant proteins. We continue to expand our infrastructure in a capital efficient, modular way.

The long gestation period for development and the capital intensity of creating new capacity for biosimilars do entail effective management of scientific and regulatory uncertainty and financial risk. We have created an 'enduring edge' by mitigating these risks through shared risk-reward partnerships that bring in complementary skills and experience. Our long standing, successful global partnership with Mylan for a range of biosimilar antibodies and insulin analogs continues to expand. We recently entered into a global partnership with Sandoz (a division of Novartis) to prepare for the next wave of biosimilar opportunities that open up towards the middle of the next decade. We also have strong regional partnerships in many key emerging markets.

It is our endeavor to create an 'enduring edge' by establishing our brand with patients, prescribers, payors and regulators through robust quality systems at an affordable price.

**How do you see the biosimilars opportunity panning out and what can biosimilar players do to accelerate the adoption of biosimilars?**

Targeted therapies, especially monoclonal antibodies, have revolutionized treatment paradigms for many chronic diseases. Almost 70% of new drug approvals are predicted to be biologics by 2025. As innovator biologics lose patent protection or exclusivity, it presents a significant opportunity for high quality affordable biosimilars to ease the strain on healthcare budgets. Where approved, there has been rapid penetration of biosimilars in price conscious emerging markets. Among developed markets, Europe has led the way with over 40 products approved, many of which have captured significant market share in a relatively short time. Importantly, the growth in biosimilar

prescription volumes indicates a dramatic expansion of access to biologic treatment naïve patients.

Governments and regulatory agencies have recognized the role of biosimilars in addressing issues of access and affordability. They have introduced several measures to support biosimilar development and approval, encourage uptake across multiple indications and foster reimbursement. Product approvals based on a tiered, scientific evidence based approach aim to provide confidence to patients and prescribers in the safety, efficacy and quality of biosimilar products whilst enabling abbreviated clinical development, which often consumes two-thirds of the development budget. Judicial pronouncements such as those related to the Biologics Price Competition and Innovation Act (BPCIA) in the U.S. have brought much needed clarity. These, coupled with patent related strategies and discouraging anti-competitive responses by innovators, have provided greater predictability on accelerated launch timing and biosimilars adoption.

**The small molecule generics industry has encountered significant headwinds this past year. How is Biocon geared to face these challenges and ensure an 'enduring edge'?**

Historically, the U.S. has been the largest value driver for the small molecule generics industry. This has changed as consolidation and alliances have led to a handful of players controlling a large percentage of generic purchasing. The accelerated rate of product approvals and the increase in the number of applicants have dramatically increased the competitive intensity even during the period of shared exclusivity.

Biocon has focused on its core biotech capabilities in selecting its differentiated API portfolio largely comprising fermentation-derived molecules such as statins, orlistat, immunosuppressants, and other speciality molecules. We have strategically embarked upon capturing a larger portion of the value chain by developing our own formulation dossiers incorporating such differentiated APIs. This vertical integration across APIs and formulations is well appreciated by potential customers who recognize Biocon's long track record in quality compliance and wish to secure their supply chain from a continuity of supply perspective.



The catalysts for securing an 'enduring edge' in the novels portfolio are all about achieving successful proof of concept especially in diseases with unmet needs.

We will also derive synergies in terms of knowledge sharing across our complex generics and biosimilar development programs, especially in the areas of characterization, bioassays, clinical equivalence and delivery devices. We expect these initiatives to deliver an 'enduring edge' over time and enable us to succeed in limited competition opportunities. Meanwhile, our mature portfolio will deliver modest growth until the new opportunities manifest upon expiry of relevant patents.

#### How do you plan to accelerate growth and profitability in the Branded Formulations segment?

Biocon's Branded Formulations business, currently operational in India and UAE (through a JV), grew 11% in FY18 over the previous year. Whilst the business in UAE showed a robust growth, we have had challenges in India.

Our focus has always been to create large anchor brands comprising speciality molecules in chronic therapy segments. We intend to sharpen our attention on key markets and key segments to drive market share. Our key brands continue to do well; in FY18, 10 of our brands featured among the Top 3 in their respective categories and accounted for over 75% of our India sales. We will improve our execution, tracking and sales force effectiveness by leveraging technology. We expect our differentiated product portfolio to expand in sync with the global development and approval cycle of our biosimilars and complex generics. Meanwhile, we continue to seek opportunities for partnerships and in-licensed speciality products in our core therapy areas as we have done previously. Branded Formulations is a peoples' business and we will ensure that our core values and global reputation will continue to be a magnet for top talent who wish to create large enduring brands in India and elsewhere.

#### What are the key catalysts that will pave the way for an 'enduring edge' in novel biologics?

Our foray into novel biologics predates our entry into the biosimilars segment and is core to our diversified business model spanning low risk investments in research services and generics, moderate risk in

biosimilars and high risk in novels. Whilst product portfolio attrition can be high in the novels segment, it is our hope that the few that succeed will have a disproportionate impact on value creation.

Our existing novels portfolio has diverse assets acquired through early stage partnerships. These include monoclonal antibodies against novel targets like CD6, against established targets like CD20 and EGFR, and a pipeline of bispecific fusion antibodies that exploit the recent understanding of the role of checkpoint inhibitors. We continue to make clinical progress with Insulin Tregopil, our orally delivered insulin analog. The results of a large investigator initiated study on head and neck cancer patients at the Tata Memorial Hospital, Mumbai, showed that Biocon's novel biologic molecule Nimotuzumab combined with chemo-radiotherapy shows superior efficacy and safety over Standard of Care.

The catalysts for securing an 'enduring edge' in the novels portfolio are all about achieving successful proof of concept especially in diseases with unmet needs. We intend to initiate clinical development under an IND/ IMPD or equivalent and ensure that strong science and experience underpin our development efforts. We will focus on accelerating development of select high potential assets like the fusion antibodies which are at the forefront of technological innovation. We already leverage the strong development and operations capabilities that we have created in Biocon for our biosimilars portfolio. The endorsement of our approach is evidenced by the financial and scientific participation of credible organizations like JDRF (U.S.) in the development of Insulin Tregopil for people with Type 1 diabetes. Such partnering, combined with a prudent stage gate approach to development will mitigate our financial exposure in these high risk but high reward initiatives.





## Board of Directors

*First row: (from left)* Mary Harney, Dr. Arun Chandavarkar,  
John Shaw, Kiran Mazumdar-Shaw, Russel Walls

*Second row: (from left)* M. Damodaran, Dr. Jeremy Levin,  
Prof. Ravi Mazumdar, Daniel M. Bradbury,  
Dr. Vijay Kuchroo

# Erudite Multidisciplinary Group

The composition of Biocon's board of directors reflects the vision of bringing together a diverse and multidisciplinary group of erudite and experienced professionals who can contribute towards providing strategic direction to the Company's management to pursue its stated mission of enhancing global healthcare whilst upholding the highest standards of Corporate Governance.

Our board's diversity, in terms of gender, age, experience, ethnicity, geography, and industry expertise, contributes significantly to enriching the quality of the Company's decision-making process. Our directors have vast insights

and experience in various fields such as Research & Innovation, Corporate & Financial Management, Regulatory & Compliance, Global Healthcare and International Marketing.

Our international board members are based in U.S., Europe and Canada and bring diverse perspectives to address the demands of global healthcare. The board of six independent and four non-independent directors provides the oversight, insight and foresight necessary for ethical and responsible corporate leadership that ensures that the interests of the board, management and stakeholders are aligned.

Names	Nationality	Gender	Corporate & Financial Management	Research & Innovation	Global Healthcare	Regulatory & Compliance
Kiran Mazumdar-Shaw	India	F	●	●	●	●
John Shaw	UK/OCI	M	●		●	●
Dr. Arun Chandavarkar	India	M	●	●	●	●
Prof. Ravi Mazumdar	Canada/OCI	M		●		
Russell Walls	UK	M	●			●
Mary Harney	Ireland (EU)	F			●	●
Daniel M. Bradbury	U.S.	M	●	●	●	●
Dr. Jeremy Levin	U.S.	M	●	●	●	●
Dr. Vijay Kuchroo	U.S./OCI	M		●		
M. Damodaran	India	M				●

\*OCI = Overseas Citizen of India

## Kiran Mazumdar-Shaw

*Chairperson & Managing Director*

First generation entrepreneur with nearly 43 years' experience in biotechnology + Global business leader + Board member, Infosys, Narayana Hrudayalaya + Recipient of Indian civilian honors Padma Shri & Padma Bhushan + Highest French civilian honor Chevalier de l'Ordre National de la Légion d'Honneur + AWSM Award for Excellence by Feinstein Institute for Medical Research U.S. + Othmer Gold Medal by Chemical Heritage Foundation, U.S.+ Forbes 'World's Most Powerful Women' + Forbes 'World's Self-Made Women Billionaires' + No. 1 Business Captain in global Medicine Maker 2018 Power List + TIME Magazine's '100 Most Influential People in the World' + Signatory to 'The Giving Pledge,' the global philanthropy initiative.

## John Shaw

*Vice Chairman and Non-Executive Director*

Foreign promoter + Former Finance and Managing Director of Coats Viyella Group + Former Chairman, Madura Coats Ltd + Honorary Doctorate from University of Glasgow, UK + M.A. (Economic Hons.) in History and Political Economy from University of Glasgow, UK.

## Dr. Arun Chandavarkar

*Chief Executive Officer & Joint Managing Director*

Core member of Biocon's leadership team + Ph.D. in Biochemical Engineering from the Massachusetts Institute of Technology (MIT), Cambridge, U.S. + B. Tech in Chemical Engineering from the Indian Institute of Technology (IIT), Mumbai + Past Chairman, Confederation of Indian Industry's (CII) National Committee on Biotechnology.

## Prof. Ravi Mazumdar

*Non-Executive Director*

University Research Chair Professor, Department of Electrical and Computer Engineering, University of Waterloo, Canada + J.D. Gandhi Distinguished Visiting Professor at IIT, Mumbai + Member of U.S. Congress Sub-Committee on Science and Technology + Fellow of the Royal Statistical Society + Fellow of the Institute of Electrical and Electronics Engineers + Has over 150 refereed publications to his credit + Ph. D. from the University of California, Los Angeles (UCLA) + M.Sc. from Imperial College, London + B. Tech in Electrical Engineering from IIT, Mumbai.

## Russell Walls

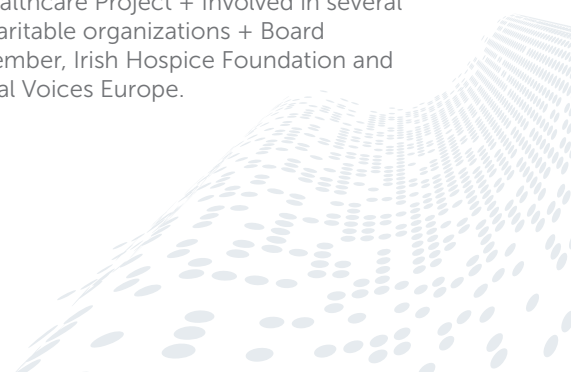
*Independent Director*

Experience of more than 48 years in the field of finance + Fellow member of the Association of Chartered Certified Accountants, UK + Experience as Director across pharmaceuticals, textiles, transport and leisure industries.

## Mary Harney

*Independent Director*

Deputy Prime Minister of the Republic of Ireland (1997 – 2006) + Held different ministerial positions in the Irish Government for 18 years + Retired from politics in 2011 and now acts as a consultant + Chancellor, University of Limerick + Chairperson, Pharmed Group and VideoDoc + Board member, Diona Technology and Euro Insurances + Chairs a Europe-wide Sustainable Healthcare Project + Involved in several charitable organizations + Board member, Irish Hospice Foundation and Vital Voices Europe.





## Daniel M. Bradbury

*Independent Director*

Life sciences executive with over 35 years of experience in creating and implementing strategies, transforming businesses + Former CEO, Amylin Pharmaceuticals, a leading metabolics company, acquired by BMS in 2012 + CEO, Chairman and Co-Founder of Equillium Inc. + Managing Member, BioBrit LLC + Member, Board of trustees of the Keck Graduate Institute, California, U.S. + Member, Advisory Council of Rady School of Management, San Diego + 'Director of the Year Award' by Corporate Directors Forum + San Diego American Diabetes Association's Father of the Year Award + Completed International Executive Program from INSEAD, France + Diploma in Management Studies from Harrow and Ealing Colleges of Higher Education, UK + Bachelor of Pharmacy from Nottingham University, UK.

## Dr. Jeremy Levin

*Independent Director*

CEO & Chairman of Ovid Therapeutics + Board member of Lundbeck + Former President & CEO of Teva Pharmaceuticals + Former Executive Committee member of Bristol-Myers Squibb + Served as Global Head of Strategic Alliances at Novartis + Recognized among 'Top 25 Most Influential People in the Biopharmaceutical Industry' + Recipient of Kermode Prize and Albert Einstein Award for Leadership in Life Sciences + Bachelor's Degree in Zoology, Master of Arts (MA) and a Doctorate (D. Phil) from the University of Oxford + Degrees of Bachelor of Medicine, Bachelor of Surgery from the University of Cambridge.

## Dr. Vijay Kuchroo

*Independent Director*

Samuel L. Wasserstrom Professor of Neurology & Director of Evergrande Center for Immunologic Diseases at Harvard Medical School + Senior Scientist at Brigham and Women's Hospital, Boston + Associate member, Broad Institute + Participant in a Klarman Cell Observatory project that focuses on T cell differentiation + Holds 25 patents + Serves on scientific advisory boards and works in advisory capacity to several companies, including Pfizer, Novartis and GlaxoSmithKline + Founded 5 different biotech companies including CoStim Pharmaceuticals and Temporo Pharmaceuticals + Published over 325 original research papers in immunology + A paper he authored on development of Th17 is one of the highest cited papers in immunology.

## M. Damodaran

*Independent Director*

Founder & Chairman, Indian Institute of Management, Tiruchirappalli + Chairman, Glocal Healthcare Systems Private Limited + Chaired Government of India Task Force to set up the Resolution Corporation of India + Former Chairman, Securities Exchange Board of India (SEBI), Unit Trust of India (UTI) and Industrial Development Bank of India (IDBI) + Former Chief Secretary, Government of Tripura + Set up Excellence Enablers Private Limited (EEPL), a Corporate Governance and Board Advisory consultancy firm + On the Boards of leading Indian Corporates as well as on the Advisory Boards of a few foreign entities.

# Scientific Advisory Board

## Prof. Alan D. Cherrington

Ph.D., Professor & Chairman of Molecular Physiology & Biophysics and Professor of Medicine & Diabetes Research, Vanderbilt University + Past President of the American Diabetes Association.

## Dr. Brian Kotzin

Medical Degree & Post-Doctoral Fellowship in Immunology & Rheumatology from Stanford University + Vice President of Global Clinical Development and Head of the Inflammation Therapeutic Area, Amgen + Vice President & Head of Medical Sciences + Member of the Advisory Council of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH + Associate Editor at Clinical Investigation.

## Dr. Brian Daniels

M.D., M.S. and B.S. from MIT + Venture Partner of 5AM Venture Management LLC + Former SVP, BMS + Directed and conducted clinical research at Merck Research Laboratories and at Genentech + Extensive experience in Clinical Development, Medical Affairs + Corporate Strategy across a broad range of therapeutic areas.

## Dr Chirag Desai

M.D., D.M., Medical oncologist + Involved with close to 20 phase-III clinical trials (national and international - multicentre) studies + Founder Member of Indian Collaborative Oncology Network + Member of ASCO, ESMO.

## Dr. David M. Essayan

M.D., Key Research Interests – Clinical and Regulatory development for small molecules and biologics + Clinical Immunologist; Former U.S. FDA Supervisory Medical Officer; Former Executive Director at Amgen.

## Dr. G. Alexander Fleming

M.D., President and CEO of Kinexum LLC + Member of numerous Scientific Advisory Boards and Expert Committees.

## Dr. Harold E. Lebovitz

M.D., FACE, Professor of Medicine, Endocrinology & Diabetes Division, State University of New York, Health Science Center, Brooklyn.

## Prof. Huub Schellekens

M.D., Ph.D. Professor at Medical Biotechnology at Utrecht University + Published more than 300 papers on development of therapeutic proteins + Member of the Dutch Medicine Evaluation Board + National Expert of the EMA.

## Dr. Jugnu Jain

Ph.D. from Cambridge University + Launched Sapien and Saarum in India + Molecular geneticist and cell biologist + Led Vertex's global immune inflammation team + Research on cytokine gene regulation at Harvard + Published over 30 papers + 2 patents.

## Dr Jayesh Desai

MBBS, FRACP, Heading the early drug development – Clinical trials in Victorian Comprehensive Cancer Centre + Lead investigator for multiple early stage oncology trials + Experienced in oncology translational research.

## Dr. Lawrence Steinman

M.D., Key Research Interests – Remission & Relapse in MS, Vaccine against MS, brain inflammation + Co-Inventor of leading MS drug Natalizumab and several new therapies for autoimmune diseases.

## Dr Moni Kuriakose

M.D., FFDRS, Professor of Oncology + Director, Translational Research for Head & Neck/Plastic & Reconstructive Surgery, Roswell Park Cancer Institute.

## Dr Susan Jerian

Regulatory and clinical development consultant + Focusing on Oncology FDA PreIND/IND/ Approval activities + Former Director of Clinical Research in Amgen.

## Dr. Vijay Kuchroo

D.V.M., Ph.D. Key Research Interests – Multiple Sclerosis, co-stimulation, Th17 + Currently on scientific review board of the National Multiple Sclerosis Society, New York.

# Key Management Team



**Kiran Mazumdar-Shaw**

*Chairperson and Managing Director*



**Dr. Arun Chandavarkar**

*CEO & Joint Managing Director*



**Siddharth Mittal**

*Chief Financial Officer*



**Dr. Narendra Chirmule**

*Head, R&D*



**Shreehas Tambe**

*Chief Operating Officer, Biocon Biologics*



**Paul V Thomas**

*Chief Commercial Officer, Biocon Biologics*



**Prasad BSV**

*Chief Operating Officer, Biocon Generics & APIs*



**Abhijit Zutshi**

*Commercial Head, Biocon Global Generics*



**Nehal Vora**

*Commercial Head, Biocon Global APIs*



**Suresh Subramanian**

*Head, Branded Formulations India*



**Sriram A.V.**

*Head, Quality*



**Amitava Saha**

*Head, Human Resources*



**Seema Shah Ahuja**

*Global Head-Corporate Communications*





## Q&A with the CFO

Siddharth Mittal,  
*President-Finance & CFO*

## Financial Endurance

Adjusting for the impact of a decrease in licensing income in FY18, Biologics segment revenues grew by 28% during the year.

### How will you describe the overall financial performance of Biocon this year?

During the year FY18, consolidated revenue grew 6% to ₹43,359 million (vs ₹40,787 million in FY17). Revenue growth was primarily led by the Research Services business, which grew 19% to ₹14,231 million (vs ₹11,925 million in FY17). Biologics business at ₹7,702 million, reported growth of 10% from ₹7,018 million in FY17. However, adjusting for the impact of a decrease in licensing income in FY18, Biologics segment revenue grew by 28% during the year. Branded Formulations business, which includes sales in India and UAE, grew 11% to ₹6,115 million (vs ₹5,489 million in FY17). Revenue from the Small Molecules business decreased 8% to ₹15,077 million (vs ₹16,405 million in FY17).

Earnings before Interest, Taxes, Depreciation and Amortization (EBITDA) declined 9% to ₹10,353 million (vs. ₹11,366 million in FY17) and Net Profit decreased 39% to ₹3,724 million (vs. ₹6,121 million in FY17). The overall profitability for FY18 was largely impacted due to pricing pressures in the generics business, lower licensing income in biologics, planned shutdown of biologics fill finish plant for requalification post regulatory audits and inclusion of fixed and operating costs relating to the Malaysia facility.

Revenue:

43,359

₹ Million

EBITDA

10,353

₹ Million

Profit for the year

3,724

₹ Million

R&D Spends Gross:

3,804

₹ Million



In FY19, we expect gross R&D spends to be approximately 15% of revenues, ex-Syngene.

**With Biocon receiving approvals for biosimilars in large markets like U.S. and EU, do you expect a significant ramp-up in Biologics segment revenue? How will biosimilar sales in developed markets aid revenue growth and margins in the consolidated P&L statement in FY19?**

FY18 witnessed significant progress of our global biosimilars pipeline, as we received approvals in the U.S. for Trastuzumab and in the EU for Insulin Glargine. We also received multiple approvals in the emerging markets through various partners. We expect a significant portion of Biologics revenue growth in FY19 to come from the emerging markets on the back of recent and expected approvals. We also expect launch of biosimilars in developed markets during FY19.

Higher sales of products in FY19 will help boost Biologics segment margins which will be partly offset by increased R&D expenses on biosimilars and novel biologics. At the consolidated level, we expect our core margins percentage, i.e. EBIDTA margins net of licensing, forex gain/ loss and R&D expenses, to be broadly similar to core margins percentage in FY18.

**You had guided for fixed expenses of around USD 48 million for the Malaysia facility in FY18. Is this likely to change this year? When do you expect the facility to break even?**

At the beginning of FY18, we had guided that fixed expenses, including depreciation and finance costs related to the Malaysia plant, totaling approximately USD 48 million annually would be charged to the P&L account. With an offset of a portion of these costs through product sales in Malaysia and other emerging markets and utilization of facility towards R&D activities, we had expected a loss at the Malaysia standalone level. In FY18, Malaysia reported an operational loss of USD 5 million at a standalone level, excluding R&D expenses for Insulin products, which are also booked in the legal entity P&L. In FY19, we project fixed expenses to be USD 50 million on account of an increase in

operating expenses. During FY19, we expect to receive additional facility and Insulin product approvals from various regulatory agencies globally while our partner Mylan is expected to launch Insulin Glargine in Europe and Australia. As a result of these, we expect an operational breakeven in Malaysia in FY19, when excluding R&D expenses.

**Do you expect the trend of soft realizations on the licensing income front to continue?**

Licensing income relates to upfront or milestone payments received from the licensing of our Biologics and Small Molecule products globally and is dependent on the number and the timing of new products being developed. Over the last few years, a significant portion of licensing income accrued from Small Molecule products, recombinant human Insulin (rh-Insulin), Trastuzumab and Insulin Glargine dossiers. These products have already been licensed in major markets till FY17 and, as a result, the licensing income has reduced from ₹1,451 million in FY17 to ₹228 million in FY18. Given the current development pipeline, we expect licensing income in FY19 to be around similar levels as FY18.

**What is your estimate for R&D spends in FY19? Does this factor in the expenses due to new biosimilar programs with Sandoz?**

In FY18, gross R&D expenses were ₹3,804 million, representing 14% of our revenues from operations, ex-Syngene. In FY19, we expect gross R&D spends to be approximately 15% of revenues, ex-Syngene. The increase in R&D expenses will primarily be on account of advancements in our Small Molecules and Novel Molecules pipeline.

R&D activities for Small Molecule APIs and Generic Formulations are expected to pick up in FY19 compared to the slow pace in the last two years. On the Novel Molecules front, a Phase II/III clinical study for Insulin Tregopil is being conducted in India on Type 2 diabetes





We plan to fund our capex through a combination of internal accruals, additional debt, partial monetization of our stake in Syngene and contribution from our partner, Mylan.

patients, dosing for which commenced in FY18. In addition to this, we expect to initiate a multiple ascending dose study in Type 1 patients, in partnership with U.S. based JDRF in FY19. In addition to these two clinical programs, we also expect spends towards other Novel Molecules in our portfolio.

R&D spends on biosimilar molecules are expected to be at the same level as in FY18. The new biosimilar molecules that we have added to the pipeline with Sandoz are in early stages of development. The R&D expenses for these molecules will increase significantly once they enter the clinic in the coming years.

**Will you continue to capitalize R&D spends? How can investors track capitalized R&D spends for the Company?**

In accordance with requirements of Ind-AS 38: Intangible Assets, product development costs are capitalized as intangible assets based on the recognition parameters by the Company. We disclose such R&D spends capitalized on a quarterly basis as part of the financials fact sheet. While we do not provide break up of the amount being capitalized at the molecule level, total capitalization can be tracked on the balance sheet as 'Intangible assets under development' under non-current assets.

**With biosimilars approvals coming in developed markets, do you plan to make fresh investments in capacity expansion in FY19? How do you plan to fund this capex?**

In FY18, we initiated construction of our second antibodies facility in Bengaluru to cater to the biosimilars pipeline in line with our projected capacity requirements. This facility will entail an investment of approximately USD 200 million and the cash outflow will be in two phases, spread over four years.

In addition to the above, we have also planned for upgradation of existing assets at the end of their useful life largely in our insulins drug substance facility in Bengaluru.

Excluding Syngene's capex and capitalized R&D/intangible assets, we expect cumulative capex spend in FY19 and FY20 to be approximately ₹14 billion.

We plan to fund this through a combination of internal accruals, additional debt, partial monetization of our stake in Syngene and contribution from our partner, Mylan.

**Going forward, will Biocon continue to fund its high-margin Biologics business from the revenue generated from its Small Molecules business? Or you will have to look at alternate sources?**

Thus far, cash flows from the Small Molecules business have funded our biologics programs. Going ahead, however, we would like the Biologics business to be self-funded.

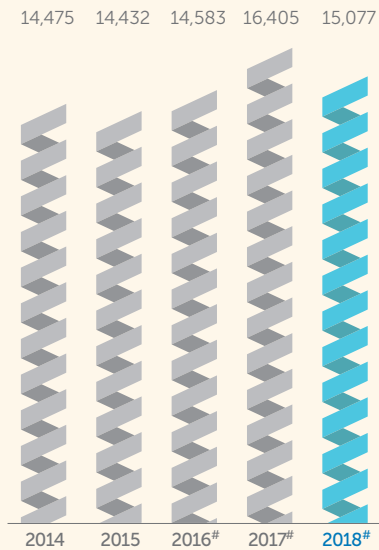
Operating cash flows from the Biologics segment will ramp up once our biosimilar products are commercialized in the U.S. and EU. We will also consider raising equity capital by unlocking value of our biosimilars business at an appropriate time. These factors coupled with additional debt to fund the capex will significantly reduce dependency of funding from the traditional Small Molecules business.

# Financial Highlights

## Segment-wise Revenue

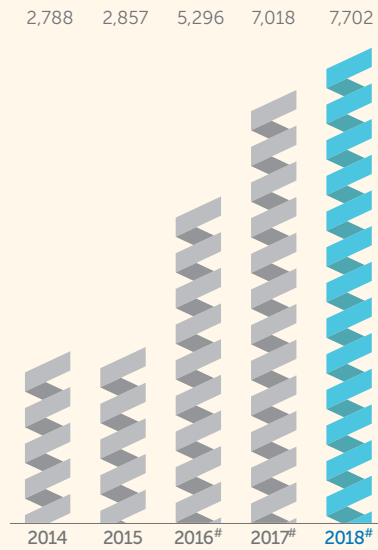
### Small Molecules

₹ Million



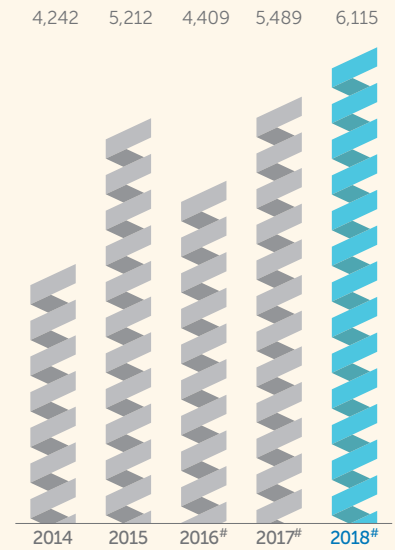
### Biologics

₹ Million



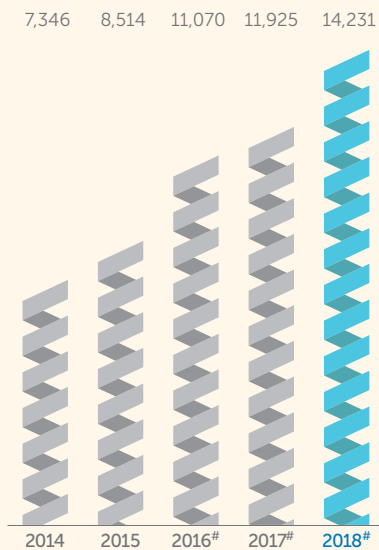
### Branded Formulations

₹ Million



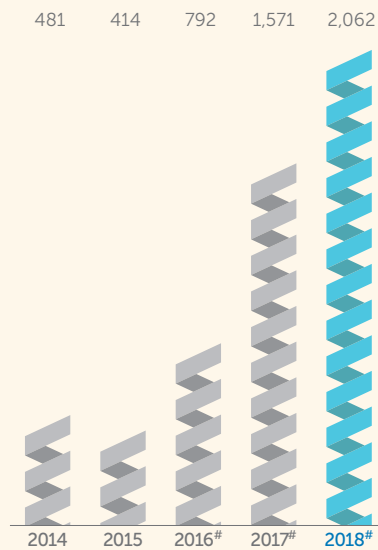
### Research Services

₹ Million



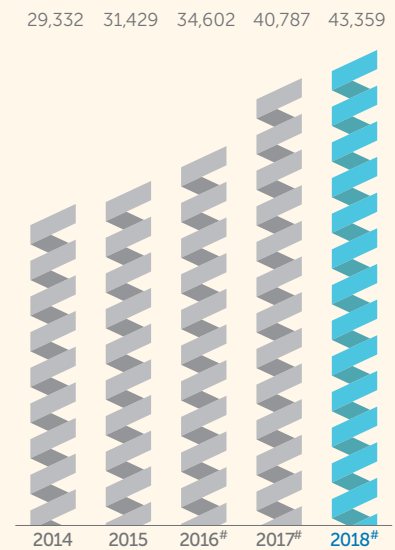
### Other Income

₹ Million



### Total Revenue

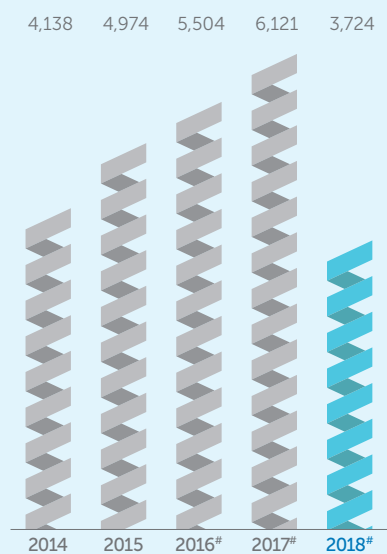
₹ Million



#2016, 2017 and 2018 figures are as per Ind AS

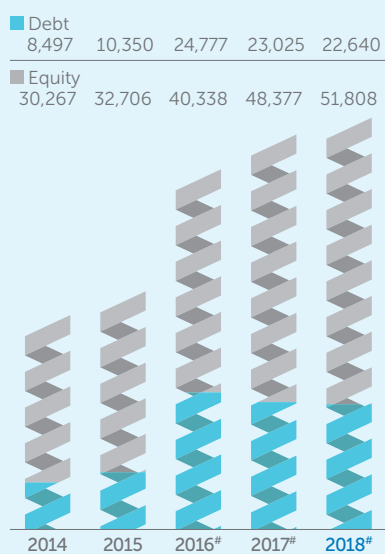
### Profit\*

₹ Million



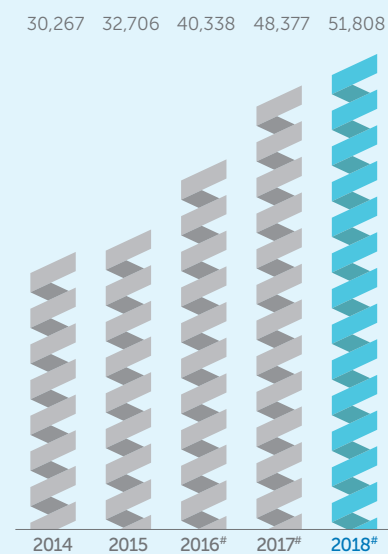
### Debt : Equity

₹ Million



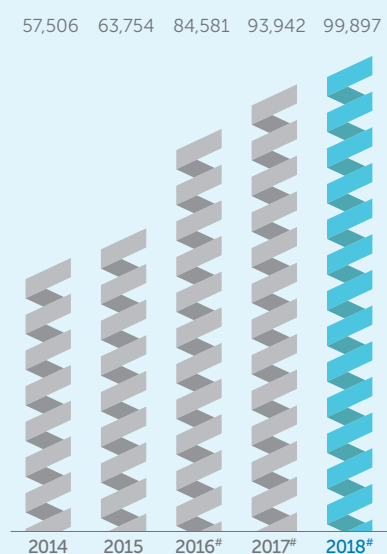
### Net Worth

₹ Million

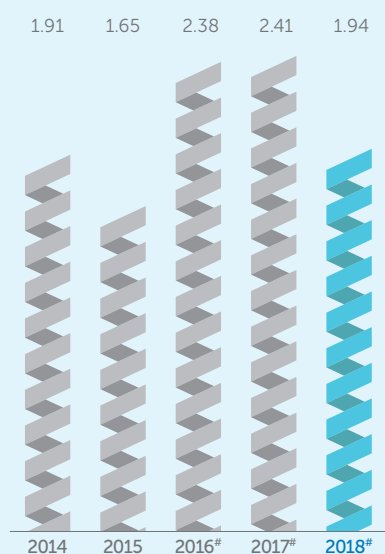


### Total Assets

₹ Million

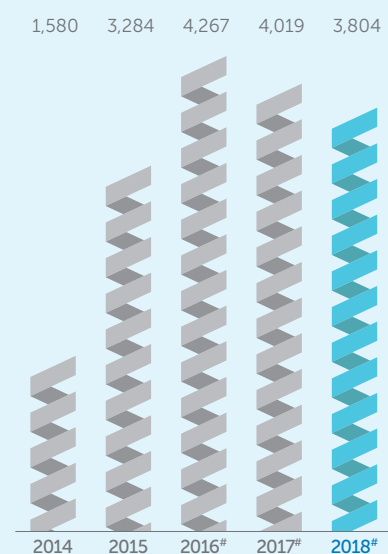


### Current Ratio



### Gross R&D Spend

₹ Million



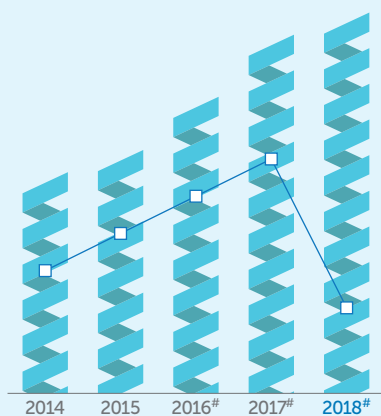
\*Includes exceptional income for the years 2015 and 2016  
#2016, 2017 and 2018 figures are as per Ind AS



# Financial Highlights

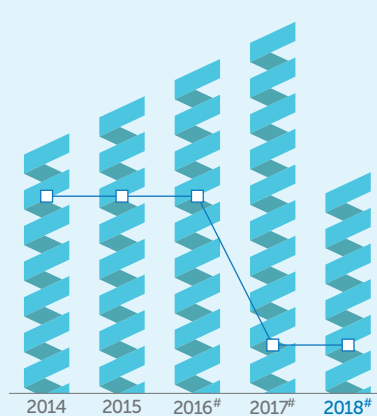
## EPS & Book Value Per Share\*<sup>Ⓐ</sup>

₹	2014	2015	2016 <sup>#</sup>	2017 <sup>#</sup>	2018 <sup>#</sup>
■ Book Value Per Share	50	55	67	81	86
□ EPS	7	8	9	10	6



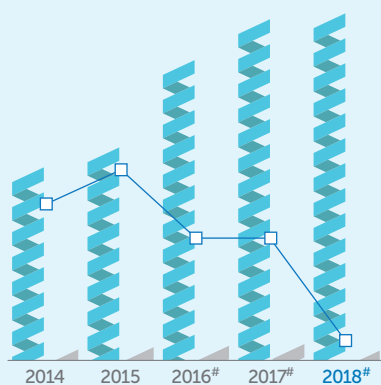
## EPS & Dividend per Share\*<sup>Ⓐ</sup>

₹	2014	2015	2016 <sup>#</sup>	2017 <sup>#</sup>	2018 <sup>#</sup>
■ EPS	7	8	9	10	6
□ Dividend per share	2	2	2	1	1



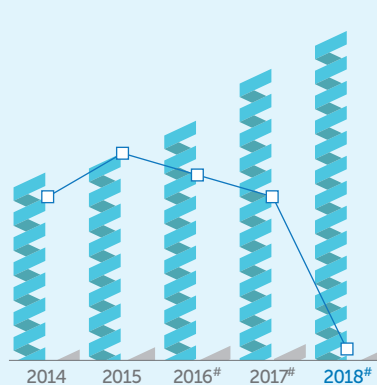
## Return on Net Assets\*<sup>Ⓐ</sup>

₹ Million	2014	2015	2016 <sup>#</sup>	2017 <sup>#</sup>	2018 <sup>#</sup>
■ Net Assets	43,710	48,207	67,924	77,159	78,484
■ Profit*	4,138	4,974	5,504	6,121	3,724
□ Return on Net Assets	9%	10%	8%	8%	5%



## Return on Net Equity\*<sup>Ⓐ</sup>

₹ Million	2014	2015	2016 <sup>#</sup>	2017 <sup>#</sup>	2018 <sup>#</sup>
■ Average Equity	28,607	31,487	36,480	44,358	50,093
■ Profit*	4,138	4,974	5,504	6,121	3,724
□ Return on Net Equity	14%	16%	15%	14%	7%



\*Includes exceptional income for the years 2015 and 2016

<sup>#</sup>2016, 2017 and 2018 figures are as per Ind AS

<sup>Ⓐ</sup>2014 to 2017 are adjusted for bonus issue in 2018

<sup>^</sup>Net Assets = Total Assets - Current Liabilities





## BIOLOGICS

# Opening Doors to Developed Markets

Biocon has meticulously scripted a differentiated story through its biologics business, from novels to biosimilars, demonstrating endurance and commitment to traverse a long and arduous journey.



## BIOLOGICS

### Biosimilars

#### MONOCLONAL ANTIBODIES

Trastuzumab  
Bevacizumab

#### RECOMBINANT HUMAN PEG - GCSF

Pegfilgrastim

#### INSULINS

Insulin Glargine  
Other Programs

### Novel Biologics

Insulin Tregopil  
Itolizumab  
Nimotuzumab  
QPI-1007 (siRNA)  
FmAb2

We are driven by our commitment to pursue high science to develop cutting edge, high quality biotherapeutics in order to provide affordable access to patients across the globe. We have thus built differentiated R&D capabilities and acquired expertise across the value chain from cloning, cell line development, CMC to large-scale manufacturing and commercialization. Our structured approach to incorporate advanced science and technology in order to build a wide portfolio of biologics has brought us the reliability and credibility of an innovation-led organization. Today, we are among the first wave of global biosimilars players to successfully gain regulatory approvals for some key biosimilars in several jurisdictions, including the U.S. and EU.





Biocon's proprietary technology using *Pichia pastoris* platform for expressing recombinant protein is used in the recombinant human insulin and insulin analog product lines. Our consistent and scalable mammalian CHO and NSO cell-based expression platforms are helping us deliver novel and biosimilar monoclonal antibodies. Our highly robust process sciences significantly augment our ability to develop world-class biotherapeutics. The upstream and downstream processes continually incorporate latest innovations in cell culture and purification. Our advanced analytical capability, which is anchored in cutting-edge tools and latest orthogonal approaches, guarantees the high quality and consistency of our products. The production of drug substance in the state-of-the-art

bio-manufacturing facilities ensures cost effective production. Our expertise in Formulation & Product Science enables us to convert drug substances into formulations for transfer into vials, cartridges and pre-filled syringes at our biologics drug product facilities. Partnerships with key global and strong local players allow us to take our products to patients worldwide.

Our capabilities and technologies have given us the 'enduring edge' and helped us emerge as an end-to-end player with a strong pipeline of approved and in-development biosimilars and novel molecules.

## Biosimilars

Biocon has one of the largest global biosimilars portfolios, spanning recombinant human Insulin (rh-Insulin), insulin analogs, monoclonal antibodies and other biologics for diabetes, oncology and immunology. We have successfully commercialized several of our biosimilars in various markets across the globe.



## MONOCLONAL ANTIBODIES

Biocon has been developing a high-value portfolio of biosimilar mAbs and recombinant proteins in partnership with Mylan since 2009. During FY18, we made significant progress with milestone approvals in key developed and emerging markets.

### Trastuzumab

December 2017 was a defining moment in our biosimilars journey when Biocon and partner Mylan became the first companies globally to receive U.S. Food and Drug Administration (FDA) approval for biosimilar Trastuzumab. Ogivri™ (trastuzumab-dkst) was the first biosimilar from Mylan and Biocon's joint portfolio approved in the U.S., and it made us the first Indian company to receive a U.S. FDA approval for a biosimilar.

This approval, ahead of major global biotechnology competitors, demonstrates our scientific depth, quality of the teams and our ability to execute on difficult-to-develop and manufacture, complex products like biosimilars. Placing us in an exclusive league of global biosimilar players, this approval has established Biocon as a credible biologics player from India that can compete with the best in the world.

The data package presented to the FDA included results from structural and functional characterization of the biosimilar molecule, non-clinical studies and pharmacokinetic (PK) evaluation in healthy volunteers. Data also included results from India Phase III and multi-centric global HERITAGE studies, which compared the biosimilar to the reference product in terms of safety, efficacy and immunogenicity in nearly 600 patients. Biocon and Mylan submitted extensive analytical, non-clinical and clinical study data to the FDA as a part of the Biologics License Application (BLA) for biosimilar Trastuzumab.

The data demonstrated that Ogivri™ is highly similar to Herceptin® and no clinically meaningful differences exist between the two in terms of safety, purity and potency.

The U.S. FDA's Oncologic Drugs Advisory Committee (ODAC) unanimously voted (16-0) endorsing the approval of our biosimilar Trastuzumab in July 2017, and in December 2017 the FDA granted final approval for our product.

Ogivri™ will enable Biocon and Mylan to provide an affordable, high quality alternative for eligible cancer patients in the U.S., where it has been approved for all indications included in the label of the reference product, Herceptin®, including for the treatment of HER2-overexpressing breast cancer and metastatic gastric cancer. In the U.S., an estimated 2,50,000 new cases of female breast cancer and 28,000 new cases of stomach cancer were diagnosed in 2017 alone. Approximately 25% of primary breast cancers are HER2-positive. Herceptin® had U.S. sales of USD 2.7 billion in 2017, according to IMS.

Our partner Mylan anticipates potentially being the first company to be able to offer this biosimilar to patients in the U.S., as a result of its ability to secure global licenses for our Trastuzumab product from Genentech and Roche earlier in 2017. The settlement gives Mylan a global license to commercialize biosimilar Trastuzumab product in various markets around the world.

#### HIGHLIGHTS

##### Trastuzumab

Type: mAb

**Indications:** HER2-overexpressing breast cancer and metastatic stomach cancer (gastric or gastroesophageal junction adenocarcinoma)

#### GLOBAL SALES:

USD **7.1** billion\*

\*Source: Company reports



We also received regulatory approvals for biosimilar Trastuzumab in Brazil and Turkey, two of the Top 4 emerging markets for this key breast cancer drug. Our product, sold as Zedora through our partner Libbs Farmaceutica, has been well received in Brazil.

Our biosimilar Trastuzumab is currently under review by regulatory authorities in Australia, Canada, EU and several additional markets.

Biocon's introduction of CANMAb™ in India in 2014 as the world's first biosimilar Trastuzumab had opened the doors for the patients to access an affordable therapy, which is now the No. 1 brand of Trastuzumab in the country, has garnered a volume market share of over 30% in India. (Source: IMS TSA February 2018).

CANMAb™ has helped treat ~12,700 HER2-positive metastatic breast cancer patients in India since its launch in 2014. (Source: IPSOS 2017).

The results of the HERITAGE study were published in the Journal of the American Medical Association (JAMA) in 2016, as well as, presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, U.S. and the European Society for Medical Oncology (ESMO) Congress in Copenhagen, Denmark. Recently, Mylan and Biocon presented new 48-week data from the HERITAGE study at the 2018 ASCO Annual meeting reinforcing the efficacy, safety and immunogenicity of Ogivri™, the first biosimilar for Herceptin® to be approved.

## HIGHLIGHTS

### Bevacizumab

Type: mAb

**Indications:** First-line treatment of patients with metastatic colorectal cancer, and is accepted as a standard treatment option in combination with chemotherapy for patients with non small-cell lung cancer, glioblastoma, cervical cancer, metastatic renal cell carcinoma and recurrent ovarian cancer.

#### GLOBAL SALES:

USD **6.8** billion\*

\*Source: Company reports

## Bevacizumab

We successfully launched our biosimilar Bevacizumab in India as KRABEVA® for patients of various types of cancer in November 2017. KRABEVA®, our second oncology biosimilar in India after Trastuzumab, is prescribed for metastatic colorectal cancer (mCRC) and several other types of lung, kidney, cervical, ovarian and brain cancers. This high quality, world-class biosimilar Bevacizumab has benefited a large number of patients in India within a few months of its launch.

Bevacizumab was one of Biocon's first endeavors in the biologics (biosimilar) sphere. The journey of developing a biosimilar Bevacizumab, which blocks blood and oxygen supply to cancerous cells arresting their growth, began in 2008 with a very extensive analysis of the protein sequence. The analysis helped us identify the sequence that encodes the DNA for the Bevacizumab antibody. This DNA sequence, inserted into the Chinese Hamster Ovary (CHO) cells, transcribed the Bevacizumab protein. Once the protein was transcribed it was purified

and formulated in a liquid to stabilize it. The expressed protein was extensively characterized using a battery of highly sophisticated techniques at various stages of development, which helped determine the analytical similarity to the reference product in terms of its structure, purity and functionality.

We conducted a three-way Phase I PK study in healthy volunteers in Europe using EU and U.S. sourced reference products, and the study met its primary endpoints.

Subsequently, our biosimilar Bevacizumab underwent a Phase III study in mCRC patients in India, which met its PK, safety and efficacy endpoints.

The Drug Controller General of India (DCGI) approved our biosimilar Bevacizumab in 2017 on the basis of our data package, which included results from the Phase I study and the Phase III India study.

The global development of our biosimilar Bevacizumab is on track. A Phase III trial in non-small-cell lung cancer patients is progressing well at more than 100 sites across multiple countries.



**HIGHLIGHTS**

**Pegfilgrastim**

**Type:** Granulocyte growth factor

**Indications:** Reducing the duration of neutropenia (low count of neutrophils, a type of white blood cells) and the incidence of fever associated with neutropenia in adult patients treated with chemotherapy in certain types of cancer.

**GLOBAL SALES:**

USD **4.7** billion\*

\*Source: Company reports

**RECOMBINANT HUMAN PEG - GCSF**

Biocon and Mylan have successfully developed a biosimilar Pegfilgrastim, a long-acting pegylated granulocyte colony-stimulating factor, to enable enhanced access to a cost-effective alternative to reduce the duration of neutropenia (low count of neutrophils, a type of white blood cells) and the incidence of fever associated with neutropenia in adult patients treated with chemotherapy in certain types of cancer.

**Pegfilgrastim**

In June 2018, Biocon and its partner Mylan became the first to receive approval for a biosimilar Pegfilgrastim from the U.S. FDA. We were able to cross the finishing line ahead of a pack of strong competitors who are also developing this product.

Once launched, Fulphila™ (pegfilgrastim-jmbd) will give cancer patients in the U.S. the first alternative and affordable treatment option to branded Pegfilgrastim. It is the second biosimilar from Mylan and Biocon's joint

portfolio to be approved in the U.S. after biosimilar Trastuzumab.

Fulphila™ will help patients with nonmyeloid cancers reduce the risk of infection following myelosuppressive chemotherapy.

The approval for Fulphila™ was based on a comprehensive package of analytical, non-clinical and clinical data, which demonstrated that there were no clinically meaningful differences between the biosimilar and the reference product in terms of safety, purity and potency. It represents a further endorsement of the Biocon-Mylan partnership's ability to successfully develop complex molecules to exacting quality and regulatory standards.

The approval of biosimilar Pegfilgrastim expands our oncology portfolio for the benefit of cancer patients and supports our mission to improve access to high quality, affordable biopharmaceuticals globally.

Regulatory reviews of our biosimilar Pegfilgrastim dossier in EU, Australia and Canada are progressing well.



## INSULINS

We made sure-footed progress towards our aspiration of providing our insulins to 'one in five' insulin-dependent people with diabetes globally.

During the year, we received approvals in key developed and emerging markets for our rh-Insulin and Insulin Glargine. Insulin and analogs present a huge global opportunity for us with a volume growth of over 20% between 2013 and 2017. (Source: IMS MAT June 2017).

### Insulin Glargine

As a credible, global insulins player, we are committed to addressing the growing healthcare challenges associated with diabetes. To deliver on this commitment, we have made significant investments in developing and manufacturing a leading portfolio of insulin analogs, including Insulin Glargine.

Semglee™ 100 units/mL 3 mL prefilled disposable pen, our biosimilar Insulin Glargine co-developed with Mylan, was approved by the European Commission for sale in all 28 European Union (EU) member states and the European Economic Area (EEA) member states of Norway, Iceland and Liechtenstein. The approval followed a positive opinion

issued by European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommending approval of our Insulin Glargine in EU. The first biosimilar approval in EU from our joint portfolio, it is yet another validation of our development, regulatory and manufacturing capabilities.

Semglee™ 100 IU/mL 3 mL prefilled pen was also approved by the Therapeutic Goods Administration (TGA), Australia.

Semglee™ is expected to be launched by our partner Mylan in Australia and Europe in the second half of 2018.

Additionally, Biocon received regulatory approvals for its biosimilar Insulin Glargine in Russia and South Korea. Russia is among the Top 3 emerging markets for Glargine.

During FY18, Biocon launched Glaricon™ (Insulin Glargine) its first biosimilar product in the UAE market.

In the U.S., Mylan's application for Insulin Glargine under the NDA pathway is under review by the U.S. FDA. A 30-month stay was triggered on Insulin Glargine approval due to expected patent litigation initiated by the innovator, which implies a potential launch timing in 2020.

### HIGHLIGHTS

#### Insulin Glargine

**Type:** Long-acting insulin analog

**Indications:** Control of high blood sugar in adults with Type 2 diabetes; adults and pediatric patients with Type 1 diabetes.

#### GLOBAL SALES:

USD **5.2** billion\*

\*Source: Company reports



Following the submission of our Insulin Glargine application, we had agreed with the U.S. FDA to provide additional clinical data in support of the manufacturing site change from Bengaluru to Malaysia. Hence, the Complete Response Letter (CRL) was anticipated and built into our plan. Together, Mylan and Biocon are executing on all required activities as agreed upon with FDA, and they are progressing according to plan. We do not anticipate any impact on the expected timing of the approval and the anticipated launch by our partner Mylan.

### Other Programs

Work on our recombinant human insulin product targeted at the U.S. market and two other global programs for insulin analogs (Insulin Aspart, Insulin Lispro) continues.

For Insulin Aspart, we have just successfully completed our Phase I study.

Our insulins manufacturing facilities in Bengaluru and Malaysia underwent several key inspections during FY18, which would enable regulatory approvals in some emerging markets going forward.

We expect that our near-term growth in biosimilars will be driven by expanding our footprint in key emerging markets through strong local partnerships. Product approvals and commercial success in the developed markets of the U.S. and Europe would be significant milestones that can help the Company lay a strong foundation to stay ahead of the game in biosimilars in the next decade. These will be supported by capacity expansions in a phased manner and additions to our product portfolio to cater to the next wave of opportunities.

### Status of Biocon's Global Biosimilars Portfolio

Partner	Therapeutic Area	Molecule	Status
Mylan	Oncology	Trastuzumab	Approved in U.S. Under review in EU, Canada and Australia. Launched in emerging markets.
	Diabetes	Insulin Glargine	Approved in EU & Australia. Under review in U.S. and Canada. Launched in Japan* through partner FUJIFILM Pharma. Launched in emerging markets.
	Oncology	Pegfilgrastim	Approved in U.S. Under review in EU, Canada and Australia.
	Diabetes	Insulin Aspart	Global Phase I study completed.
	Diabetes	Insulin Lispro	Preclinical.
	Autoimmune	Adalimumab	Global Phase III completed.
	Oncology	Bevacizumab	Global Phase III ongoing. Launched in India.
	Oncology	Filgrastim	Preclinical.
	Autoimmune	Etanercept	Preclinical.
Lab Pisa	Diabetes	Recombinant Human Insulin	Preclinical.
Sandoz	Oncology & Immunology	Various	Early Stage / Preclinical.

\*Japan launch is outside of Mylan partnership.

## Expanding Our Biosimilars Pipeline

After successfully collaborating with Mylan for near-term biosimilars opportunities, we have partnered with Sandoz, a Novartis division and a global player in biosimilars.

This collaboration is targeted at developing a next-generation biosimilars portfolio which will help patients worldwide gain access to a range of high quality, affordable immunology and oncology biologics. Biocon and Sandoz will strategically leverage their combined strengths to address the next wave of the global biosimilars opportunities.

Under the terms of the agreement, both companies will share the responsibility

for end-to-end development, manufacturing and global regulatory approvals for a number of products and will have a cost and profit share arrangement globally. Worldwide commercialization responsibilities will be divided and each company's strengths tapped within specific geographies. While Sandoz will lead commercialization in North America (U.S. & Canada) and the EU, Biocon will lead commercialization in Rest of the World including India, Russia and the CIS.

We have agreed to extend the Mylan partnership to include two new assets.

Through both these collaborations, we are targeting opportunities that are expected to open up in the middle of next decade.



## Novel Biologics

As practitioners of frontier science, we have built a pipeline of novel biologics that can address the unmet medical needs in diabetes, cancer and autoimmune conditions. Our basket of novel assets under development, representing an interesting combination of early and advanced stage programs, progressed in the clinics in FY18.

### Insulin Tregopil

Our quest for a game changing delivery method for insulin led Biocon to endure an arduous journey to clinically validate Insulin Tregopil, a first-in-class oral insulin molecule for post-prandial glycaemic control. As a novel insulin molecule it mimics the physiological benefits of direct delivery into the portal vein and promises to offer better patient compliance. Biocon has endured and invested in this long development phase driven by its strong belief in the attributes of this asset.

Our conviction that our success would enable us to make a very significant change in diabetes management continues to push us forward. Studies conducted in people with Type 1 diabetes, Type 2 diabetes as well as normal healthy volunteers have demonstrated an excellent safety profile for Tregopil, with evidence of significant post-prandial glucose excursion control in Type 2 diabetes patients.

During the fiscal, we initiated a pivotal Phase II/III study in Type 2 diabetes patients in India with Tregopil. We also tied up with JDRF, a leading U.S. organization funding Type 1 diabetes research and advocacy worldwide, for a multiple ascending dose study in Type 1 diabetes patient population. These combined studies in different diabetic populations will form the foundation of

a broad global program envisioned for Insulin Tregopil.

### Itolizumab

Itolizumab is a novel first-in-class humanized anti-CD6 monoclonal antibody approved in India for treating psoriasis. Itolizumab binds to a specific molecule (CD6) on the surface of white blood cells, known as T cells. The binding of Itolizumab to CD6 on T cells blocks the autoimmune activation of these cells, which would otherwise have resulted in the formation of skin rashes, known as plaques in patients with psoriasis.

After receiving approval from the DCGI, we launched our Itolizumab under the brand name ALZUMAb™ in 2013, offering dermatologists the option of prescribing a biologic to treat acute psoriasis and ensuring a better quality of life for patients. This novel product has been well received by doctors and patients alike, benefiting several hundred patients in India.

Our global development of Itolizumab continues to progress. We completed a Phase I clinical trial in Australia, in which the intravenous route of administration was compared to the subcutaneous route in normal healthy volunteers. Using this data, along with the toxicology data and extensive characterization of the product quality attributes, Biocon





is preparing to submit a request for an investigational new drug application to initiate clinical trials in various other diseases.

### Nimotuzumab

Nimotuzumab is India's first indigenously produced novel biologic developed by Biocon and launched in the country as BIOMAb EGFR® for head and neck cancer in 2006.

Nimotuzumab is a targeted therapy that specifically blocks the EGFR protein

and impedes cancer cell growth. EGFR (Epidermal Growth Factor Receptor) is overexpressed in about 80-100% of head and neck cancers.

Through the introduction of this molecule, Biocon has enhanced the treatment outcome as well as quality of life of cancer patients in India.

With an excellent safety and efficacy profile, BIOMAb EGFR® remains one of the most preferred targeted therapies in the treatment of head and neck

cancers. BIOMAb EGFR® has helped treat thousands of patients since launch. It has seen nearly 1,200 new patient enrollments in FY18.

Recently, the results of a randomized controlled clinical study conducted in 536 patients with our Nimotuzumab at the Tata Memorial Hospital (TMH), Mumbai were presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting held in Chicago.

The investigator-initiated study, one of the largest randomized clinical studies on head and neck cancer patients in India, evaluated the efficacy and safety of administering Nimotuzumab during concurrent chemo-radiation in locally advanced head and neck squamous cell carcinoma (LAHNSCC). Adult patients of LAHNSCC were randomized 1:1 into either radical radiotherapy with weekly cisplatin (CRT arm) or the same schedule of chemo-radiation with weekly Nimotuzumab (NCRT arm). The primary endpoint of the study was 'progression free survival', while other key secondary endpoints were 'disease free survival', 'duration of loco-regional control' and overall survival. The study successfully met the primary endpoint Median progression free survival of 60.3 months in NCRT arm as compared to 21 months in CRT arm which was statistically significant.

Dr Kumar Prabhaskar, Head, Solid Unit, Medical Oncology, TMH and his team has conducted this large patient study over a period of six years to establish the superior profile of Nimotuzumab and the difference it can make to patients. The

results also showed that the addition of Nimotuzumab to chemo-radiotherapy improved the locoregional control rate, disease free survival and had a trend towards improvement in overall survival.

The positive results from this study are a significant milestone in Biocon's ongoing efforts to establish Nimotuzumab's 'best-in-class' status for the treatment of one of the most common forms of cancer in India.

### QPI-1007 (siRNA)

Our partnered program with Quark Pharma, QPI-1007, a novel siRNA molecule to treat non-arteritic ischemic optic neuropathy (NAION), continued to make good progress in pivotal global Phase II/III studies during the year, with patients randomized in India. Biocon is the first biopharma organization in India to have forayed into the exciting space of (small interfering RNA) siRNA-based therapeutics.

### FmAb2

In Immuno-Oncology, Biocon's lead program, FmAb2, is a fusion protein of EGFR mAb and TGFβ RII ECD. This fusion antibody works on the concept of preferentially delivering immune modulators to the tumor site, providing a potentially broad clinical opportunity in multiple tumor types. With this molecule, we have already established Pharmacology and Mechanism of Action (MoA) via in-vitro and in-vivo tumor models. This fusion antibody progressed in pre-clinical development during FY18.

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Biocon recognized the importance of developing the technology, critical mass and skillsets required for biologics at a time when few international players existed with almost no Indian player in this space. Today, we have developed a robust biosimilars pipeline, perhaps one of the largest in the world. As a result, we are now attractively positioned to capitalize on the unfolding global opportunity for these advanced therapies.

## Creating a Sustainable Future

As Biocon partners India in achieving the country's ambitious target of becoming a USD 100 billion bioeconomy by 2025, the company is equally committed to enable the nation achieve its sustainable development goals. Sustainability continues to remain at the centre of our integrated outreach strategy designed to make a meaningful impact on the environment, people and society. From preserving the environment to reducing our carbon footprint and promoting the well-being of the communities, employees and other stakeholders, our business practices go beyond compliance, thus contributing to the larger goal of sustainable development.







ENVIRONMENT

- Energy Conservation
- EHS Management System
- EHS Training
- Saving the Lakes
- Ensuring Sustainability in the Supply Chain

PEOPLE

- Overview
- Learning & Organizational Development
- Employee Engagement
- Talent Acquisition

SOCIAL

- Biocon Foundation
- Healthcare Programs: eLAJ Smart Clinics
- Education Programs
- Awards

SKILL DEVELOPMENT

- Biocon Academy



## Environment



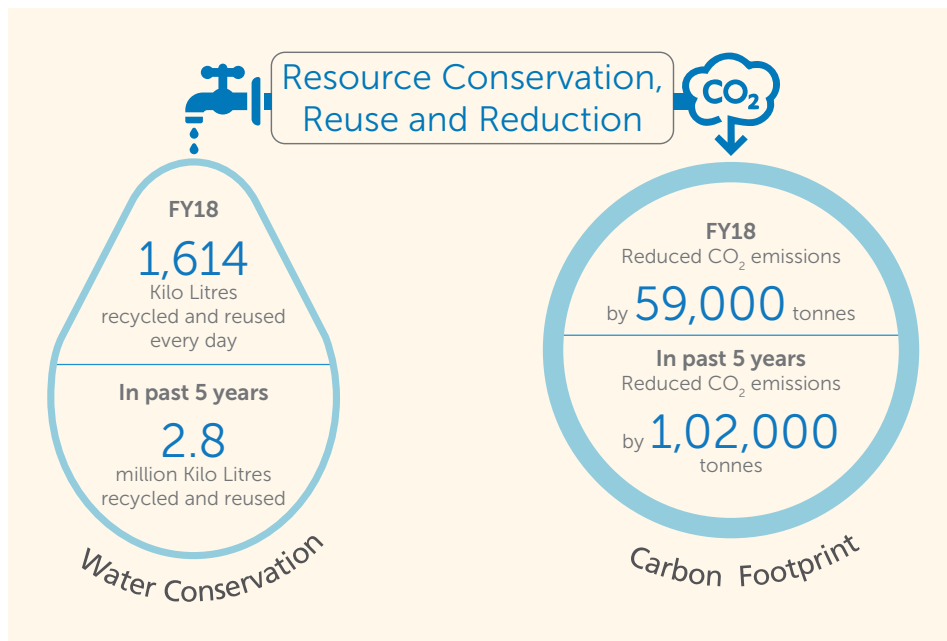
Our environmental sustainability strategy is built around the philosophy of doing more with less. Our holistic approach encompasses conservation of natural resources, reduction of our carbon footprint, switching to renewable energy, improving energy efficiency, minimizing waste generation, sustainable sourcing and contributing to biodiversity.

Constantly striving to implement global best practices in environment management, we have designed robust Environmental, Health & Safety (EHS) policies and procedures. The focus is on ensuring that environmentally sustainable practices are incorporated across businesses to create a safe atmosphere for all our employees as well as the community at large. The ISO 14001:2015 and OHSAS 18001:2007 certifications,

a dedicated environment management cell comprising highly qualified and experienced professionals and an online legal compliance tracking system together create an ecosystem for effective compliance management at Biocon.

### Energy Conservation

Our energy conservation efforts are centered around optimizing energy consumption, reducing waste and utilizing clean energy in our business operations. Adoption of innovative measures such as energy efficient centrifugal air compressors, water chillers and motors have enabled us to achieve this objective. Variable Refrigerant Volume systems, LED lighting and condensate recovery measures have significantly enhanced energy savings at Biocon.

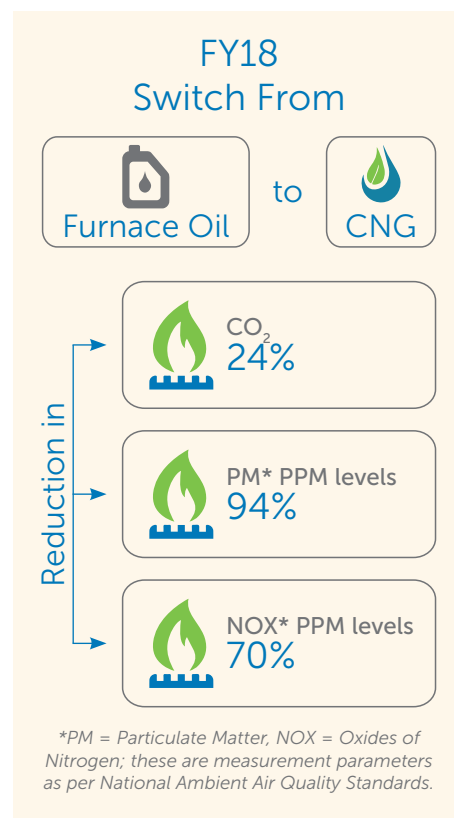


With procurement of 66 million units of wind power, from a wind farm in Mangoli, Bijapur district of Karnataka, we successfully reduced our carbon footprint in FY18 by about 59,000 tons. The continuous adoption of renewable energy as a preferred source has enabled us to increase its share in our total power consumption to 39%.

To further reduce our carbon footprint we have switched from furnace oil to natural gas for steam generation. Using natural gas instead of oil/coal produces less chemicals that contribute to greenhouse gases, acid rain, smog and other harmful forms of pollution.

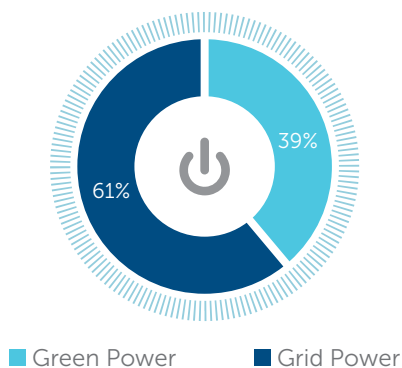
### EHS Management System

As a highly responsible corporate organization, we have in place the best-in-class EHS management system conforming to internationally recognized standards of environmental and occupational safety. Our comprehensive compliance culture is aligned with applicable local, national and international laws and regulations.





### Focus on Green Power



It covers all our internal and external stakeholders and extends to the group, joint ventures, suppliers, contractors and other stakeholders.

### Environment Management

We have, since long, been making concerted efforts at reducing our environmental footprint. Our comprehensive approach focused on resource optimization, recycling, recovery and reuse has brought significant results.

Given that India is fast moving towards becoming a water stressed country, reducing water consumption remains an important part of our agenda. As a resource respecting organization, we have focused our efforts at making our processes more water efficient. Substantial investments in zero-liquid discharge systems across our manufacturing units have resulted in 100% wastewater being recycled and reused in the processes or utilities. Effective water treatment technologies and rainwater harvesting have meant significant reduction in per capita water consumption across our campuses.

The benefits from our environment management initiatives have been

driven by training and communication programs aimed at waste segregation and waste minimization across our operations. Our food waste, is also treated onsite through composting which is used in the greenbelt area.

### EHS Risk Assessment & Process Safety Management

With safety at workplace being paramount, we continuously assess, identify and manage occupational health and safety risks. Fitted with manufacturing equipment designed to conform to highest safety standards, we ensure conformance using world class monitoring equipment and regular internal and external audits.

Our integrated process safety management systems ensure all existing processes and new developments are assessed for risk. Process safety studies such as Process Hazard Analysis, Equipment Safety Study through techniques including HAZOP, What-if and Risk Matrix are conducted by cross functional teams. These rigorous processes ensured that Biocon's units in Bengaluru, Hyderabad and Vishakapatnam experienced zero reportable incidents in FY18.

Biocon's commitment to safety was endorsed through the "Unnatha Suraksha Puraskara", an award for excellence in safety management across operations given by the State National Safety Council.

### EHS Training

All our employees, both full-time and contract staff, undergo EHS training to make them well aware of workplace hazards and equip them with skills to effectively deal with a situation when it arises. During FY18, 17,000 man hours of classroom and e-learning training were conducted. First aid training, specialized training and workshops by experts and external trainers were also organized.



Before rejuvenation



After rejuvenation

## Industrial Hygiene Management

Our product-wise industrial hygiene studies and exposure reduction drives have proven to be very effective. Based on the detailed industrial hygiene risk assessments of manufacturing processes at the pilot stage, risk mitigation measures are incorporated before commencement of commercial production. Regular qualitative and quantitative assessments also help identify possible hazards.

## Saving the Lakes

As a part of our efforts to ensure environmental sustainability, Biocon has launched an ambitious initiative to contribute to Bengaluru's lake revival mission. With our Detailed Project Report for revival of the 35-acre Hebbagodi Lake having been approved by the Karnataka Lake Conservation and Development Authority, we began a comprehensive lake revival drive. While the thick sludge and accumulated garbage was removed from the lakebed, weeds were cleared from the surface and composted for use in green belt. A new embankment with a fence was built to prevent further encroachments. An eco-friendly bioremediation process including use of microorganisms and enzymes to clean up the polluted water, energy efficient cascading aerators and submersible mixer, to enhance the level of dissolved

oxygen in the water and floating wetlands with species like vetiver and canna were used to clean the water body. A bioreactor has been set up inside the Biocon campus to produce 3,000 litres of bio-enzyme every day for dosing the lake. Our bio-remediation processes to treat the polluted lake water have resulted in significant improvement in the water quality of the lake.

Streetlights have been installed on the lake periphery making it safe for the community.

The proof of concept established at Hebbagodi Lake has opened the path for Biocon Foundation to initiate other lake rejuvenation projects. Based on our learning and experience of Hebbagodi Lake we have developed a Detailed Project Report for the revival of Yarandahalli Lake and initiated bund strengthening, bridge construction and cleaning of inlets.

Constant stakeholder engagement including communities, government bodies, residents, monitoring of the lake and awareness creation are some prime enablers of long-term sustainability.

Under the Namma BioCommunity initiative, Biocon employees have exhibited high levels of commitment in the community development activities around the facility, by contributing their personal time and effort. On Rajyotsava Day, November 1, 2017, all the employee

volunteers cleaned the trash around Yarandahalli Lake, leveled the road and painted the walls of the lake boundary and the nearby government school.

As a part of the of World Environment Day celebrations, over 1,000 saplings were planted by employees along with nearby school children to create awareness about the importance of environmental conservation.

### Ensuring Sustainability in the Supply Chain

With a view to ensure our supply chain practices support our sustainability goals, we encourage our suppliers to fulfill their commitments to the society and environment. As a policy,

preference for long term commitments is given to suppliers who meet these criteria. Initiatives are taken to improve awareness about legal compliances to enhance eco-friendly efficiencies and packaging/logistics improvements at the suppliers end.

The Company engages with suppliers and transporters at regular meets to encourage them to undertake sustainable practices across the supply chain. Local sourcing options that would reduce the logistics involved and thus our carbon footprint are explored wherever possible. While reducing our own carbon emissions, we also encourage our suppliers and consumers to reduce these during sourcing and consumption.





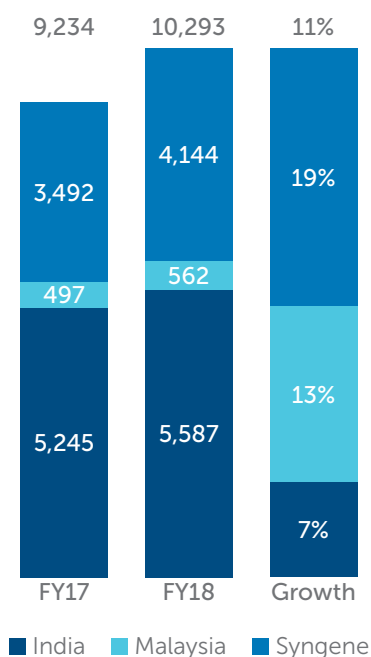
## People



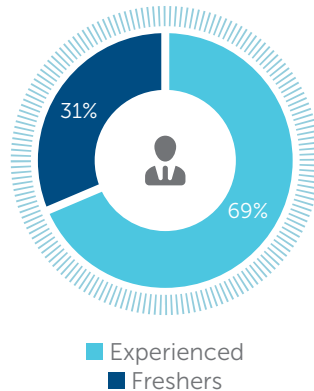
We are committed to promoting, supporting and ensuring a gender diverse and inclusive work environment, where each individual is treated fairly and with respect. Our people-centric work culture encourages innovative thinking, focuses on excellence, instills a sense of ownership and builds confidence in our employees to make a difference. Building a people friendly culture based on these values has placed us amongst the most preferred biotech & pharma employers across the world.

The Science Careers Top 20 Employers Survey 2017 rankings placed us at No.9. We have held on to our position amongst the Top 20 Best Employers since 2012, the only company from Asia to feature in this prestigious list, consistently.

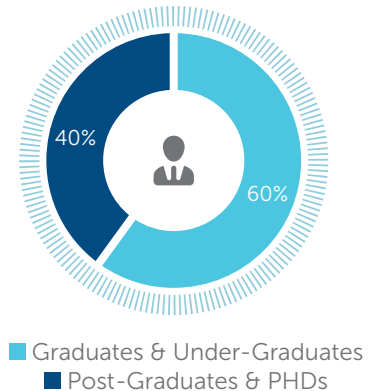
### Global Employee Base



Employer of Choice



Talent Profile of Employees



### Learning & Organizational Development

As a performance-driven company, we believe in creating a culture of meritocracy that provides all our employees with equal opportunities to excel, learn and progress.

#### Learning & Development

We strongly believe that continuous learning builds an empowered team, creating the foundations of a world-class organization. We have put together a series of programs to bridge the skill gap where necessary, to help build new skills across levels.

Our MPower program, designed to build strong technical capabilities in high performing junior employees, saw 90 participants in FY18. It was a proud moment when 30 of them completed

the course with distinction. i-LEAP, our holistic leadership development platform for mid-level managers, saw close to 100 employees participate in the first batch this year. Knowing that SOPs enhance an organization's efficiency, we have partnered with Information Mapping, a world leader in solving critical documentation issues. With a view to building strong capabilities in SOP design, we have trained a team with Information Mapping.

Biocon also rolled out a series of world class e-learning technical courses for employees based in India as well as Malaysia. In addition to these programs, over 4,400 employees attended various training programs, clocking over 45,000 learning people hours, during the year.

#### Performance Management

At Biocon, meritocracy is a key organizational value. We sharpened our performance management processes further this year, by introducing a mandatory mid-year review to identify training needs based on skill gaps and give employees an opportunity to course correct well in time. Goal Setting Workshops, Feedback Sessions and Certification of Assessors involved in the promotion process were some of the other measures that brought robustness to the performance management systems.



## Employee Engagement

At Biocon, we make every effort to make the workplace engaging for our staff as well as ensuring their well-being. With a strong belief that healthy employees are happy and involved employees, we continued to conduct annual health checks for all employees. Customized programs on diabetes, healthy eating, heart health and smoking cessation were conducted under our wellness initiative, BioPulse. Preventive health awareness sessions on cancer, kidney disease and stress management were also part of our wellness initiatives this year.

The Biocon Adventure and Sports Club (BASC), a platform for our employees to pursue their interests beyond work, organized several sports and adventure activities during the year.

In pursuit of building a gender inclusive workplace, we provide a forum for women employees to freely share workplace problems and suggest possible solutions. Over 180 women employees participated in a brainstorming session organized under the BioWin initiative. Some of the interesting suggestions made in this forum were implemented this year. A well-equipped crèche provides a safe, affordable and high quality place for children while parents are at work at Biocon.

We believe that transitioning from 'Good to GREAT', will enable us to collectively embark on our next phase of growth, with a steady stream of positive milestones leading to robust revenues and profits. The 'Good to GREAT' (g2G)

initiative was thus unveiled during FY18, to reinforce Biocon's core values aimed at achieving excellence in every field.

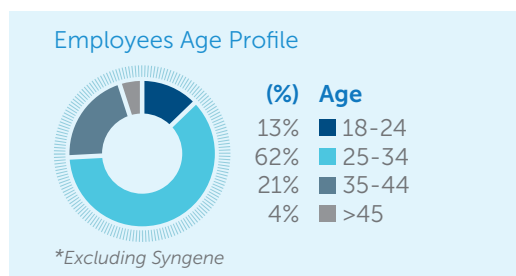
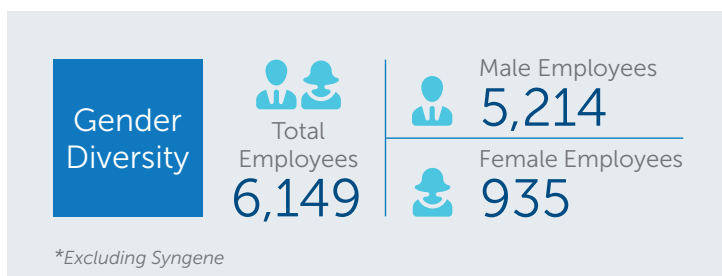
## Talent Acquisition

With a firm commitment to recruit high caliber employees through a fair and transparent process, we improved our talent acquisition practices in FY18. To achieve this objective we are developing a stronger sourcing engine that will help us select the right talent best suited to various roles.

More than half of Biocon's human capital is under 30 years of age, a demographic that is very active on social media. Our extensive use of social media channels to attract talent, converted into almost 54,000 job applications with an apply rate of 22%, which is significantly better than our peers. Our participation in a Global Virtual Career Fair, organized by Science Careers (Science International Inc., Cambridge, UK), attracted 550 registered users from U.S., India, Spain, UK and Switzerland.

## Internship Programs

In keeping with the leadership position in the Indian biotech industry, Biocon offers internship opportunities to students from India and abroad. This year the internship program covered over 500 students, including those from international institutes such as Illinois Institute of Technology, Chicago and the Universities of Washington, Maryland, Minnesota and Santa Clara from the U.S.; Kings College London, UK; and the University of Hong Kong.





## Social



At Biocon, Corporate Social Responsibility (CSR) is not about philanthropy, but about creating an ecosystem to empower the stakeholders. We believe that access to good education, healthcare services and civic infrastructure form the three pillars of an empowering ecosystem. Driven by the principle of making an enduring impact, Biocon Foundation partners the society to promote social and economic inclusion. Over the last decade, Biocon has thus made significant investments in enhancing access to quality healthcare, educational and improved civic infrastructure. Combined with field initiatives, these programs create a momentum to lift up the marginalized sections of the society.

In pursuit of our philosophy of empowerment, we are striving to

create a globally competitive biotech ecosystem in India. The Biocon Academy, an advanced centre of biosciences learning, was set up to address the current skill deficit, critical for India's youth to become employable. Given that over 48% of India's population is female (census 2011), we are making efforts to address the gender disparity gap in education, healthcare and employment. On a completely different note, we have also launched several initiatives to preserve India's rich heritage in art & culture.

Our comprehensive CSR policy guides the CSR Committee in overseeing and monitoring the CSR initiatives at Biocon. This Board level Committee ensures that these initiatives follow the course of the larger social vision of the company.



## BIOCON FOUNDATION

Over the years, Biocon Foundation has built a strong reputation for the quality of its programs and their impact in addressing social, humanitarian and environmental challenges facing India. Based on our strong belief that our programs would make a more meaningful impact if delivered in partnership with the government and like-minded organizations, we have partnered with government agencies for all our programs.

### Healthcare Programs

Based on the conviction that access to good healthcare is a basic human right, our public healthcare initiatives are intended to provide sustainable

solutions. Our adoption of digitization and information technology is changing healthcare delivery in rural India and making a more meaningful impact. Biocon constantly addresses the burden of chronic diseases such as cancer, diabetes and hypertension amongst the marginalized communities of the country.

#### eLAJ Clinics

ICT enabled processes have the potential to build sustainable healthcare delivery systems. The Foundation thus invested in developing eLAJ Smart Clinics, a platform to deliver evidence-based primary healthcare based on Electronic Medical Records (EMRs) of patients who visit eLAJ clinics. The model has been well received by healthcare providers at all levels, especially those who work

with communities having poor access to quality healthcare. These Smart Clinics have enabled the Foundation to establish a link between innovation and scale. Over 2.3 lakh patient visits were recorded at the eLAJ clinics during FY18.

In Rajasthan, Biocon Foundation adopted five PHCs and 32 associated sub-centers in 2015. Healthcare services delivery was improved in several of these centers in Jaipur, Sawai Madhopur and Jhalawar districts. Within two years (by August 2017) the improvement in services was such that the Government of Rajasthan declared the upgraded PHCs at Jhalawar as Adarsh PHCs (Model PHCs) with ownership getting transferred to the Government. Under a new Memorandum of Understanding (MoU), signed in March 2018, the Foundation is providing services such as electronic capturing of patient records and diagnostic services at the remaining three PHCs.

Under a MoU signed with the Government of Karnataka in December 2016, the Foundation has integrated the eLAJ module into operations of 15 Government-run PHCs. Additionally, at the Government's behest, laboratory devices have been provided at the Central Prison, Parappana Agrahara, Bengaluru.

#### Non-Communicable Diseases

At Biocon, we believe that an integrated community based risk factor management program is a cost-effective and efficient approach to address non-communicable diseases (NCDs) such as cancer. To date, the Foundation has screened over 53,000 men and women for oral, cervical and breast cancers and supported patients with potential risks, to undergo further evaluation.

At our monthly NCD clinics focused on diabetes mellitus and hypertension, we not only conduct screenings but also draw up management plans for diet related NCDs. Continuum of care is ensured through regular follow up by Community Health Workers (CHWs).

In FY18, 10 new eLAJ Smart Clinics were added, taking the total number to 21.

#### eLAJ Smart Clinic Footprint

	Number
Govt of Karnataka	15
Govt of Rajasthan	3
Biocon Foundation	3
<b>Total</b>	<b>21</b>

#### Capacity Building of Medical Practitioners

In rural areas, primary care physicians are the first, and often the only point of contact to manage health related issues. It therefore becomes imperative for physicians to have a comprehensive understanding of the disease for effective disease management with limited resources available. Given their importance for managing the health challenges of the rural population, the Foundation conducts workshops and conferences to improve the knowledge and skills of front-line health workers. In FY18, workshops on family planning, mental health and HIV in children, facilitated improved effectiveness of these workers.

#### WASH Initiatives

Open defecation, unsafe drinking water and poor hygiene have been the bane of the rural population with far reaching impact on public health, education, environment and gender equality. The Foundation's concerted and coordinated strategy to ensure access to Water, Sanitation & Hygiene (WASH) is helping reduce the negative impact of these ills. In FY18, reverse osmosis (RO) water plants of 1 kilolitre capacity, installed in Kyalasanahalli, Marutinagar and Sriramapura villages of Bengaluru, enabled access to safe drinking water for over 6,000 residents. Toilet blocks were constructed in the Government Primary School, Mayasandra and Government School & Junior College, Bagalur, under the Biocon sanitation program. Apart from improving good hygiene practices,





it is hoped that it would improve the enrollment of girls in these educational institutions.

#### Child Malnutrition

Child malnutrition is one of the biggest social challenges facing India, with half of all childhood deaths being attributed to malnutrition. It is also a major chronic health challenge for the underprivileged communities. First 5 years after birth are crucial for a child's growth and development, with potential to make long term impact on their cognitive ability and health. The steep rise in malnutrition in children during the first two years of life is indicative of poor infant feeding practices. As per the Global Nutrition Report, 155 million children are stunted and 52 million children are wasted. NFHS-4 (National Family Health Survey, India) reports that 35.7% of Under 5 children in India are

underweight, 21% wasted, 38.4% stunted and only 62% have full immunization coverage.

The Biocon Foundation has launched several programs to help India fight malnutrition. The Foundation has been working in partnership with the Government authorities in Bagalkot district of Karnataka, since 2012 to combat malnutrition. A robust scalable model to address child malnutrition was rolled out in four Taluks of Bagalkot district. In FY18 health check-ups for severely malnourished children were coordinated at the PHCs in collaboration with the Bagalkot district authorities, benefiting over 460 severely malnourished children.

#### Education Programs

Biocon's education initiatives are targeted at underprivileged children in

line with the company's commitment to ensuring inclusive and equitable quality education. As a first step, it is important to build a strong foundation of basic concepts in children. To achieve this objective, Biocon Foundation has, in partnership with Macmillan Publishers, developed Chinnara Ganitha to help children develop basic concepts in mathematics. Having touched the lives of over half a million students, since 2006, these workbooks reached over 1,00,000 students in about 1,000 government schools in the current year. The Bangalore Political Action Committee (BPAC), as our distribution partner ensured that these workbooks reached all the students of classes I to VII at these schools.

The Biocon CSR Wing encourages employees for community service. During the year several members volunteered to teach and assess fundamental mathematics skills of the students using Chinnara Ganitha workbooks at 10 government schools in Karnataka. The sessions proved to be a fulfilling experience for both the volunteer, teachers and the students.

## Awards

During FY18, Biocon Foundation received recognition from Government and non-government organizations as well as the corporate sector. Some of our initiatives were recognized as the most innovative, sustainable and impactful CSR programs of the year.

### Biocon Foundation Awards

Indian Drug Manufacturers' Association (IDMA)  
Corporate Citizen Award  
2017

The Social Change Award  
2017 for eLAJ Smart Clinics

CSR Health Impact Award-  
India Health and Wellness  
Summit 2017

CSR Excellence Award 2017-  
CSR Health Project of the  
Year- IICSR Conclave 2017

1st Runner-up, CSR Journal  
Excellence Awards 2017

Award & Certificate  
of Appreciation from  
Government of Rajasthan to  
Soorwal PHC for exemplary  
services in Pradhan Mantri  
Surakshit Matritva Abhiyan

## Skill Development



Biocon Academy is committed to create a globally competitive Biotech ecosystem in India through skill development programs at its Center of Excellence for Advanced Learning in Applied Biosciences.



### BIOCON ACADEMY

An evolving biotech sector has led to a peaking of demand for highly-skilled people in India. However, the quality of the available talent pool does not match the industry requirements.

Biocon Academy leverages rich industry experience of Biocon and subject matter expertise of its education partners to deliver industry-oriented training programs to biotech students.

The programs offered by the Academy aim to empower the Biotechnology and engineering graduates with advanced

learning and industrial proficiency through job-skills development essential to build a promising career in the Biotech industry.

Under a strategic collaboration with the Keck Graduate Institute (KGI), California we launched the unique **Biocon KGI Certificate Program in Biosciences** in 2014. It is the first-of-its-kind international program that imparts specialized training through a rigorous, multidisciplinary, project-oriented approach, combining classroom sessions with practical training in actual industrial settings. In 2016, we continued our



collaboration approach by partnering with BITS, Pilani, India, to introduce the **BITS Biocon Certificate Program in Applied Industrial Microbiology**. To ensure our students get practical training, this year the Academy collaborated with the global life sciences company, Thermo Fisher Scientific, India.

Building on the success of these programs in imparting rigorous academic and industrial training, the Academy introduced two new programs this year: the **Faculty Development Program (FDP)** and the **Clinical Development Program (CDP)**. The FDP for biotechnology faculty is designed to give deeper insights into industry requirements and help them equip their students with focused and practical training. This program has already benefited 23 Biotechnology faculty members from 18 colleges across the country. The **Biocon KGI Certificate Program in Clinical Development**, is aimed at enhancing the quality of clinical research professionals in India. Students from the CDP program underwent practical training at Narayana Health, one of the best hospitals in India and in state-of-the-art facilities of Syngene International to get hands-on training on various operational aspects of Clinical Research. The first batch of this exclusive program, designed to accelerate learning in the fast growing field of clinical development, graduated this year.

In FY18, nearly 145 students and faculty members have benefited from the various courses being delivered by the Academy. Cumulatively, over

400 students have benefited since the Academy was launched. We are proud to be able to help life sciences graduates in India build promising careers in the biotech industry. The Academy continued to maintain its record of 100% placements this year too. More than 55% of the students have been recruited by some of India's leading life sciences companies, apart from Biocon.

Given that the international programs are very expensive, we subsidize the cost for all students by offering scholarships of up to 75% of the program fee. Several hundred students who have graduated from the Academy over the last four years are contributing immensely to the Indian life sciences industry through their knowledge, talent and technological orientation.

Apart from developing a talent pool for the industry, we are also lending our expertise to other academic institutions to expand India's ecosystem for biotechnology sector. In FY18, we facilitated the development of new courses by the Delhi Institute of Pharmaceutical Sciences and Research.

Biocon Academy is continuously looking at ways to align with the growing needs of the global biotech industry and developing new programs to address such requirements. To strengthen this industry, we are designing an MBA Program in Biosciences Management and a PG Certificate Program in Quality Control Analytical Techniques.

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When we look back on our sustainability journey, it gives us a sense of satisfaction. We have driven our CSR initiatives with a holistic perspective since inception to make a difference to the lives of marginalized communities. As a socially responsible organization, we have invested significantly in our sustainability programs. Every initiative has been rooted in the philosophy of making a sustainable impact on the lives of the communities that we work with.



## Corporate Information

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### Forward Looking Statement

#### Biocon FY18 Annual Report

In this Annual Report we have disclosed forward-looking information to enable investors to comprehend our prospects and take informed investment decisions. This report and other statements - written and oral - that we periodically make contain forward looking statements that set out anticipated results based on the management's plans and assumptions. We have tried wherever possible to identify such statements by using words such as 'anticipates', 'estimates', 'expects', 'projects', 'intends', 'plans', 'believes' and words of similar substance in connection with any discussion of future performance. The market data & rankings used in the various chapters are based on several published reports and internal company assessment.

We cannot guarantee that these forward looking statements will be realized, although we believe we have been prudent in our assumptions. The achievement of results is subject to risks, uncertainties and even inaccurate assumptions. Should known or unknown risks or uncertainties materialize, or should underlying assumptions prove inaccurate, actual results could vary materially from those anticipated, estimated or projected. Readers should bear this in mind. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

### Concept

#### Enduring Edge

The theme of Annual Report 2018 captures Biocon's journey of endurance across the arduous and long path of innovation-led biotechnology research, which has given the Company the edge in bringing to patients life-saving biopharmaceuticals for chronic therapies like Diabetes, Oncology and Immunology that are affordable and thus accessible.

#### Creative Concept and Story Telling:

Team Corporate Communications, Biocon

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#### Design:

Trisys Communications

E – [info@trisys.com](mailto:info@trisys.com)

#### Photography:

E – [vivanmehra@gmail.com](mailto:vivanmehra@gmail.com)

**NOTE:** *The Financial Report Section of the Annual Report 2018 has been printed on eco-friendly, recycled paper as part of our commitment to sustainability. Keeping the weather condition in mind, a plastic envelope has been used, however, we have taken care to use recycled plastic.*



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