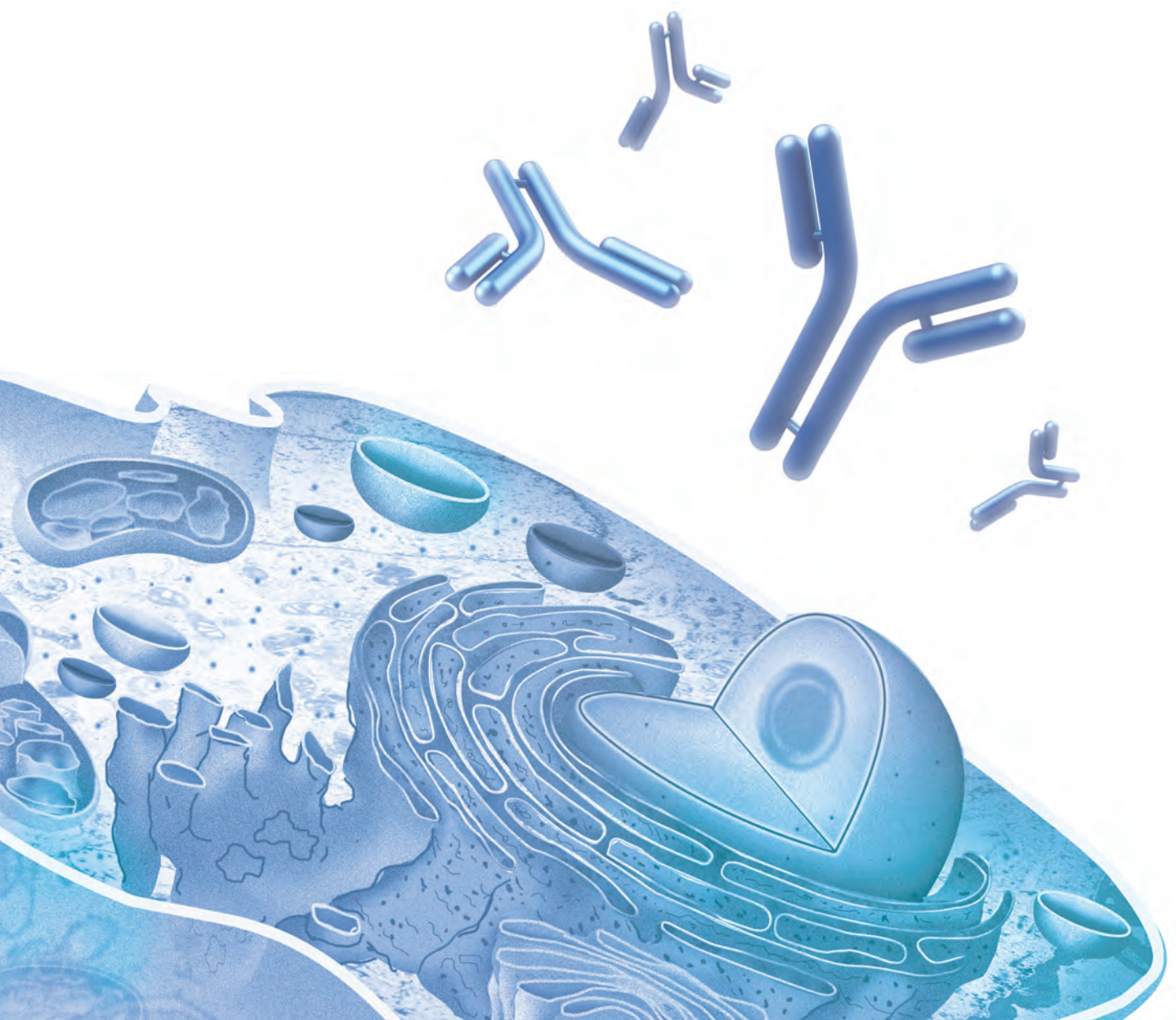




# Ahead of the curve

Annual Report 2017



# Ahead of the curve



In an environment of constant technological disruption, success hinges on the ability to stay 'ahead of the curve'.

To strike ahead, Biocon broke from the pack.







We evaluated the prospects and pitfalls of being a technology pioneer and took eclectic scientific bets to generate new knowledge. We plunged into uncharted waters of innovation-led biotechnology research. We believed that the audacious wagers we were making today would pay off disproportionately tomorrow.

The path we chose was capital intensive, research-intensive and IP-intensive with inherently long gestational time lines for product commercialization. Undaunted, we made counter-cyclical investments. We took proactive steps to be future-ready and equipped ourselves to manage the uncertainties of the economic cycles.

In the face of market skepticism, we encouraged a culture of experimentation, constantly acquired new knowhow, focused on breakthrough innovation, and ran R&D programs to bring new drugs with the potential to change the course of disease.

To evenly spread risk and reward, we sought the right partners and forged enduring relationships. We pursued an incisive IP strategy to create robust intellectual capital.

In a market place where leadership is transient and innovation is king, Biocon now stands 'ahead of the curve', committed to 'make a difference' to 'global healthcare'.

## BIOCON'S STRENGTHS HAVE BEEN DERIVED FROM STRATEGIC CLARITY AND INVESTMENT COMMITMENT



Robust infrastructure and a talent pool with extensive global product development experience.



Capabilities and expertise in an array of expression platforms that include microbial and mammalian systems.



Proprietary technology based on the *Pichia pastoris* platform for the expression of recombinant proteins.



Robust analytical capability anchored in cutting-edge tools, latest orthogonal approaches and world class technology.



Scientifically rigorous, ethically compliant and stage gate-based structured preclinical and clinical development strategy.



400-member strong scientific team, including MDs, PhDs and Masters degree holders, drawn from within India and global biopharma organizations.



Products approved by key regulatory agencies from US, EU, Japan, France, Brazil, Mexico, Turkey and Gulf countries.



Strategic global and regional partnerships across novel molecules and biosimilars.



Global-scale, complex biologics manufacturing capabilities.



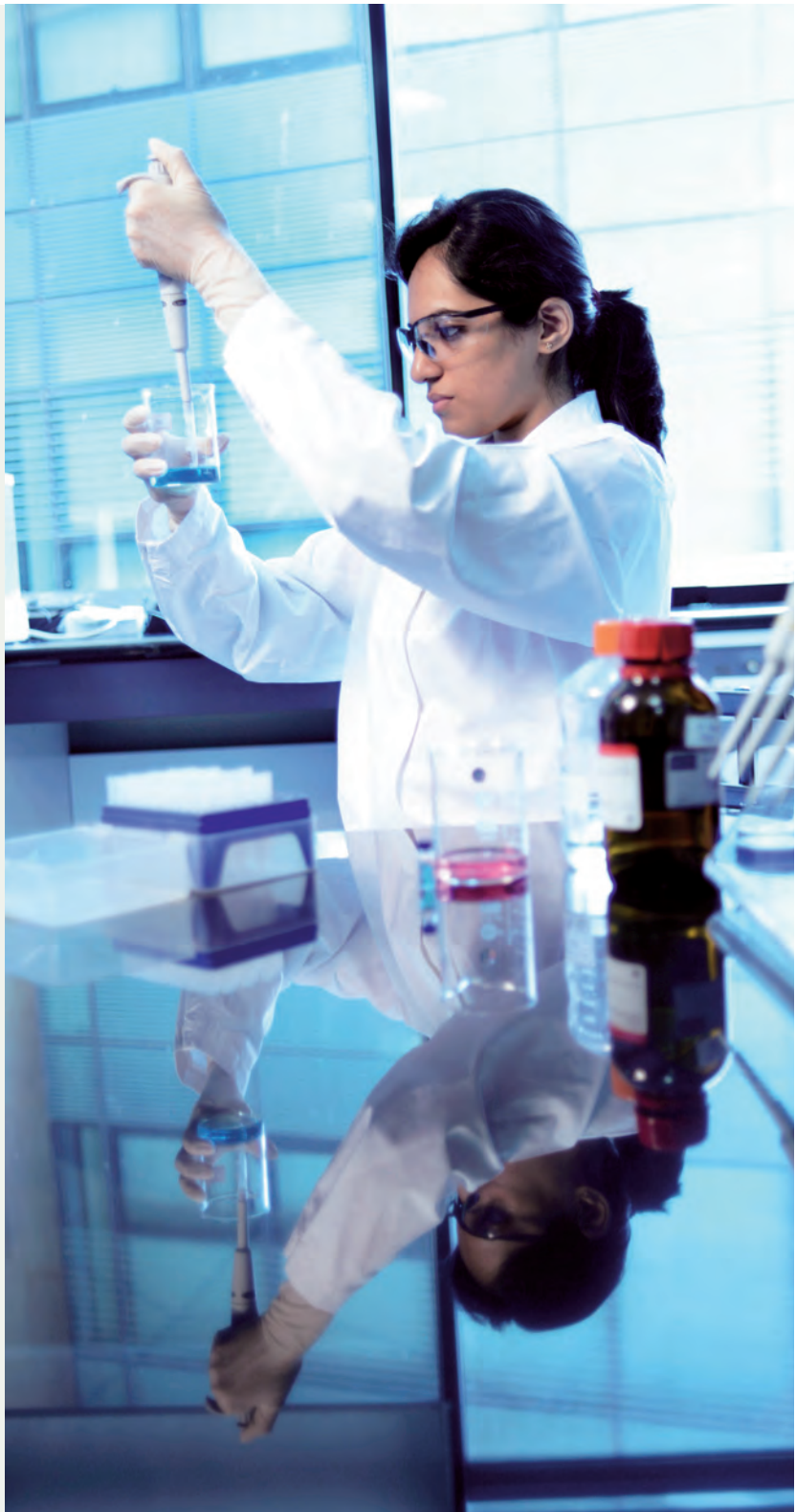
Strong foundation in process sciences that enables the development of biologics with economical scalability and high productivity.



Comprehensive presentation in biologics across Drug Substance, Drug Products (Liquid Vials, Lyophilized Vials, Cartridges & Prefilled Syringes) and Delivery Devices (Reusable & Disposable Prefilled Pens).



Wide presence with marketing footprint across 120 countries.



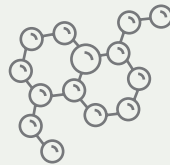




## BIOCON IS A DIFFERENTIATED PLAYER IN THE GLOBAL PHARMACEUTICALS SPACE



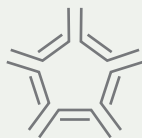
Among a handful of Indian pharma companies working in the area of biologics.



First and only listed 'pure play' biopharmaceuticals company in India.



Globally recognized biopharmaceuticals enterprise with a unique business model that straddles both products and services.



Extensive experience and demonstrated expertise in taking two novel biologics and five biosimilars from 'lab to market'.



Diversified portfolio of biosimilar insulin analogs and antibodies in advanced stages of development.



R&D strategy covers early, mid and late-stage novel assets.



In-house expertise across the drug value chain; pipeline includes proprietary and partnered programs.



Incisive intellectual property strategy recognized by several national and international awards.



Experience of multiple global regulatory filings in insulins, biosimilar antibodies and complex generic formulations.



A strategy of being profitably smart and socially good to provide affordable access to advanced biopharmaceuticals for global patient populations.



A motivation to enter niche areas where we perceive the potential to moderate costs and widen patient access.



A collaborative model that allows us to share risk and reward of drug development through research partnerships and extend our global footprint through local marketing alliances.

BIOCON'S  
BUSINESS  
MODEL WOVEN  
AROUND  
COMMITMENT  
TO CORE  
VALUES



A business philosophy built around the core values of quality, affordability, reliability and innovation.



An unwavering commitment to stringent quality controls in compliance with best-in-class global standards.



A relentless focus on chronic disease spaces like diabetes, cancer and autoimmune / inflammation.



A portfolio approach focused on chronic disease segments and integrating well validated target-to-clinic-to-counter capabilities.



An obligation to develop affordable blockbuster drugs with the potential to benefit a billion patients.

## GLOBAL BIOLOGICS LANDSCAPE PRESENTS A GOOD OPPORTUNITY FOR BIOCON

Of the Top 15  
Global pharma  
brands by revenue  
in 2016

10

were biologics\*

Worldwide  
prescription drug  
market in 2022  
forecasted to grow to

US\$ 1.1

trillion#

Worldwide  
biotechnology drug  
market in 2022 projected  
to grow to

US\$ 337

billion#

Global biosimilars market in 2020 projected to be between

US\$ 25 billion & US\$ 35 billion@

Emerging markets have historically seen a very high penetration of generic drugs; similar trends could apply to biosimilars.

Markets such as the US, EU and Japan have defined regulatory requirements for registration of biosimilar products and payers are pushing to contain costs.

In the US, actions at the payer and regulatory levels and increased political noise around drug pricing are very encouraging towards acceptance of biosimilars.

Source: \*Genetic Engineering & Biotechnology News; #Evaluate Pharma; @Allied Market Research



1979

First Indian company to manufacture and export enzymes to the US & Europe >

1993

First biotechnology company in India to get ISO 9001 certification from the German authority RWTUV >

1994

India's first Custom Research Services Organization, Syngene, set up >

2000

India's first Clinical Research Organization, Clinigene, set up >

2001

First Indian company to get US FDA approval for manufacturing Lovastatin >

2004

First Indian company to submit a DMF (Drug Master File) for rh-insulin API to the US FDA >

2004

First company globally to commercialize rh-insulin manufactured through *Pichia* fermentation technology >

2004

First biotech company in India to list on the Indian stock exchanges >

2006

India's first indigenously produced novel monoclonal antibody for head & neck cancer, BIOMAb EGFR®, launched in India >

BIOCON  
HAS GROWN  
THROUGH  
THE YEARS BY  
CONSISTENTLY  
INVESTING  
AND PLANNING  
AHEAD OF THE  
CURVE



2006

Biocon Park, India's first private corporate biotechnology SEZ, became operational >

2009

Signed with Mylan one of the earliest partnerships in the global pharma industry for the co-development of biosimilars >

2010

Evertor™, India's first generic everolimus for the treatment of advanced renal cell carcinoma, launched >

2013

The world's first novel anti-CD6 monoclonal antibody for psoriasis, ALZUMAb™ (Itolizumab), launched in India >

2013

First Indian biopharmaceuticals company to venture into the exciting space of siRNA-based (small interfering RNA) therapeutics through a partnership with Quark Pharma >

2014

The first biosimilar Trastuzumab to be approved anywhere in the world launched as CANMAb™ in India >

2015

The first biosimilar to be approved in Mexico as per the Biocomparable Approvals Pathway is Biocon's Insulin Glargine >

2016

The first Indian company to launch a biosimilar Insulin Glargine pen in Japan >

2017

Biocon's Insugen® is the first locally manufactured biosimilar product to be approved for sale by the Malaysian drug regulator >



## FY17 AT A GLANCE

Revenue

40,787

₹ Million

Profit for the year

6,121

₹ Million

EBITDA Margin

28%

R&D Spend (Gross)

4,019

₹ Million

EPS

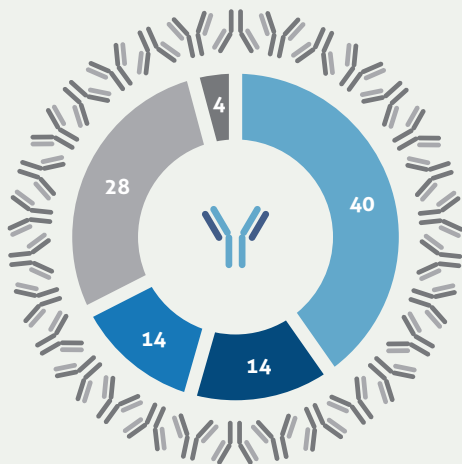
31

₹

Employees

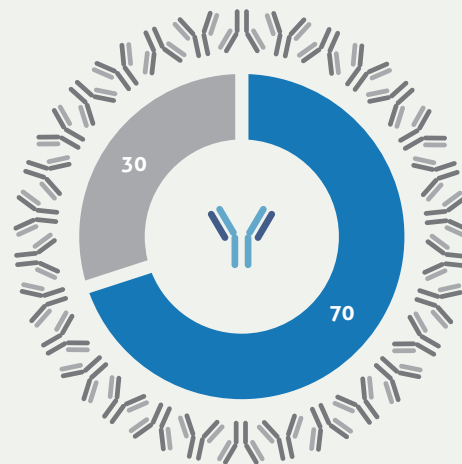
9,000+

### Business Revenue Mix (%)



- Small Molecules ₹16,330 million
- Biologics ₹5,793 million
- Branded Formulations ₹5,489 million
- Research Services ₹11,604 million
- Others ₹1,571 million

### Geographic Distribution (%)



- International
- Domestic

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# Chairperson's Review

Kiran Mazumdar-Shaw, *Chairperson*



Dear Shareholders,

## The Era of Biologics

The global pharmaceuticals industry is witnessing transformative change. Biologic drugs or protein therapeutics like antibodies, interleukins, and vaccines derived from microbial and mammalian cells have ushered in a paradigm shift in treating chronic diseases. Targeted therapies and precision medicine are poised to disrupt the future of disease management.

The Indian pharmaceuticals sector built global scale and leadership by reverse engineering expensive, chemically synthesized, small molecule drugs to produce cost effective generic alternatives. In doing so, it earned the label of being the 'Pharmacy of the World'. After dominating the traditional generic drugs industry for decades, many Indian companies are now in the race to create generic versions of biologic drugs, or biosimilars, which are far more complex to make but offer a large global opportunity.

Biocon is ahead in the pursuit to develop the first wave of biosimilars for global markets and expand access to a number of essential and lifesaving biologic drugs that are facing patent expiry. We are also developing a pipeline of patented biologics to address unmet medical needs.

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Source:

\*Genetic Engineering & Biotechnology News,

#Evaluate Pharma® World Preview 2016.

It is noteworthy that 10 of the Top 15 drugs by sales in 2016 were biologics\* and it is forecast that by 2022 biologics will contribute up to 50% of the value of the Top 100 drug products sold globally#. Global sales of biotechnology drugs are projected to grow to USD 337 billion# by 2022.

## Getting 'Ahead of the Curve'

At the turn of the millennium, Biocon chose to embark on a biologics-led pharmaceutical journey with a differentiated business strategy. We invested 'ahead of the curve' in the promising future of targeted biologics that are revolutionizing the treatment of chronic diseases. We recognized that for a company of our size, it was an audacious plan. We took the plunge because we believed it would provide us with a head start in an overcrowded generics market place. We decided to take on the complex development, manufacturing and regulatory challenges inherent to biologics as we were confident of our capabilities. This stemmed from our knowledge and expertise in enzyme technology, with which we started our biotechnology business. We pursued an innovation strategy rooted in affordability by leveraging India's cost base and set out to address the unfolding opportunities. By choosing to lead rather than follow, we have been able to transform scientific discoveries into advances in human healthcare and generate incremental value for our shareholders.

## Biologics: At the Cutting Edge

In 2006, Biocon earned the distinction of being the first company in India to launch a novel biologic, Nimotuzumab, a humanized anti-EGFR (epidermal growth factor receptor) monoclonal antibody (mAb), for head & neck cancer patients.

We followed up with the launch of our second novel biologic, Itolizumab, in 2013 for psoriasis patients in India. This was a path-breaking anti-CD6 mAb that offered a less aggressive dosing regimen and a longer treatment free period.

We had entered into a co-development partnership with US-based Mylan for a portfolio of biosimilars in 2009. This collaboration led to the launch of the world's first biosimilar Trastuzumab in 2014. Patients suffering from



We have put three of our advanced biosimilar assets on track for anticipated regulatory approvals in developed markets.

HER2-positive metastatic breast cancer in India gained access to an affordable version of this lifesaving drug when the rest of the emerging world only had recourse to the expensive innovator product.

Biocon and Mylan have one of the longest-standing partnerships in the global biosimilars space. We have leveraged our mutual strengths to build one of the largest and most diverse biosimilar pipelines, spanning insulin analogs and monoclonal antibodies.

#### First off the Blocks

As early movers in the biosimilars space, we have put three of our advanced biosimilar assets on track for anticipated regulatory approvals in developed markets. These address an aggregate market opportunity of USD 20 billion.

During FY17, we filed two Biologics License Applications (BLAs) in the US and three Marketing Authorization Applications (MAAs) in EU.

We were the first to file regulatory applications for a proposed biosimilar of Trastuzumab in both the US and EU. This has positioned Biocon and Mylan among the first companies to be able to address the critical need for a high-quality biosimilar to treat certain HER2-positive breast cancers in the US and EU.

Our applications for biosimilar Pegfilgrastim have also been accepted for review in the US and EU.

We submitted a Marketing Authorization Application for our biosimilar Bevacizumab with the Indian drug regulator after completing an emerging market-targeted India clinical trial. The MAA has recently been granted.

The global clinical trials for our biosimilar Adalimumab in plaque psoriasis have been completed. We expect regulatory submissions in various geographies to start in FY18.

Our biosimilars development capability was endorsed this year with the publication of the HERITAGE study by the prestigious *Journal of the American Medical Association (JAMA)*. The study results confirmed the efficacy, safety



We are now moving steadfastly towards our aspiration of providing our insulins to 'one in five' insulin-dependent people with diabetes, around the world.

and immunogenicity of the proposed biosimilar Trastuzumab co-developed by Biocon and Mylan in comparison to the reference product.

The presentations of the study results at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, US and the European Society for Medical Oncology (ESMO) Congress in Copenhagen, Denmark in 2016 by Dr. Hope Rugo were appreciated immensely by the scientific community.

### Consolidating Market Leadership

We have built market leadership in insulins on the back of our global manufacturing scale. We are now moving steadfastly towards our aspiration of providing our insulins to 'one in five' insulin-dependent people with diabetes around the world.

We achieved a key milestone in our journey towards this visionary goal when we launched our ready-to-use, disposable Insulin Glargine pen in Japan through our partner FUJIFILM Pharma. Our Insulin Glargine is the first biosimilar from India to be launched in Japan. It is also our first biosimilar in a developed market. The confidence our product has gained among prescribers and patients in Japan has endorsed the quality and efficacy of our product and enhanced Brand Biocon's reputation across the world.

We also started commercial supplies from our first overseas insulins manufacturing facility in Malaysia this year. Our recombinant human insulin (rh-insulin) became Malaysia's first locally manufactured biosimilar product to be sold in the Southeast Asian nation after we signed a three-year, MYR 300 million Off-Take Agreement with the Malaysian government.

We are looking forward to our insulins foray into larger developed markets following the submission and acceptance of our filings for Insulin Glargine with the European Medicines Agency (EMA) and the US FDA.

The commercialization of the Malaysia facility in FY17 will strengthen our position among the Top 3 biosimilar players globally for insulins<sup>#</sup>.

<sup>#</sup>*in terms of volume market share-Units (Source: IMS Year End 2016)*



The successful journey of Itolizumab from the laboratory to the market in India has put us ahead in the race of anti-CD6 antibody to unlock the potential of its unique mechanism of action in multiple autoimmune indications.

### Novel Molecules: Poised for the Leap

As practitioners of frontier science, we have built a pipeline of novel biologics to address local as well as global unmet medical needs in diabetes, cancer and autoimmune diseases. The basket of novel assets under clinical development represents an interesting combination of early and advanced stage assets.

We believe Insulin Tregopil, a 'first-in-class' oral prandial insulin, is the most advanced program in the global oral insulin space and promises to transform diabetes management. We have set the stage for pivotal studies with Insulin Tregopil on different diabetic populations in India, which will form the foundation of a broad global program envisioned for this novel molecular entity.

The successful journey of Itolizumab from the laboratory to the market in India has put us ahead in the race to unlock the potential of its unique mechanism of action in multiple autoimmune indications. In FY17, we reported encouraging progress in our tests with a patient-friendly subcutaneous form of Itolizumab.

### Small Molecules: Enabling Partners

The significant brand equity that we have built worldwide for our fermentation-derived small molecule APIs across statins, immunosuppressants and other specialty products has made us a leading global supplier of these products. We built on this reputation to emerge among the first wave of suppliers of Rosuvastatin API to our partners for the US launch upon patent expiry in 2016. During the year, we received our first generic formulation approval for Rosuvastatin Calcium from the US FDA.

To become a vertically integrated player in the niche space of difficult-to-make generic formulations, we have leveraged our strengths in fermentation technology and molecular characterization.

### Branded Formulations: India & UAE

We initiated our Branded Formulations business in India in 2004 with the launch of the country's first indigenously developed rh-Insulin, which brought down the cost of insulin therapy by a third. Since then, we have aimed at staying 'ahead of the curve' by deftly balancing innovation and affordability



As a front-runner in the contract research services space, Syngene further expanded its role in FY17 as an 'innovation partner'.

with an intent to bring cost-effective biologics and differentiated small molecule formulations for chronic conditions to patients in India, UAE and other select markets.

This year, the business reported an overall growth of 24%, on a like to like basis this segment was down marginally compared to last year. Though sales in India were sluggish, we continued to improve prescription share for some of our key brands such as Insugen<sup>®</sup>, Basalog<sup>®</sup> and CANMAb<sup>™</sup>. Our robust growth in UAE placed us among the Top 15 pharma companies this year with most of our products ranked among the Top 5 brands in their respective segments.

The recently announced leadership changes across our India Branded Formulations business will provide us the ability to pursue a strong growth trajectory.

#### Syngene: Integrated Research Services Provider

Syngene, our Research Services subsidiary, is the only publicly listed Contract Research Organization (CRO) in India that offers end-to-end drug discovery and development services for novel molecular entities to the global life sciences sector. As a front runner in the contract research space, Syngene further expanded its role in FY17 as an 'innovation partner' through new strategic partnerships with Amgen and Herbalife Nutrition with dedicated R&D centers.

In December 2016, a fire accident at one of Syngene's research blocks in Bengaluru affected the strong revenue momentum of the business. Syngene's value proposition to its customers remains strong as it expanded its capacities and acquired new capabilities during the year. An important acquisition to this effect was that of a bioinformatics business from a Bengaluru based genomics company, Strand Lifesciences. On a standalone basis it reported a revenue growth of 14% with a healthy EBITDA margin.

#### Quality: Unwavering Focus

A culture of quality excellence has helped Biocon maintain a strong compliance track record in regulatory inspections over the years. During FY17, we underwent multiple regulatory audits from various international regulators.



We continue to be the only Asian company on the Global Best Biotech Employers list.

### Best Employer Brand

We continue to be the only Asian company on the Global Best Biotech Employers list brought out by the prestigious *Science Careers* magazine, which I believe is a great testament to our work culture and the opportunities our scientists get within the company. In 2016, we featured among the Top 10 employers globally.

### Financial Highlights

We matched our operational performance in FY17 with an equally strong financial performance. We grew our topline by 18% to ₹40,787 million, while simultaneously improving the quality of our earnings. Our EBITDA margin for the year expanded to 28% from 24% a year ago. Adjusting for the exceptional item that boosted the bottomline in FY16, Net Profit for FY17 jumped 54% to ₹6,199 million.

### Declaration of Bonus Shares & Final Dividend

The Board of Directors of the Company has recommended the issue of two bonus shares for every one share held in Biocon, which has been subsequently approved by the shareholders. The Board also recommended a final dividend of ₹3/- per share for FY17 (pre bonus), which works out to be ₹1/- per share post approval.

### Being Socially Responsible

We strongly believe that the use of technology can address several challenges associated with public health delivery in our country. Biocon Foundation, the CSR arm of Biocon, has taken ahead this belief to develop a unique e-healthcare model and introduced eLAJ Smart Clinics a few years ago.

These clinics are designed to facilitate effective preventive and primary healthcare intervention in the rural areas of India for the benefit of communities with poor access to healthcare. The foundation currently runs 14 eLAJ Smart Clinics covering over 30 gram panchayats across Karnataka and Rajasthan.

Through the eLAJ Smart Clinics we are paving the way for evidence-based public health interventions in these locations by enabling multiple diagnostic tests and generation of Electronic Medical Records (EMRs) of patients. Over



Through the eLAJ Smart Clinics we are paving the way for evidence-based public health interventions using technology for multiple diagnostic tests and generation of Electronic Medical Records (EMRs) of patients.

the past year, patient footfall at eLAJ clinics has gone up by 50% to more than 9,000 a month.

The eLAJ model is facilitating on-time treatment, helping reduce out-of-pocket healthcare spending and cutting down the need for trips to tertiary hospitals, which is in line with our commitment to enable the 'Right to Healthcare' for every citizen.

Biocon Academy, our one-of-a-kind initiative in the area of skills development, delivered on its commitment to prepare industry-ready students for the biotech sector. FY17 saw the successful completion of three batches of the Biocon KGI Certificate Program in Biosciences and the second batch of the BITS Biocon Program in Applied Industrial Microbiology. The Academy maintained a 100% placement record this year too, even as more than 35 companies visited it for recruiting fresh talent. More than 60% of our students are being employed outside of Biocon and Syngene.

### Looking Ahead

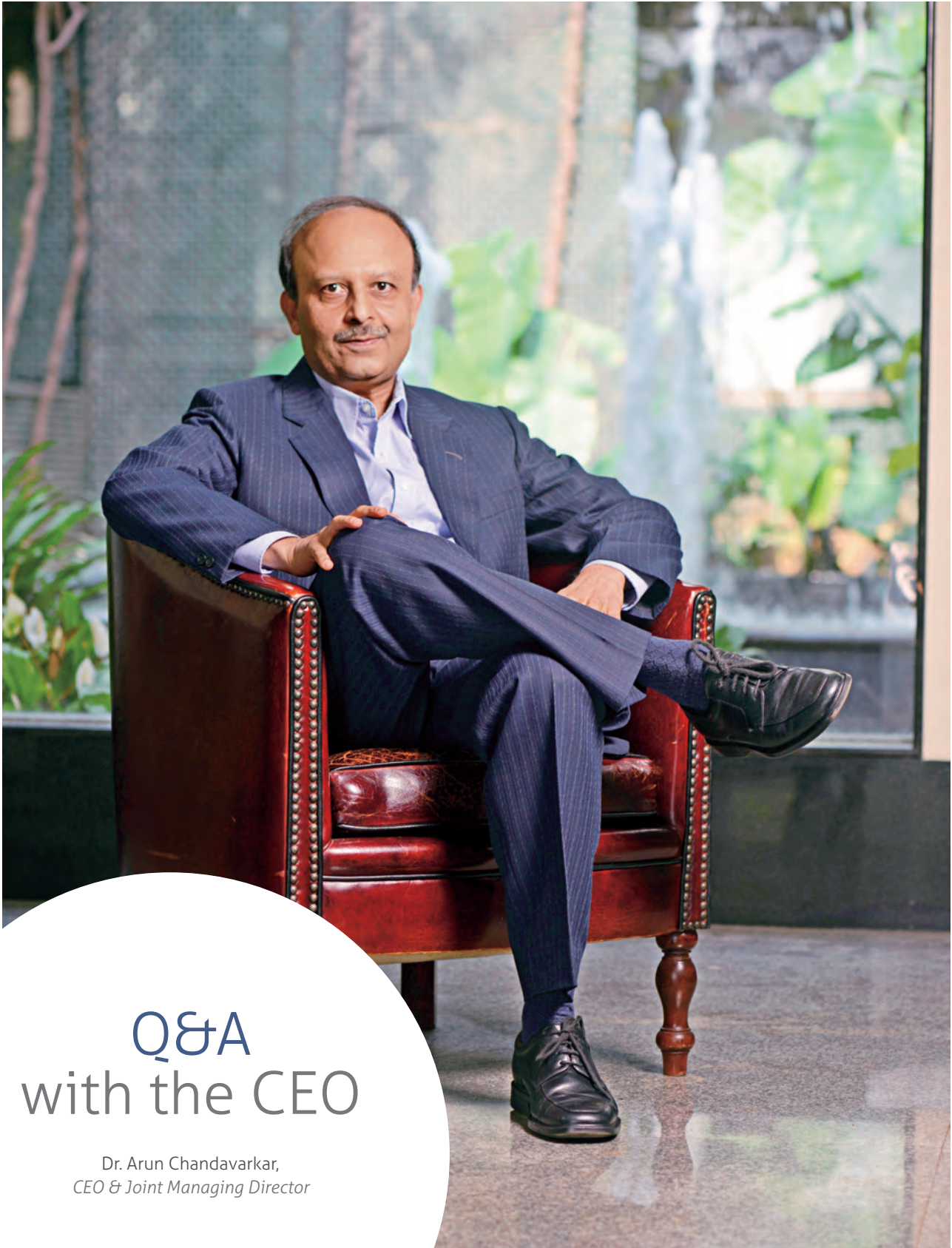
FY18 promises to be an exciting year for Biocon as some of the developed market regulatory submissions for our biosimilars could translate into marketing approvals, opening up immense growth opportunities for the Company.

Finally, I would like to thank our shareholders for the trust they have placed in us. We are in a humanitarian business of making a difference to people's lives. It is this mission that has spurred us on to fight our way through years of credibility challenges and market skepticism and emerge as the leading Indian company working in the cutting-edge sphere of biosimilars.

Best Wishes,

Kiran Mazumdar-Shaw  
Chairperson & Managing Director

June 8, 2017



# Q&A with the CEO

Dr. Arun Chandavarkar,  
*CEO & Joint Managing Director*





### How has Biocon consistently stayed 'ahead of the curve'?

Biocon's focus on innovation and differentiation pre-dates our entry into the pharmaceuticals sector. Our entrepreneurial culture rooted in building strengths in the then nascent field of biotechnology was instrumental in us identifying opportunities based on market and technology trends, both during our initial years as an enzyme company and during our subsequent foray into biopharmaceuticals. This led us to proactively invest in capabilities aligned to these opportunities to be 'ahead of the curve'.

Biocon commenced its pharma journey in 1999 by leveraging its capabilities in fermentation technologies derived from its long experience in manufacturing enzymes; this was unlike other companies in India which were largely focused on generics made by chemical synthesis. Furthermore, we were amongst the early movers in developing a portfolio of fermentation-derived statins which gave us a leadership position in this segment. We simultaneously chose to expand our strategic options from small molecules like statins to recombinant proteins like insulin to address the growing healthcare challenges associated with diabetes.

We did not hesitate to exploit differentiated technologies, such as a proprietary yeast platform based on '*Pichia pastoris*' to create a portfolio of insulins. In 2003, we initiated work on mammalian cell culture based expression systems to develop monoclonal antibodies (mAbs) targeting cancer and autoimmune diseases. Our product portfolio was not limited to generics or biosimilars; we sought opportunities to be 'ahead of the curve' in addressing unmet needs in these therapeutic segments through novel biologics and novel targets. These were marked by high entry barriers wherein we were required to make significant investments in a full range of R&D capabilities, spanning process and analytical development to pre-clinical and clinical research.

The early anticipation of the increasing dominance of biologics in global development pipelines helped us to be 'ahead of the curve' in crafting a differentiated product portfolio based on fermentation and recombinant technologies. We believe these would provide us a sustainable competitive advantage in the years ahead.

The early anticipation of the increasing dominance of biologics in global development pipelines helped us to be 'ahead of the curve'.

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During the year gone by, we further demonstrated our capabilities through the dossier submissions in Europe by our partner Mylan for three biosimilar products based on diverse technology platforms and scale of operations.



### How did being 'ahead of the curve' translate into tangible achievements at Biocon?

The strategic choice of focusing on biotech and fermentation-derived biopharmaceuticals resulted in a unique and differentiated product portfolio straddling fermentation-derived small molecules, recombinant proteins including insulins and mAbs.

Biocon's growth in the mid 2000s, triggered by the first approval of our statin API facility by the US FDA, was driven by our early mover advantage in Lovastatin, Pravastatin and Simvastatin. We were amongst only a few companies with approved APIs for these fermentation-derived statins, which helped lower the competitive intensity otherwise typical of chemistry-based APIs. We expanded our portfolio of fermentation-derived APIs to establish a strong competitive position in immunosuppressants and certain other speciality APIs.

Likewise, we were one among just two non-originator companies to commercialize recombinant human insulin in India in 2004 and subsequently rapidly expand our footprint into multiple emerging markets. This was followed by the launch of Insulin Glargine in India in 2009 and, more recently, by an important endorsement of our product quality on account of the approval and launch of Glargine disposable pens in Japan in 2016.

We were also pioneers in developing, manufacturing and launching a couple of novel biologics in India, namely an anti-EGFR mAb (Nimotuzumab) for head and neck cancer in 2006 and an anti-CD6 mAb (Itolizumab) for psoriasis in 2013.

When we embarked on our biosimilar journey, we anticipated some of the risks, the long gestation period for development, the evolving regulatory landscape and significant financial outlay for R&D and manufacturing infrastructure. We proactively mitigated some of these risks by entering into regional and global partnering agreements such as the one with Mylan for

biosimilar mAbs in 2009, which was then expanded to insulin analogs in 2013. These partnerships, structured as a sharing of risks and rewards, leveraged the complementary strengths of each partner and were a forerunner of many global partnerships that exist today in the biosimilar space, including those involving many innovator companies. I believe that 'partnering' as a strategic choice early in the investment cycle of biosimilars is another example of how we have been 'ahead of the curve'.

A tangible outcome of our partnership with Mylan has been the launch of biosimilar Trastuzumab in 2014 in India and other emerging markets. Our collaboration also reached important milestones in FY17 with our Trastuzumab and Pegfilgrastim dossiers being accepted for review by the US FDA and EMA followed by our Glargine filing in Europe.



### What does Biocon's 'ahead of the curve' strategy mean for its prospects?

Biocon's annual report to shareholders for FY16 highlighted our efforts and initial successes at being 'Credibly Capable'. This was based on our first approval for a biosimilar product, namely Insulin Glargine, in a very demanding developed market like Japan, and the progress we had made in advancing our other biosimilar programs through the clinic.

During the year gone by, we further demonstrated our capabilities through the dossier submissions in Europe by our partner Mylan for three biosimilar products based on diverse technology platforms and scale of operations, namely Trastuzumab, Pegfilgrastim and Insulin Glargine. Last year, we also had the US FDA accept the dossiers of Trastuzumab and Pegfilgrastim for review, with Insulin Glargine to follow in early FY18. These three products target a market opportunity of about USD 18-20 billion at current innovator pricing. We continue to develop the other biosimilar assets in our collaboration with Mylan.

Our near-term growth in biosimilars will be driven by expanding our footprint in key emerging markets through strong local partnerships. Product approvals

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The successful commissioning of our Malaysian facility for insulins in FY17 and the three-year MYR 300 million contract from the Malaysian Ministry of Health augur well as we seek approvals in other key emerging markets.



and commercial success in the developed markets of the US and Europe would be significant milestones that can help the Company reinvent itself and lay a strong foundation to stay 'ahead of the curve' in the next decade. These will be supported by capacity expansions as needed in a phased manner and additions to our product portfolio to cater to the next wave of opportunities. We will continue to adopt a risk-balanced approach to advance our promising first-in-class novel biologics that target critical unmet needs.

We will strive to remain 'ahead of the curve' in developing fermentation-derived, complex, potent or niche small molecule generic APIs and forward integrate them to finished dosage forms.

We believe that our strategy of being 'ahead of the curve' through a well-diversified portfolio of small molecules, biosimilars and novel biologics can help us overcome the headwinds facing the generic pharmaceutical sector today in terms of pricing pressure, tougher regulatory expectations and increased competition.

#### What are Biocon's key priorities for FY18?

FY18 positions us at a key inflection point in our journey to be amongst the first wave of successful entrants in the global biosimilar arena. We look forward to receiving approvals in the US and Europe for the biosimilar filings done in FY17 and launch of some of these products in a few markets. We also expect to have a couple of additional filings in FY18 in these markets.

The successful commissioning of our Malaysian facility for insulins in FY17 and the three-year MYR 300 million contract from the Malaysian Ministry of Health augur well as we seek approvals in other key emerging markets. These approvals and the commercial launches thereafter, expected in the latter part of FY18, would help partly defray the annual fixed costs of about USD 48 million associated with our Malaysian facility. The approvals will also debottleneck the capacity constraint we had for insulins in our Indian facility.

We will continue to seek approvals and expand our commercial footprint for biosimilars in the key emerging markets of LATAM, MENA, CIS and Southeast Asia. This can unlock value for our first set of assets whilst waiting for the developed markets to open up. We expect to break ground for a new brownfield mAbs facility in Bengaluru.

On the R&D front, we will continue to invest in progressing our biosimilars and novel biologics. Whilst we completed an ROW-focused Phase III trial in metastatic colorectal cancer for our proposed biosimilar Bevacizumab in FY17, a separate global Phase III trial in non-small cell lung cancer is on track with patient recruitment. We will continue to develop rapid-acting insulin analogs to enable progress to the clinical stage. We will shortly initiate a significant clinical study of our novel Insulin Tregopil (oral insulin) to validate its positioning as an orally-delivered, rapid-acting, prandial insulin and establish its safety and efficacy in Type 2 diabetes patients. We expect to conclude the Stage 2 study of our novel anti-CD6 mAb, Itolizumab, in Australia, which can provide valuable data in terms of a subcutaneous route of administration.

Our Small Molecules segment is expected to see steady growth on the back of increased volume offtake in our base products comprising statins and immunosuppressants. We will continue to invest in developing the next portfolio of small molecules and forward integrating them from APIs to finished dosage forms. We expect our newly constructed oral solids formulations facility to be operational in the latter part of FY18 which will reduce our current dependence on outsourced manufacturing.

A key focus in FY18 will be re-booting our Branded Formulations business under a recently revamped leadership team with the intent of gaining market share profitably through our anchor brands. This will be augmented through new launches of in-house and in-licensed products.

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Our Small Molecules segment is expected to see steady growth on the back of increased volume offtake in our base products comprising statins and immunosuppressants.



# Financial Review by CFO

Siddharth Mittal,  
*President-Finance & CFO*

Revenue:  
**₹40,787** million  
18%

EBITDA:  
**₹11,366** million  
34%

Net Profit:  
**₹6,121** million  
11%

EBITDA Margin:  
**28%**  
4%



### Can you comment on your transition to the new Indian Accounting Standards from FY17?

Biocon is amongst the early adopters of the new Indian Accounting Standards, referred commonly as 'Ind AS'. The transition from the older standard to 'Ind AS', starting April 1, 2016 applied to both our standalone and consolidated financial statements.

In line with 'Ind AS', we changed our segment reporting to better reflect the way we view and measure our overall business. We started reporting four segments – Small Molecules, Biologics, Branded Formulations and Research Services – instead of just two, Biopharmaceuticals and Research Services, which we used to report under the previous accounting standard. This is in line with the growth strategies represented by the four business segments and provides a clearer picture of those segments to our shareholders than earlier.



### How do you rate the performance this year?

The overall financial performance during the year was very satisfactory and in line with our expectations. In FY17, our consolidated revenue at ₹40,787 million grew by 18% while Net Profit at ₹6,121 million reported 11% growth. Adjusting for an exceptional income in FY16, Net Profit actually jumped 54% to ₹6,199 million during the year. Earnings before Interest, Taxes, Depreciation & Amortization (EBITDA) for the year rose 34% to ₹11,366 million, while EBITDA margin markedly improved to 28% from 24% last year.

The extraordinary gain recorded in the previous year was on account of the deferred revenue recognition pertaining to rh-insulin development and impairment of an intangible asset in Biocon SA.

The Company's strong performance during the year was led by the Small Molecules business reporting a growth of 12% at ₹16,330 million and Biologics business at ₹5,793 million, reporting a growth of 43%. Branded Formulations business, which now includes sales in UAE, reported a growth of 24% at ₹5,489 million and Research Services through Syngene contributed ₹11,604 million to Biocon's sales.

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Adjusting for an exceptional income in FY16, Net Profit actually jumped 54% to ₹6,199 million during the year.



### What does your operating margins trajectory look like in the medium term?

The Company's core operating margins, which is operating margins adjusted for licensing income, R&D expenses and forex gains or losses, continue to remain healthy in spite of increased operational expenses, like salaries and other costs. In FY17, our EBITDA margin was at 28% while core operating margins stood at 32%, resulting from growth in our Small Molecules business and Biosimilars business in the emerging markets.

In the medium-term, we will endeavor to maintain our core operating margins at 30% levels despite an increase in R&D expenses and inclusion of Malaysian expenses in the P&L. We anticipate margins to improve once we launch biosimilar products in the developed markets and enjoy a reasonable penetration that reflects in the optimum utilization of our manufacturing assets.



### With Goods & Services Tax (GST) expected to be rolled out nationwide on July 1, 2017, what would be its anticipated impact on Biocon?

From a long-term perspective, GST is good for the nation as it will replace a number of different taxes companies have to deal with currently with a single nationwide tax that would simplify operations.

We do expect a short-term impact on the Branded Formulations India business as it is anticipated that the distribution channel could destock market inventory before GST roll-out; and hence sales in Q1 FY18 could be impacted. The impact could roll-over into Q2 FY18 as well depending on how quickly the channel becomes GST-ready and compliant. We expect things to normalize by the second half of the fiscal.

Under GST, the Company can claim input credit for certain items, which was not possible in the earlier tax structure. However, these savings would ultimately have to be passed on to customers, given the anti-profiteering clause in the GST Bill.



### What is the expected tax rate for Biocon at the consolidated level for FY18?

At a consolidated level, the effective tax rate for FY17 was 19%. After adjusting for one-time deferred tax benefit that the Company availed, the effective tax rate was 22% for the year.

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In the medium-term, we will endeavor to maintain our core operating margins at 30% levels despite an increase in R&D expenses and inclusion of Malaysian expenses in the P&L.



This rate is expected to go up by 200-300 bps (100 bps = 1%) in FY18 due to the expiry of the 10-year tax holiday for some of our manufacturing facilities. Further, the government is gradually phasing out the R&D tax benefit availed by Biocon thus far. The 200% weighted deduction will reduce to 150% in FY18 and be completely eliminated in the next couple of years.



### Biocon has stopped capitalization of expenses from the Malaysia plant at the end of FY17. How will it affect the bottom-line in FY18?

We stopped capitalizing pre-operating expenses relating to Malaysia plant at the end of FY17. Consequently, depreciation and fixed expenses related to the Malaysia plant will be charged to the P&L account starting Q1 FY18. We estimate annual depreciation of approximately USD 18 million and fixed plant operating expenses, which includes the finance cost, to be approximately USD 30 million.

We have already commenced commercialization from Malaysia plant with supply of rh-Insulin for the domestic market. In FY18, we also anticipate approvals followed by commercial supplies in other emerging markets where previously our India plant was qualified. Lastly, we will partly utilize the plant for development of other pipeline Insulin products wherein the costs will be shared with our partner Mylan or will be accounted under R&D expenses.

As a result of the above, we do expect an adverse impact on our bottom-line from Malaysian operations in FY18. However we will endeavour to minimize the impact.



### What will be the trajectory of R&D expenditure across the foreseeable future?

The Company will continue to focus on development of biosimilars, complex generics and novel biologics. These programs require intensive R&D efforts and have long gestation periods. We have guided for gross annual R&D expenses to be in the range of 12-15% of sales, excluding Syngene. We expect R&D expenses in FY18 to be in line with that guidance.



We also have sufficient leverage on the Balance Sheet to raise additional debt to fund the remaining portion of capex. We do not foresee raising fresh equity funding from the capital markets to fund any of our short-term capex requirements.



### What is the rationale behind the capitalization of R&D expenses for select biosimilar products?



In accordance with requirements of Ind AS 38: Intangible Assets, development costs are capitalized as intangible assets based on the recognition parameters summarized below:

- a. The product is technically and commercially feasible i.e. future economic benefits are probable and the Group intends to complete development with an intent to use or sell the asset.

We establish technical feasibility once we have demonstrated biosimilarity of our product in terms of safety and efficacy through various pre-clinical and clinical activities. This occurs upon receipt of regulatory approval for the product in a major territory.

We establish commercial feasibility once we have demonstrated that the intangible asset will generate probable future economic benefits. This occurs when it is probable that we will be able to successfully commercialize the product in the intended markets.

Once the technical and commercial feasibilities are established, and we believe we have adequate technical, financial and other resources to complete the development activity, we capitalize all future development costs incurred.

- b. The expenditure can be measured reliably.

Costs of development are identified at a product level and hence development cost eligible for capitalization can be measured reliably. Broad category of expenses capitalized include the cost of materials, salaries, and other appropriate overheads used in product validation, costs for conducting clinical trials etc.



### What are Biocon's capex plans for FY18?

We are nearing the completion of two capex projects, an oral solid dosage facility and the biologics fill-finish line in Bengaluru, which are expected to be commissioned in FY18, after which we will commence the qualification process. Our maintenance capex is estimated to be between ₹750 million and ₹1 billion for the year.

In terms of a new large project, we expect to start construction of our second monoclonal antibodies facility in Bengaluru during FY18 after receipt of all regulatory approvals. The investment will be phased over a period of three to four years and the associated capex will be shared with our partner Mylan.



### What is the debt position of the Company? How does Biocon plan to fund the upcoming capex? Would Biocon need to raise funds from the markets to fund its future growth plans?

Biocon has a consolidated gross debt (long term plus short term debt) of ₹23,025 million as on March 31, 2017 with corresponding cash & liquid investments of ₹22,551 million. Excluding Syngene, the gross debt and cash & liquid investments stood at ₹14,961 million and ₹11,875 million respectively.

Cash & liquid investments on our Balance Sheet coupled with free cash flow from operations will be used to fund a significant portion of the capex. We also have sufficient leverage on the Balance Sheet to raise additional debt to fund the remaining portion of capex. We do not foresee raising fresh equity funding from the capital markets to fund any of our short-term capex requirements.

From a long-term perspective, we have restructured our legal entities to reflect each of our key business segments. The new structure provides us flexibility to unlock value and raise capital if required for any of our business segments in the future.



### Does Biocon have a specific dividend policy?

Yes, Biocon does have a dividend policy. The dividend, if any, will be distributed to our shareholders depending upon multiple factors, including (but not limited to) our future earnings, financial condition, cash flows, planned capital expenditures and working capital requirements. The declaration and payment of dividends will be recommended by our Board of Directors and approved by the shareholders, at their discretion, subject to the provisions of the Articles of Association and the Companies Act.

*For more details please read page 107.*

# Board of Directors



*Sitting from left:*

Dr. Vijay Kuchroo, John Shaw, Mary Harney, Kiran Mazumdar-Shaw, Russell Walls, Daniel M. Bradbury

*Standing from left:*

Dr. Jeremy Levin, M. Damodaran, Dr. Arun Chandavarkar, Prof. Ravi Mazumdar

**Kiran Mazumdar-Shaw***Chairperson & Managing Director*

First generation entrepreneur with nearly 42 years' experience in biotechnology

Well recognized global business leader

Independent Member of the Board of Infosys Limited

Chairperson of the Board of Governors of the Indian Institute of Management, Bangalore

Recipient of two most prestigious national awards, the Padma Shri and the Padma Bhushan

Recipient of 'Othmer Gold Medal 2014' from U.S. based Chemical Heritage Foundation

Recipient of '2014 Global Economy Prize for Business' from Germany's Kiel Institute

Featured in '100 most Powerful Women' and Asia-Pacific's 48 'Heroes of Philanthropy' by *Forbes* magazine

Recognized as the '100 Leading Global Thinkers of 2014' by US-based *Foreign Policy* magazine

*Fortune* magazine's 'Top 25 Most Powerful Women in Asia-Pacific 2014'

Featured among the Top 10 'Medicine Maker Power List', an index of the 100 most influential

people across the globe in the field of medicine, being recognized consecutively for the third year since 2015

Conferred with the highest French distinction - Chevalier de l'Ordre National de la Légion d'Honneur (Knight of the Legion of Honour) in 2016

Most recently, bestowed with the Advancing Women in Science and Medicine (AWSM) Award for Excellence 2017 by The Feinstein Institute for Medical Research, USA

**John Shaw***Vice Chairman and Whole-Time Director*

Foreign promoter and a whole-time director

Master's degree in Arts (Economic hon.) in History and Political Economy from Glasgow University, UK

Served as the Finance and Managing Director of Coats Viyella Group

Served in senior corporate positions around the world

Former Chairman, Madura Coats Ltd.

**Dr. Arun Chandavarkar***Chief Executive Officer & Joint Managing Director*

Core member of Biocon's leadership team

Played a pivotal role in the evolution of Biocon over the last 27 years

Ph.D. in Biochemical Engineering from the Massachusetts Institute of Technology (MIT), Cambridge, USA

B.Tech. in Chemical Engineering from the Indian Institute of Technology, Mumbai

Chairman, Confederation of Indian Industry's 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 several advisory committees and working groups, including the US Congress Sub-Committee on Science and Technology

Fellow of the Royal Statistical Society

Over 150 referred publications

Ph. D. from the University of California, Los Angeles (UCLA)

M.Sc., DIC from Imperial College, London

B.Tech in Electrical Engineering from IIT, Mumbai





### Russell Walls

#### *Independent Director*

Chairman, Aviva Life Holdings Ltd.  
Experience of more than 47 years in the field of Finance

Fellow member of the Association of Chartered Certified Accountants, UK

Board of Mytrah Energy Ltd, Aviva Italia Holdings SpA and Signet Jewelers Ltd

### Mary Harney

#### *Independent Director*

Tánaiste (Deputy Prime Minister) of the Irish Republic from 1997 – 2006

Longest serving woman ever in the Irish Parliament, for over 30 years

Member of the Board of CRANN, Trinity College, Dublin's largest research institute

Chair of AMBER, the Advanced Materials and Bio-Engineering Research Centre at Trinity, a joint research enterprise with University College Cork, the Royal College of Surgeons in Ireland and industry

Honorary member of the International Women's Forum

Economics graduate of Trinity College Dublin

### Daniel M. Bradbury

#### *Independent Director*

On the board of trustees of the Keck Graduate Institute, California, USA

Member, San Diego's Rady School of Management's Advisory Council

Member, Miami's Innovation Corporate Advisory Council

Life Sciences Executive with over 30 years of experience in creating and implementing strategies, transforming businesses

Honoured with the Corporate Directors Forum 'Director of the Year Award' for Enhancing Economic Value (2012)

The Ernst & Young's Entrepreneur of the Year finalist

Holds a postgraduate diploma in Management Studies

Diploma of the Chartered Institute of Marketing from Harrow and Ealing Colleges of Higher Education, UK

Bachelor's degree in Pharmacy (Hons.) from Nottingham University, UK

### Dr. Jeremy Levin

#### *Independent Director*

Former President and CEO of Teva Pharmaceuticals

Former Executive Committee member of Bristol-Myers Squibb

Was responsible for global strategy, alliances and operational transactions

Led 'String of Pearls' strategy at BMS which helped transform the company pipeline

Served as Global Head of Strategic Alliances at Novartis

Recognized among the 'Top 25 Most Influential People in the Biopharmaceutical Industry'

Recipient of Kermode Prize for work on novel hypertension drugs

Albert Einstein Award for Leadership in Life Sciences awarded by Mr. Shimon Peres

Officer's Cross of the Order of Merit of the Republic of Hungary

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 (MB, B. Chir) 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, USA

Co-Director, Center for Infection and Immunity, Brigham Research Institutes, Boston

Named 'Distinguished Eberly Lecturer' in 2014

Obtained Nobel Laureate Peter Doherty Lecture / Prize in 2014

Holds 25 patents

Has founded 5 different biotech companies including CoStim Pharmaceuticals and Tempero Pharmaceuticals

Published over 325 original research papers in the field of immunology, co-stimulation and the role of Th17 cells

Won the Fred Z. Eager Research prize and medal for his Ph.D. research work at the University of Queensland

Specialization in pathology at the University of Queensland, Brisbane (Australia) where he obtained a Ph.D.

### M. Damodaran

*Independent Director*

Founder & Chairman, Indian Institute of Management, Tiruchirappalli

Chairman, Glocal Healthcare Systems Private Limited

Chairing 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. David M. Essayan

M.D., Key Research Interests – Clinical and Regulatory development for small molecules and biologics + Clinical Immunologist; Former 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

## 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. 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

## 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 and Corporate Strategy across a broad range of therapeutic areas.

## Dr. Jugnu Jain

PhD 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

## 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 and National Expert of the EMA



# Core Committee



**1. Kiran Mazumdar-Shaw**

*Chairperson & Managing Director  
Founder, Biocon Limited*

**2. John Shaw**

*Vice Chairman*

**3. Dr. Arun Chandavarkar**

*Chief Executive Officer &  
Joint Managing Director*

**4. Dr. Narendra Chirmule**

*Sr. Vice President & Head, R&D*

**5. Siddharth Mittal**

*President, Finance & CFO*

**6. Ravi Limaye**

*President, Marketing*

**7. Amitava Saha**

*Sr. Vice President & Head,  
Human Resources*

# Vision, Mission & Values



## 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

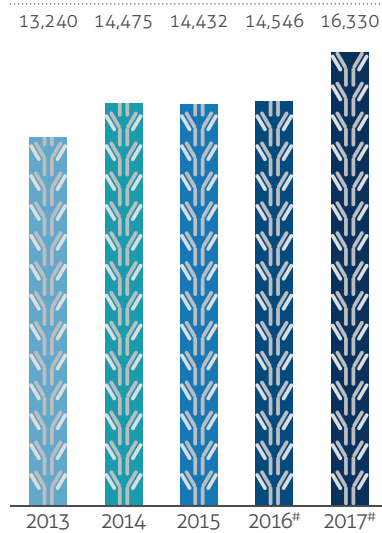
- Integrity and Ethical Behaviour
- Performance Driven Work Culture
- Value Creation through Innovation and Differentiation
- Quality through Compliance and Best Practices
- Collaboration, Team Work and Mutual Respect

# Financial Highlights

## Segment-wise Revenue

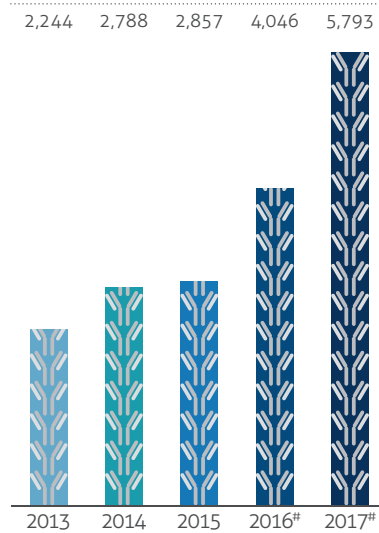
### Small Molecules

₹ Million



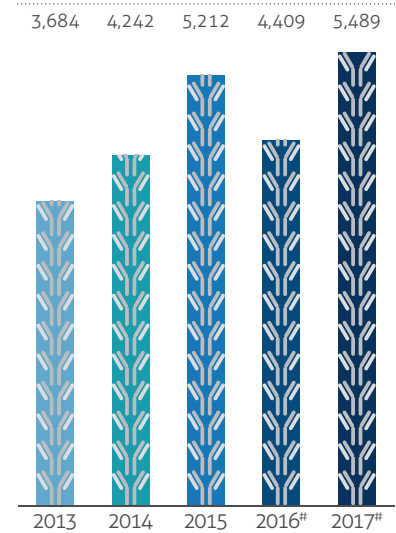
### Biologics

₹ Million



### Branded Formulations

₹ Million



### Research Services

₹ Million



### Others

₹ Million



### Total Revenue

₹ Million



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



### Profit\*

₹ Million



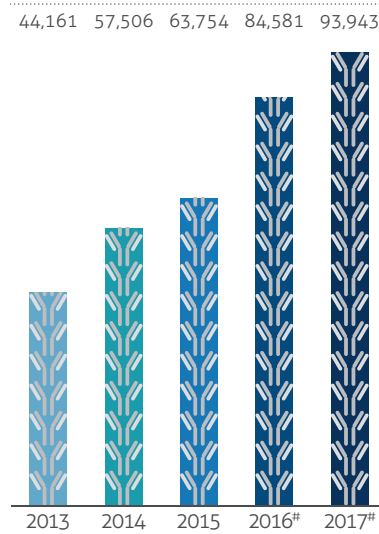
### Debt : Equity

₹ Million



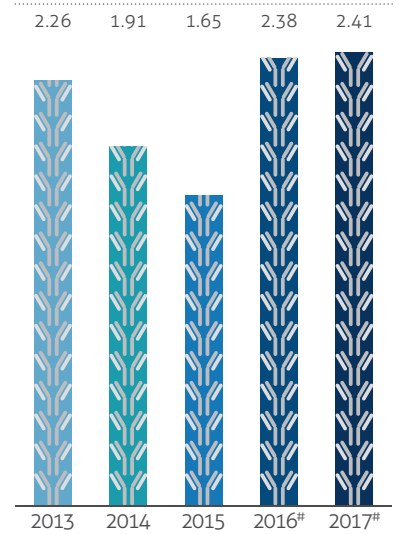
### Total Assets

₹ Million



### Current Ratio

₹ Million



\* Includes exceptional income for the years 2013, 2015, 2016

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

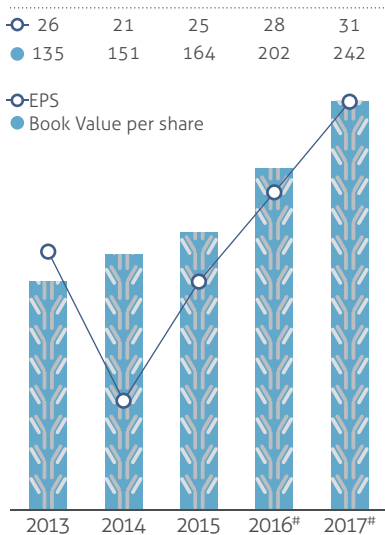
### Net Worth

₹ Million



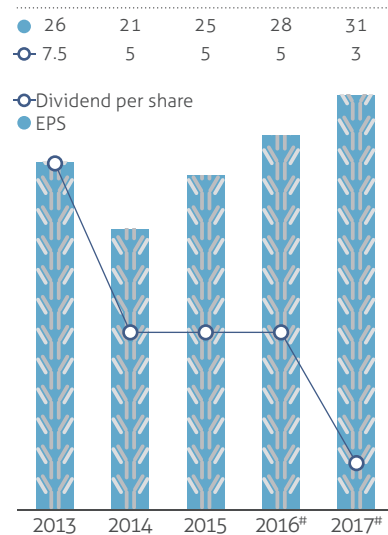
### EPS & Book Value Per Share\*

₹ Million



### EPS & Dividend Per Share\*

₹ Million



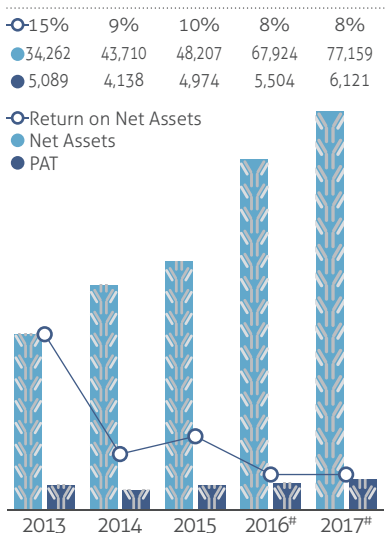
### Gross R&D Spend

₹ Million



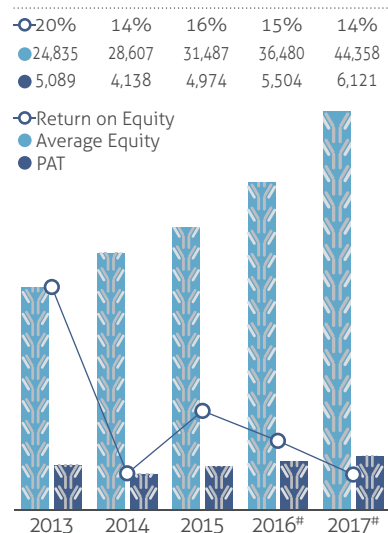
### Return on Net Assets\*

₹ Million



### Return on Net Equity\*

₹ Million



\* Includes exceptional income for the years 2013, 2015, 2016

# 2016 and 2017 figures are as per Ind AS



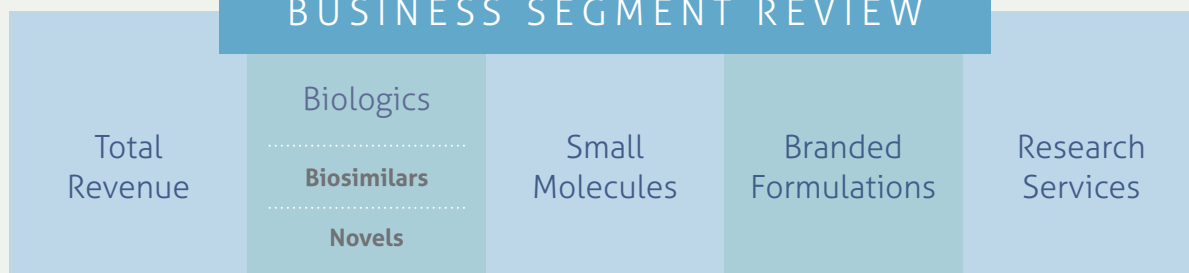
*Sitting from left:*

Suresh Subramanian, *Sr. Vice President & Head - Branded Formulations India*  
Dr. Narendra Chirmule, *Sr. Vice President & Head - R&D and Novel Biologics*

*Standing from left:*

Paul Thomas, *Vice President & Head - Biosimilars - mAbs*  
Prasad B.S.V, *Sr. Vice President & Head - Small Molecules*  
Shreehas Tambe, *Sr. Vice President & Head - Insulins*

## BUSINESS SEGMENT REVIEW



Total Revenue	Biologics Biosimilars Novels	Small Molecules	Branded Formulations	Research Services
18% Growth	43% Growth	12% Growth	24% Growth	7% Growth
₹40,787 million	₹5,793 million	₹16,330 million	₹5,489 million	₹11,604 million

- Biocon's greenfield insulins manufacturing facility in Malaysia commercialized
- Regulatory filings for biosimilar Trastuzumab and Pegfilgrastim accepted for review by the US FDA and the EMA
- HERITAGE study data on biosimilar Trastuzumab published in JAMA
- Progressed on a key clinical study for subcutaneous version of Itolizumab in Australia

- Audits conducted by US FDA, Mexico's COFEPRIS and Korean FDA
- Continued work on the development of niche and margin-accretive API molecules
- Development laboratory for oncology APIs commissioned
- Progressed the construction of Biocon's first oral solid dosage facility

- CANMAB™ featured among the Top 10 oncology brands in the country
- Oral Paper presentation on ALZUMAb™ at International Conference of Psoriasis in the US
- Initiated physician-centric registry programs for ALZUMAb™ and CytoSorb®
- NeoBiocon jumped five places and ranked among the Top 15 pharma companies in the UAE

- Expanded business with two additional Dedicated R&D Centers for Amgen and Herbalife Nutrition
- Expanded capability in bioinformatics through the purchase of assets of Strand Life Sciences related to Systems Biology, Heptox and pharma bioinformatics services

# Biologics



43% Growth

₹5,793 million

Revenue

Biocon's innovation-led strategy is aligned with the global trend of increased use of biologics to address unmet medical needs. As one of the earliest players in the realm of biologics in India, we have created a rich pipeline of novel and biosimilar assets, some of which are available to patients in India and other emerging markets.

Biocon is poised to enter developed markets with its biosimilar products at a time of increasing acceptance of biosimilars. US pharmacy benefit managers (PBMs) have taken steps to exclude originator products from formularies in favour of biosimilars. A group of European regulators has published a paper supporting the appropriateness of switching patients from originator to biosimilar\*, and a study conducted by the Norwegian government\*\* has established further evidence supporting the safety of biosimilar "interchangeability". Scandinavian and other countries have also taken strong national level steps to encourage biosimilar uptake. At the same time, emerging markets are also showing an inclination for wider biosimilars use. The WHO is expected to launch a pilot project for prequalifying biosimilars,

*Source: \*BioDrugs. 2017 Apr;31(2):83-91. doi: 10.1007/s40259-017-0210-0; \*\*The Lancet, Volume 389, Issue 10086, 10-16 June 2017, Pages 2304-2316.*



a step towards making expensive treatments for cancer and other chronic diseases more widely available in low- and middle-income countries.

During FY17, the Biologics segment reported a strong growth of 43% to ₹5,793 million, driven largely by sales of biosimilars, including rh-Insulin, Insulin Glargine and Trastuzumab in global markets. Our Novel Biologics also advanced through their clinical development programs during the year.

## BIOSIMILARS

Biocon has a portfolio of 10 biosimilars spanning insulins, monoclonal antibodies and other recombinant proteins that address critical chronic diseases such as diabetes, cancer and autoimmune disorders, and collectively target a global market opportunity of over USD 60 billion.

## Insulins & Analogs

Biocon is among the Top 3 biosimilar players globally for insulins in terms of volume market share (measured in number of units sold; Source: IMS Year End 2016). The Company has a diversified portfolio spanning recombinant human insulin and long-acting insulin analog Glargine complemented by a comprehensive product presentation across vials, cartridges, disposable and reusable

pens. The business recorded strong double-digit growth during the year led by higher offtake in some of our existing markets and the expansion of our commercial presence to more markets worldwide, including Japan.

Revenue growth in the emerging markets was propelled by robust sales of rh-Insulin cartridges and reusable insulin pens to the Ministry of Health (MoH), Malaysia under the three-year, MYR 300 million contract we won during the year.

Besides Malaysia, we also launched Insulin Glargine and rh-Insulin in some emerging markets in the regions of Latin America, Africa and Middle East.

In Japan, our ready-to-use, pre-filled disposable Insulin Glargine pen has been well accepted by prescribers and patients. We are the second player to have received regulatory approval to sell biosimilar Insulin Glargine in this estimated USD 118 million (Source: IMS Year End 2016) market.

The successful Japan launch has enhanced our credibility to expand our footprint in other developed markets. The European Union, Canada and Australia accepted for review our regulatory submissions for Insulin Glargine co-developed with Mylan. We expect to file our Marketing Authorization Application for Insulin Glargine with the US FDA shortly. These key developments

"As one of the leading global players in insulins, we are committed to deliver affordable diabetes therapy options through our range of basal, rapid and intermediate acting generic insulins. Our insulins portfolio is complemented by high-end, patient-friendly devices that offer 'ease of use' to people with diabetes, resulting in improved compliance to therapy."

*Shreehas Tambe,  
Sr. Vice President & Head - Insulins*

augur well for our Insulin Glargine to address a USD 6.4 billion global market opportunity at current innovator pricing.

The Marketing Authorization Application (MAA) for Insulin Glargine submitted to the European Medicines Agency is the first filing in a developed market that incorporates product validated at our new state-of-the-art Malaysia facility.

Other molecules from our insulin analogs portfolio, Insulin Aspart and Insulin Lispro, are under pre-clinical development.

## Commercialization of Malaysia Insulins Facility

An important milestone during the fiscal was the commercialization of our greenfield insulins manufacturing facility in Malaysia,

one of the largest in Asia. The Malaysian government contract enabled us to start supplying inulin products from this overseas facility in which we have invested nearly USD 250 million.

Our rh-Insulin is Malaysia's first locally manufactured biosimilar product to be approved for commercial sales in the country. Our Insulin Glargine, manufactured in India, has also been approved for sale in Malaysia.

Biocon is distributing its insulin and insulin delivery devices through a leading local pharmaceutical player, which has an extensive supply chain network to service primary healthcare clinics and hospitals across Malaysia.

Our products are enabling the Malaysian government expand access to affordable insulin therapy for the nearly 3.3 million people with diabetes in the Southeast Asian country.

Several regulatory filings and audits are underway at the Malaysian manufacturing facility. We expect the facility to be qualified by a few more emerging markets, which will ramp up commercial sales from the site in FY18.

The unlocking of additional capacity in Malaysia through emerging market approvals would help accelerate our journey of making global impact in

diabetes management through our affordable biosimilar insulins and analogs.

In India, too, we made significant investments in capacity debottlenecking to meet projected demand for both our insulins Drug Substance and Drug Product in emerging markets.

## Monoclonal Antibodies & Other Recombinant Proteins

Biocon and Mylan are co-developing a high-value portfolio of six biosimilar mAbs and recombinant proteins; Trastuzumab, Bevacizumab, Adalimumab, Pegfilgrastim, Etanercept and Filgrastim, targeting chronic diseases such as cancer and a range of autoimmune disorders.

We commenced sales of our biosimilar Trastuzumab in emerging markets in FY16. During the year, we took this product to newer geographies, including some of the larger emerging markets. Trastuzumab boosted the biologics business revenue as well as our licensing income for the year. We continue to seek regulatory approvals for Trastuzumab as we increase our presence in the emerging markets.

### Trastuzumab & Pegfilgrastim

Our regulatory submissions for proposed biosimilar Trastuzumab

and Pegfilgrastim were accepted for review by the US FDA and the EMA, which mark key milestones for the business in FY17.

The global addressable market opportunity for Trastuzumab, indicated for treating HER2-positive breast and gastric cancers, is USD 6.9 billion. For Pegfilgrastim, which is administered to patients undergoing chemotherapy, the market opportunity is USD 4.6 billion.

Biocon and Mylan are the first to file for regulatory approvals of biosimilar Trastuzumab in both the US and EU. The FDA's target action dates for Trastuzumab and Pegfilgrastim are in September and October 2017, respectively, which indicates that we could be one of the first biosimilar entrants for these products in the US and EU markets.

Our regulatory submissions for biosimilar Pegfilgrastim have also been accepted in Australia and Canada.

### Bevacizumab & Adalimumab

In FY17, we completed the emerging market targeted clinical trial for our proposed biosimilar Bevacizumab in metastatic colorectal cancer patients and submitted our Marketing Authorization Application in India.

An additional global Phase III trial in non-small cell lung cancer commenced in late FY17.

The global clinical trial for biosimilar Adalimumab in plaque psoriasis patients is complete. We will begin our regulatory submission after completion of sample data analysis. We expect submissions in various geographies to start in FY18.

### Biocon, Mylan Study Published in JAMA

During the year, the results of the HERITAGE study for biosimilar Trastuzumab were published in the prestigious *Journal of the American Medical Association (JAMA)*, which is the flagship publication of the American Medical Association. This is a significant development considering studies published in *JAMA* are highly respected as they undergo a very rigorous peer review process.

The results of this trial were first presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, US and the European Society for Medical Oncology (ESMO) Congress in Copenhagen, Denmark in 2016. The presentations made by Dr. Hope S. Rugo, the Chair of the Steering Committee for the HERITAGE study, were appreciated immensely by the scientific community.

*JAMA* has recognized the results of the HERITAGE study, which was the last major step of a multi-phased program to demonstrate that Biocon-Mylan's proposed biosimilar Trastuzumab meets the criteria for equivalence in comparison to the reference product when used in

conjunction with chemotherapy on patients being treated for HER2-positive metastatic breast cancer.

"Biocon had a vision to be global leaders in the field of biosimilars several years ago and that is manifesting itself now. With several biosimilar assets on track for anticipated regulatory approvals in developed markets, it's a real tribute to what Team Biocon has been able to accomplish in this complex area, in a relatively short period of time."

Paul Thomas,  
Vice President & Head - Biosimilar-mAbs

## Our Global Generic Insulins & Biosimilars Portfolio

Category	Molecule	Status
Regular Acting Insulin	Recombinant Human Insulin	Pre-clinical (US market). Marketed in Emerging Markets
Long Acting Insulin Analog	Insulin Glargine	Filed in EU, Australia & Canada. US filing in H1 FY18 Marketed in Japan (since July 2016) and Emerging Markets
Rapid Acting Insulin Analog	Insulin Aspart	Pre-clinical
Rapid Acting Insulin Analog	Insulin Lispro	Pre-clinical
Cancer	Trastuzumab	Filed in US, EU. Marketed in Emerging Markets
Autoimmune	Adalimumab	Global Phase III completed
Neutropenia	Pegfilgrastim	Filed in US, EU, Canada & Australia
Cancer	Bevacizumab	India/Emerging Markets Phase III completed. Global Phase III commenced
Neutropenia	Filgrastim	Early development
Autoimmune	Etanercept	Early development



## NOVEL BIOLOGICS

At Biocon, we are developing novel biologics aimed at addressing local as well as global unmet medical needs in the areas of diabetes, autoimmune/ inflammation and oncology. The basket of novel assets under clinical development represents an interesting combination of early and advanced stage assets. Some of these programs are now generating encouraging and exciting data. The ultimate success of these programs will bring transformational growth to our business.

### Insulin Tregopil

Biocon's lead program in diabetes, Insulin Tregopil, is a first-in-class oral insulin molecule for post-prandial glycaemic control. We had announced successful results from the Phase I clinical studies on the drug candidate that had concluded in the US in FY16. These studies established the target product profile of this molecule, including food effects, drug-drug interaction and PK/PD profile. In FY17, we followed up on the positive Phase I data to continue development of this program in

treating both Type 1 and Type 2 diabetes. A pivotal Phase III study for Type 2 diabetes is expected to start in India in FY18. A Clinical Trial Application (CTA) has been filed with the Indian regulator for this study. A multiple ascending dose study in Type 1 diabetes patient population is also planned in FY18 in collaboration with the Juvenile Diabetes Research Foundation. These combined studies in different diabetes populations will form the foundation of a broad global program envisioned for Insulin Tregopil.

## Itolizumab

In the autoimmune / inflammatory diseases space, our novel first-in-class anti-CD6 humanized monoclonal antibody, Itolizumab, is being marketed as ALZUMAb™ for the treatment of chronic plaque psoriasis in India since 2013. Biocon is the first and the only company in the world to clinically validate CD6 as a target for autoimmune diseases.

In FY17, we have progressed on the key clinical studies using a sub-cutaneous version of Itolizumab in Australia, for evaluation in multiple indications. The bridging Phase I PK and safety study in normal healthy volunteers in Australia seeks to evaluate the pharmacokinetics and pharmacodynamics of a sub-cutaneous route of administration of Itolizumab in comparison to intravenous route for which the Company has marketing approval in India. In Stage 1 dosing, the subcutaneous route of administration showed equivalent bioavailability of the drug. We plan to initiate Stage 2 dosing shortly. Understanding of the CD6 pathway being led by scientists in Biocon has the potential for developing novel therapies for patients with immune dysfunctions.

## QPI-1007 (siRNA)

Biocon is the first biopharma

organization in India to have forayed into the exciting space of siRNA-based (small interfering RNA) therapeutics.

In FY17, we made progress on one of the high potential novel assets, QPI-1007. We are developing the asset on the siRNA platform with Quark Pharma for a rare ophthalmology indication. The pivotal global Phase II/III studies for Non-Arteritic Ischemic Optic Neuropathy (NAION) initiated by Quark Pharma in FY17 in the US, now includes patients randomized in India.

## FmAb2 (Fusion Protein)

In Immuno-Oncology, our lead molecule FmAb2 combines a monoclonal antibody against EGFR with TGF Receptor fragment that binds and neutralizes TGF. This fusion antibody, which is currently in pre-clinical development, works on the concept of preferentially delivering immune modulators to tumor site, thus enhancing efficacy and delivering larger doses of TGF to the tumor micro-environment. An IND for this molecule is planned for FY18, and is currently ready with Pharmacology and Mechanism of Action (MoA) established in in-vitro and in-vivo tumor models. It provides us with a potentially broad clinical opportunity in multiple tumor types.

## Anti-CD20

We have a second generation humanized antibody targeting CD20 for which the path to IND has been mapped out and we plan to advance this asset in neuro-inflammatory diseases, e.g. Multiple Sclerosis.

**W**e are developing novel biologics aimed at addressing local as well as global unmet medical needs in the areas of diabetes, autoimmune/ inflammation and oncology."

*Dr. Narendra Chirmule,  
Sr. Vice President & Head - R&D and  
Novel Biologics*

# Small Molecules



12% Growth

₹16,330 million

Revenue

Biocon is one of the leading global suppliers of complex small molecule Active Pharmaceutical Ingredients (APIs) spanning cardiovasculars, anti-obesity agents, immunosuppressants and narrow-spectrum antibiotics / antifungals.

Our unique strengths in fermentation technology and complex chemistry, a successful track record of regulatory

audits and an entrenched presence in the chronic therapies space have made us a preferred partner for pharma customers in India and overseas.

When Lovastatin went off patent in 2001, Biocon was one of the only three companies in the world to get US FDA approval to supply the API for the drug. Since then we have emerged as the world's largest statins manufacturer, with our drug substance being used to produce 'one in every three' statin pills globally. Over the years we have also emerged as a leading player in

complex immunosuppressants.

More recently, our generic formulations strategy hinges on leveraging our strengths in characterization and manufacturing of biologics to build a robust pipeline of difficult-to-make niche formulations for chronic conditions in order to address global needs for affordable therapy.

## APIs

Biocon's ability to stay 'ahead of the curve' placed it among the first wave of suppliers of Rosuvastatin API to its partners. The acquisition of new

customers for our other statins and immunosuppressant APIs helped drive the healthy performance of this business during the year.

Sales of Rosuvastatin API to key customers targeting the US post patent expiry in 2016 were supplemented by a higher offtake of immunosuppressant APIs, especially in the Latin American market.

We maintained the momentum of regulatory filings with 10 Drug Master Files (DMFs) submitted in the US and other key regulated markets.

During the year, we successfully completed audits by the US FDA, Mexico's COFEPRIS and Korean FDA.

Going ahead, the regulatory submissions and the eight approvals that we received for our key APIs in US and EU augur well for this business.

To meet the increase in demand, we expanded capacity of our statins and immunosuppressants during the year.

In our endeavour to expand the small molecule oncology portfolio, our development laboratory for oncology API has been commissioned while the investments towards enhancing our manufacturing capabilities is under progress.

## GENERIC FORMULATIONS

As part of our strategy to sustain long-term growth for the Small Molecules business, we are working on building a robust pipeline of differentiated generic finished dosages for the global markets.

From a commercial perspective, this strategy gives Biocon a competitive advantage as it will enable us to be an integrated player offering both the drug substance and the drug product in niche areas.

This Generic Formulations business obtained its first ANDA approval from the US FDA for Rosuvastatin Calcium tablets in 2016.

We plan to leverage this experience to scale up our regulatory submissions with the US FDA and file more ANDAs. The launch of our generic formulations in the US will add to the profitability of the business, which already enjoys healthy operating margins.

The completion of 'full-cycle' development of generic drug products have positioned us to file for regulatory approvals of five-six molecules every year across emerging markets and developed markets such as US and EU.

We made progress on the construction of our first oral solid dosage facility, which will play an important role in our Generic Formulations strategy. The work on the facility is on track for us to start exhibit batches and various other product qualification activities in FY18.

“As a differentiated APIs player, our focus has been to provide our partners with best in class statins, complex immunosuppressants and specialty molecules, thus enabling their formulations business. We are committed to exploit new opportunities within the small molecules space through a niche portfolio of generic formulations that can enhance access to affordable therapy for chronic diseases.”

Prasad B.S.V.  
Sr. Vice President & Head - Small Molecules

# Branded Formulations



24% Growth

₹5,489 million

Revenue

Biocon's Branded Formulations business was ahead of the curve in anticipating the critical need for affordable therapy for chronic diseases in India and other emerging markets. Accordingly, it prepared itself to address this challenge through differentiated world class biopharmaceuticals and personalized medical support. Over the years, the Branded Formulations business has enabled Biocon to carve out a niche for itself as a biologics-led, specialty pharmaceuticals company.

"Biocon's unique combination of world class products, personalized patient support and physician engagement initiatives have enabled us to make an impact in the therapeutic areas of diabetology, oncology and immunology in India. Focused execution and new launches will enable us to deliver superior results for the Company going forward."

*Suresh Subramanian,  
Sr. Vice President & Head – Branded  
Formulations India*



## INDIA

We have been pioneers in bringing innovative, globally benchmarked biologics to patients in India. Our strategy of 'highest quality at lowest cost' has enabled us to build premium brands in chronic therapeutic areas such as diabetes, cancer, end-stage renal disease, immune disorders and other life-threatening conditions.

Over the years, we extended our presence into niche areas where we saw the potential to moderate costs and widen patient access. We introduced patient-centric initiatives for disease awareness, prevention and management. We partnered with key stakeholders like governments, healthcare professionals and advocacy groups to increase access to lifesaving medicines. We licensed products from global innovators in our core therapeutics areas to bring the latest in therapeutic advances to India. We engaged with physicians through targeted educational programs related to best treatment practices for complex medical conditions. We adopted an evidence-based engagement strategy with Key Opinion Leaders by leveraging the clinical experiences of our novel biologics and biosimilars.

This unique combination of specialty products, patient support and physician engagement programs

have enabled Biocon's brands to assume leadership positions. In FY17, 15 of our brands featured among the Top 3 brands in their respective categories in India. The Top 10 brands in our India portfolio accounted for over 70% of our revenues in the year.

In FY17, we witnessed a significant increase in the prescriptions share for Insugen® and Basalog®, the flagship brands of the Metabolics division. Basalog®, which is ranked as the number two Insulin Glargine brand in India, registered strong double-digit sales growth during the year. Insugen® retained its position among the Top 3 brands of rh-insulin available in India.

BIOMAb EGFR®, CANMAb™, EVERTOR®, and Nufil® from our Oncotherapeutics portfolio featured among the Top 3 brands in their respective categories, continuing to make a significant impact in the realm of cancer care in India.

BIOMAb EGFR®, our novel biologic for head and neck cancer, witnessed more than 1000 new enrollments in FY17. CANMAb™, our biosimilar Trastuzumab brand, has helped treat several thousand HER2-positive metastatic breast cancer patients in India since its launch in 2014. In FY17, CANMAb™ continued to gain traction and featured among the Top 10 oncology brands in the country with a volume market share of nearly

30%. The publication of the results of the HERITAGE trial involving biosimilar Trastuzumab in the *Journal of the American Medical Association* has helped build additional confidence in the product among the medical fraternity in India. We stopped offering Abraxane®, a key in-licensed oncology molecule, to patients in FY17 due to a decision taken by the licensor to discontinue supplies.

TACROGRAF™, a key immunosuppressant brand, reported double-digit growth in FY17. It is the number three Tacrolimus brand in India.

PSORID™, one of our key Immunotherapy brands, continued to be the most prescribed brand of cyclosporine in India.

Our novel biologic ALZUMAb™ (Itolizumab) has made psoriasis management easier for several hundred patients in India since its launch in 2013. In FY17, an oral paper on the role of Itolizumab in psoriasis management was presented at the International Conference of Psoriasis and Skin Specialists Meeting in Dallas, US. Data generated from 155 patients treated with ALZUMAb™ were also accepted for publication in the Indian Dermatology Online Journal. A multi-center, pan-India study has been initiated to identify potential biomarkers for treating subgroups



of chronic plaque psoriasis patients with ALZUMAb™.

CytoSorb®, a 'first-in-class' extracorporeal cytokine filter used to manage a wide range of life-threatening conditions seen in the intensive care unit, underwent a pan-India study to evaluate clinical outcomes when administered in patients suffering from sepsis and septic shock.

We also initiated physician-centric registry programs for ALZUMAb™ and CytoSorb® during the year.

#### **ABIDE Awarded by RSSDI**

In 2012, Biocon had introduced ABIDE, a unique education initiative for medical practitioners who treat diabetes on a regular basis. We conduct a basic course for primary care physicians and an advanced course for consultant physicians and diabetologists. The courses are delivered in a non-commercial setting and offer learning opportunities through 'experience sharing' in small group engagements. The pragmatic and application-

based approach of ABIDE helped physicians improve their practice with enriched patient connect and enhanced clinical outcomes. Since its inception, ABIDE has empowered nearly 3,000 physicians spread across 300 towns/cities across India.

ABIDE was conferred the 'Award of Recognition' by the prestigious Research Society for the Study of Diabetes in India (RSSDI) for its benefits, coverage and impeccable quality of delivery during the 44th Annual Conference of RSSDI held in Hyderabad in 2016.

This recognition from RSSDI, the largest organization for diabetes researchers and healthcare professionals in Asia, is a validation of the positive impact by Biocon to enrich the healthcare ecosystem of India.

#### **UAE**

Our Branded Formulations business in UAE, represented by NeoBiocon, sustained its momentum with a 25% increase in sales\* in FY17,

and jumped five places to be ranked among the Top 15 pharma companies in UAE.

The UAE business is supported by 27 brands and sales are diversified across a portfolio that includes cardiovascular drugs, anti-histamines, proton pump inhibitors and oral anti-diabetics.

Several of our brands are ranked among the Top 3 in their respective therapy segments in the UAE market.

One of our key products Statix (atorvastatin) is the only generic brand to feature among UAE's Top 5 cardiovascular brands, a segment dominated by innovator products.

Jalra® & Jalra®-M, two of the in-licensed innovator brands from Novartis, made significant inroads in the anti-diabetes space since their launch in FY16, positioning us as one of the key players in this segment in UAE.

We strengthened our alliance with Novartis in FY17 through a transaction to in-license the company's second brand of Exforge, a high blood pressure medication, which will be launched shortly.

The launch is expected to strengthen our position in the UAE cardiovascular market, where we currently rank among the Top 10 companies.

*\* Source: IMS FY16 & FY17*

# Global Marketing



Biocon's Global Marketing team has been 'ahead of the curve' in anticipating the growing worldwide need for affordable, high quality drugs to address the increasing burden of non-communicable diseases. We have consistently aligned ourselves to the increasing trend among governments to adopt generic formulations to cut their healthcare spends.

During FY17, 70% of our revenue came from international markets.

While sales in the Asia-Pacific (APAC) and Commonwealth of Independent States (CIS) regions almost doubled over the previous year, our revenue from the Africa, Middle East & Turkey (AFMET) and Latin America (LATAM) regions witnessed strong double-digit growth. We have started executing on our strategic roadmap to enter the Top 10 emerging markets for our insulins and mAbs portfolio through multiple licensing agreements.

## Increasing our Global Biosimilars Footprint

Biocon's expertise in biologics has given it the first-mover advantage for its biosimilars portfolio.

Following the success of Biocon's Insulin Glargine launch in Japan, we made inroads in some of the emerging markets, which positions us for a greater play in addressing a market opportunity of over USD 220 million. We also introduced Brand Insugen in one of the CIS markets, where it is currently the market leader in the generic rh-insulin space.

In the APAC region, we strengthened our position by successfully winning an exclusive Malaysian government contract for the supply of Insugen and also introduced Insulin Glargine.

We also introduced rh-Insulin and Insulin Glargine in some of the LATAM and NAFTA markets during FY17.

Having significantly benefited breast cancer patients in India with our biosimilar Trastuzumab, we increased our product penetration in Algeria thus capturing a dominant market share and also prepared ourselves for market entry through licensing partnerships in some of the LATAM and APAC countries during FY17.

## Widening the Scope of Our Differentiated Small Molecules Portfolio

We scaled up our leadership position in statins and immunosuppressants to enable our partners to launch formulations in the NAFTA, AFMET and LATAM regions.

Biocon emerged among the first wave of suppliers of Rosuvastatin API to its partners for the US market upon patent expiry in 2016. This enabled our partners to capture a double digit share of the Rosuvastatin market. We also experienced a revival of sales for our Fidaxomicin API and increased traction for Tacrolimus API in the US during the year. Our anti-obesity product, Orlistat API, has made significant inroads in emerging markets due to its safety profile and high-end quality.

Another differentiated and complex API product, Glatiramer Acetate, for multiple sclerosis was introduced in a key emerging market of the NAFTA region through our partner.

Over the years, we have built strong global and regional partnerships to provide affordable small molecule and speciality APIs, generic insulins and biosimilars thus giving payers, physicians and patients greater choice of treatment options. In doing

so we have furthered our mission to provide affordable access worldwide to therapies for chronic diseases.

Our ability to make an impact in global markets with a strong portfolio of cutting-edge chronic therapeutics holds the key to unlocking the next level of growth for Biocon. We plan to address these markets through synergistic alliances and a diversified portfolio that reflects a strong orientation towards difficult-to-make small molecule generics and biosimilars."

Ravi Limaye,  
President, Marketing

# Research Services



7% Growth

₹11,604 million

Revenue

Syngene began its journey in the early 1990s as India's first Contract Research Organization (CRO) at a time when the industry in the country was still in its infancy. Over the years it has evolved into an integrated discovery and development service provider for new molecular entities across multiple platforms like small and large molecules, antibody drug conjugates and oligonucleotides. Today, Syngene is the only publicly listed 'pure play' CRO in India.

With a talented pool of over 3,000 scientists and world-class infrastructure spread across more

than 1.3 million sq ft, Syngene is positioned to address a global drug discovery outsourcing market opportunity expected to grow at a compounded annual rate of 7% to USD 29 billion in 2022.

Our Research Services business through Syngene reported a revenue of ₹11,604 million in FY17. On a standalone basis, Syngene's total revenue rose 14% to ₹12,716 million. The growth was broad based across all its three business verticals - Dedicated R&D Centers, Discovery Services and Development & Manufacturing Services.

## Capability Expansion

During the year, the company expanded its business to include two new Dedicated R&D Centers – one each for Amgen and Herbalife Nutrition. With this, Syngene now has five Dedicated R&D Centers including that of BMS, Abbott Nutrition and Baxter.

The growth in business was driven by the addition of new customers as well as the extension of its ongoing collaborations.

The Syngene Amgen Research & Development Center (SARC) will be staffed by a team of more than 100 highly qualified Syngene scientists, who will work closely with Amgen researchers around the world on the discovery and development of innovative medicines. The dedicated nutrition research center set up for Herbalife will develop and formulate world-class nutrition products for Indian consumers that will enable them to lead healthier lives. Syngene also extended its collaboration with Abbott Nutrition till end of CY 2017.

During the year, the company also added new capabilities in bioinformatics by acquiring the assets related to systems biology, heptox and pharma bioinformatics services of Bengaluru-based Strand Life Sciences. The deal also brought onboard a team of highly skilled data scientists who will not only complement Syngene's existing scientific intellectual capabilities but

will also help meet its customers' growing needs for bioinformatics and data analytics support.

A state-of-the art GMP (Good Manufacturing Practices) and GLP (Good Laboratory Practices) compliant Viral Testing facility was also set up to address the needs of several pharma and biotech clients in this area.

As the key R&D programs of a number of Syngene's clients moves into advanced phases of development, it opens up new opportunities for expanding the scope of work. In line with this strategy, Syngene commissioned the first phase of its new formulation facility, which is capable of manufacturing clinical and commercial supplies of small volume niche technology products and complies with regulatory requirements of the US FDA, EMA and other health authorities.

During the year, the company also commissioned the first phase of its Syngene Research Center, spread across 50,000 sq ft. When fully commissioned, the center will have a total area of 200,000 sq ft that will support integrated discovery and development programs.

Syngene's clinical development facility successfully underwent US FDA and EMA audits during the year. The company's commitment to quality and compliance is reflected in its track record of clearing six

US FDA audits without any observations in the last three years.

The company also received environmental clearance for the commercial-scale manufacturing facility that it is setting up in Mangalore to manufacture novel small molecules for innovator companies.

## Fire Incident

In December 2016, there was a fire at one of Syngene's research facilities in Bengaluru. This facility, including office and laboratory space, contributed approximately 20% of its total revenues. The fire was caused due to a chemical reaction being conducted at the facility. There was no injury or loss of life. As a part of its business continuity plan, most of the client-related projects were redeployed to other labs and enhanced shift working was introduced to minimize revenue impact.

**W**e made good progress through the year on our strategic priorities. With Syngene's track record in building successful, long-term relationships with clients, our newly expanded capabilities, world-class scientists and infrastructure, we look forward to accelerating our growth in the coming year."

*Jonathan Hunt,  
Chief Executive Officer - Syngene*

# Enablers



RESEARCH &  
DEVELOPMENT



SUPPLY CHAIN  
MANAGEMENT



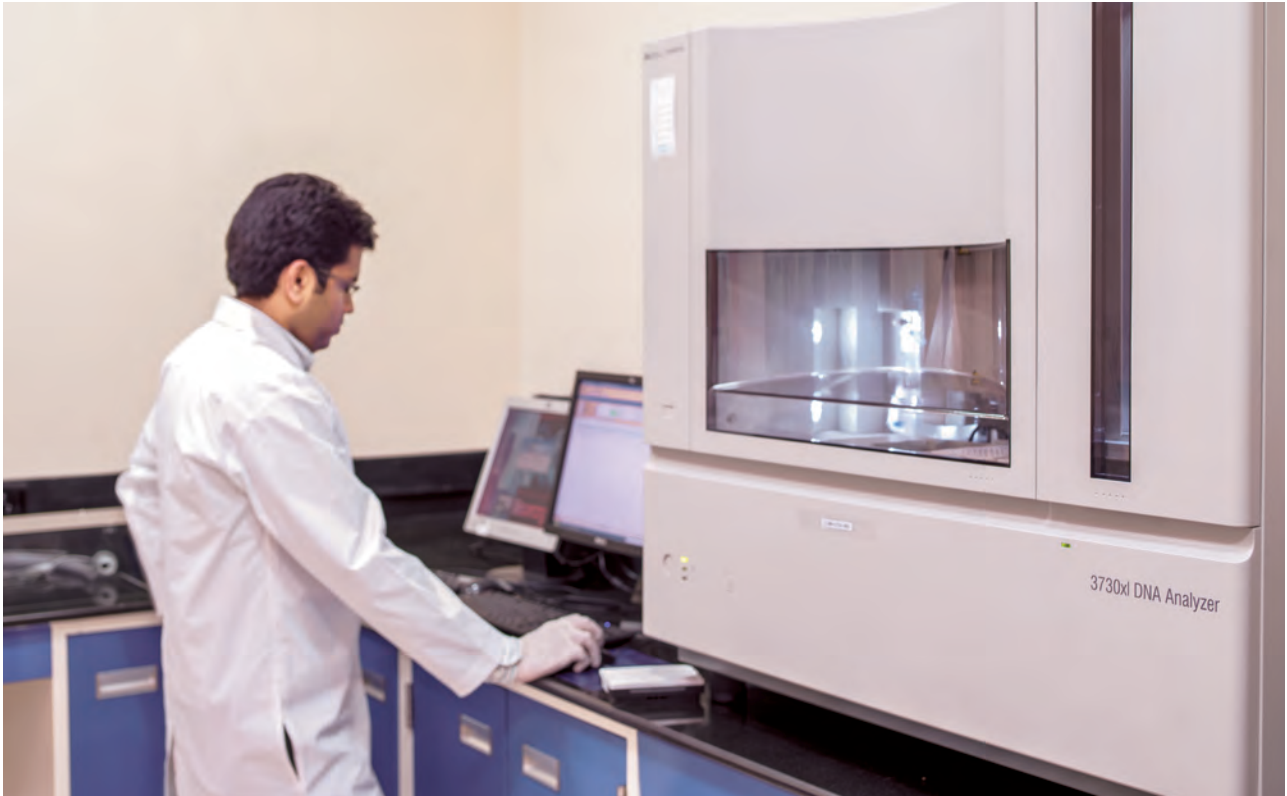
HUMAN  
RESOURCES

ENVIRONMENT,  
HEALTH &  
SAFETY

CORPORATE  
SOCIAL  
RESPONSIBILITY



# Research & Development



At Biocon, R&D is poised to lead the future of biotechnology. With several successful regulatory filings of biologics dossiers in ICH regulated regions, Biocon has established itself as a well-recognized, significant player in drug development. We have led the way in the development of biosimilars and worked at the leading edge of science with top global regulatory agencies such as the US FDA and EMA, exemplified by the first-to-submit biosimilar Trastuzumab (anti-HER2 monoclonal antibody for treatment of breast cancer).

The advent of genomics has heralded the future of therapies for difficult-to-treat human diseases. Biocon is one of the leading players in developing manufacturing and analytical processes for small interfering RNA (siRNA) technology. This unique method of treatment, which interferes with the nuclear machinery of the cell, will enable development of novel molecules to target many diseases with unmet medical needs.

Biocon has leveraged cutting-edge technologies since inception. We

“Research and development forms the bedrock of Biocon’s endeavour to deliver affordable therapeutics globally to address unmet patient needs. Biocon’s unique R&D story is built on world-class competence and capability, robust infrastructure and a talent pool that has extensive global product development experience.”

*Dr. Narendra Chirmule,  
Sr. Vice President & Head - R&D*



were the first to set up a biologics commercial bioreactor in India and today have the country's largest bioreactors developing protein therapeutics. The ability to create global scale has made Biocon one of the top insulin manufacturers in the world. Over time we have established ourselves as India's foremost innovative science and technology driven organization that is constantly working to address the global disease burden.

Biocon R&D has nurtured a pool of highly talented scientists who are experts in their fields, ranging from bioengineering, molecular biology, analytical science, clinical science, regulatory science and intellectual property management. Biocon's reputation has enabled collaborations with leading academic institutions across the world. The combination of high technology, talent, and a culture of deep science at Biocon has the potential to transform the field of biotechnology in the world.

As India's top Biotech Company, our efforts and constant focus on being 'ahead of the curve' have been instrumental in establishing India among the Top 12 biotech destinations of the world and the second in Asia.

### R&D Capabilities & Enablers

Driven by our passion to impact global health, we have built differentiated R&D capabilities over the years in the areas of biologics development, for both novels and biosimilars. We leveraged these capabilities to be among the first to successfully complete submissions of some key biosimilars in several jurisdictions across the world, including the US and EU. Our structured approach to incorporate cutting-edge science and technology in order to deliver our exciting portfolio of biologics has brought us, reliability and credibility, of an innovation-led organization focussed on providing affordable healthcare. The impressive pipeline of approved and in-development biosimilars and novel molecules is testimony to Biocon R&D's vision of being 'ahead of the curve'.

To support the exciting deliverables in our molecule pipeline, the technological enablers and capabilities at R&D have always been our strength. Our excellence in platform technologies spanning, i) Process and Product Development, ii) Analytical and Bioanalytical Capabilities, iii) Pre-clinical and Clinical Development Strengths, iv) Intellectual Property and

v) Regulatory Sciences have helped us position Biocon ahead of many other pharma players in India.

### Process & Product Development

We have expertise in an array of expression platforms that include both microbial & mammalian systems. Biocon's *Pichia pastoris* platform for expression of recombinant protein is our proprietary technology. Our consistent and scalable mammalian CHO and NSO cell-based expression platforms are used to deliver novel and biosimilar monoclonal antibodies while our bacterial host system is utilized for numerous small molecule APIs and peptides.

Our highly robust process sciences significantly augment our ability to develop world-class biologics with economical scalability and high productivity coupled with high quality. The upstream processes involving fermentation technologies and downstream processes for protein purification to develop bulk drug substance have been established for more than a decade. To prepare for the next decade of exponential growth, we are working on improving process efficiencies through novel approaches such as flexible and continuous

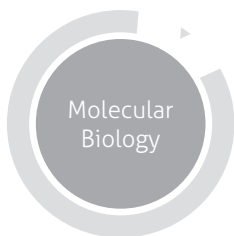
manufacturing. For this, we are working in collaboration with leading academic institutions such as the Indian Institutes of Technology (IIT) and National Institute for Pharmaceutical Educational and Research (NIPER) in India as well as Harvard University, Massachusetts Institute of Technology (MIT) and several reputed international universities. Our analytical capability, which is anchored in cutting-edge tools, latest orthogonal approaches and world class technology, ensure

the high quality and consistency of our products. Learning from our extensive regulatory interactions in previous years, we have evolved our process development. This process has resulted in exponential improvements and being 'ahead of the curve' for future processes.

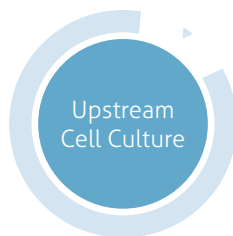
Formulation & Product Science is an essential part of the drug development process of biologics and biosimilars, where the bulk drug substance is converted into

a formulation and transferred into vials and cartridges to make a drug product. This process requires extensive science, complex technology, and understanding of protein structures, product stability and extractable/leachables studies. Our expertise in Formulation & Product Science has enabled us to manufacture high quality drug products for patients worldwide.

## Biological Process Sciences



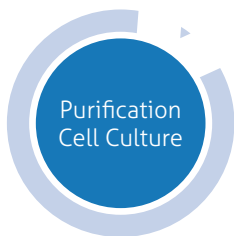
Development of recombinant clones; Gene knockouts; PCR based analytical methods



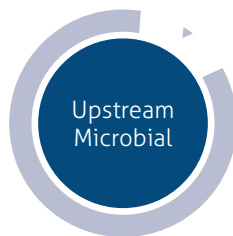
Process development and scale-up of perfusion and Fed batch technologies; Control of post translational modifications in cell culture



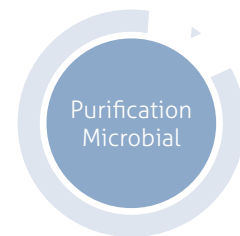
Development and scale-up of liquid, suspension, high concentration and lyophilized formulation



Development of purification processes to match characteristics of biosimilar proteins



Process development and scale-up: bacteria, fungi and yeast, primary or secondary metabolites and recombinant protein and peptides fermentation



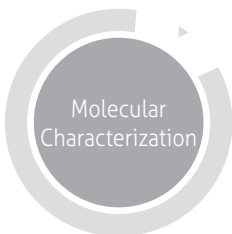
Scaling up high pressure chromatography in large columns

### Analytical & Bioanalytical Sciences

We have been a pioneer in process and product development, which, in turn, is a result of Biocon’s state-of-the-art equipment and deep technical expertise with nearly 20 years of experience in Analytical and Bioanalytical Sciences. Physicochemical and functional analytical technologies are the key components of the process and product. These analytical tools are applied for in-process as well as finished drug substance and drug product analyses. Additionally, a major percentage of these methods are routed towards the quality groups in manufacturing to be utilized as product release assays.



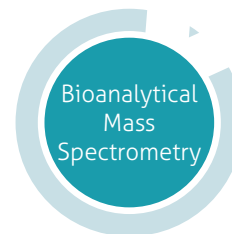
### Analytical Sciences & Characterization



Characterization of proteins, small molecules, N-linked and O-linked glycosylation and glycations, post translation modifications; Identification and characterization of low abundance impurities



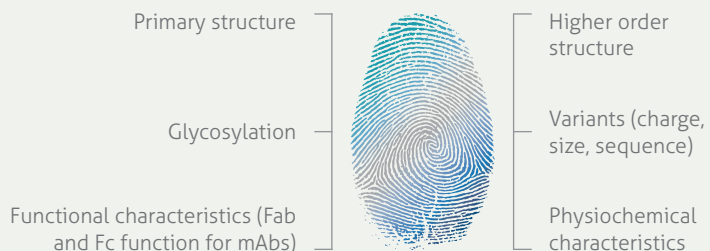
Method development for peptides and for quality control; Expertise in method development for showing clearance of process related impurities



Development of methods for quantifying peptides and small molecules from biological fluids

### Establishing Similarity through Analytics

Our R&D strength in biosimilar and biologics development is focused on a strategic QbD driven approach, orthogonal techniques and fingerprint similarity.



## Drug Discovery & Preclinical Sciences

Selecting the right molecule for clinical development is prerequisite to drug development and successful regulatory approval.

We have been able to achieve relevant pharmacokinetic and pharmacodynamic endpoints and establish the safety and efficacy of our products, courtesy our scientifically rigorous, ethically compliant and stage gate-based

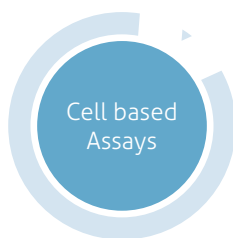
structure. Moreover, we are introducing innovative ways of predictive toxicology and adaptive clinical trial designs. Hopefully, it would significantly reduce costs and increase the quality of our trials in the future.

## Translational Research & Development Sciences



Bioanalytical

Development, qualification and valuation of PK and immunogenicity measures using ELISA and MSD formats; Cell based potency assays for neutralizing antibody determination



Cell based Assays

Potency assays for insulins, peptides, mAb and mAb conjugates



Binding Assays

Development and validation using BIACORE, radioligand binding and flow cytometry



In-Vivo Pharmacology

'Mechanism of Action' (MOA) studies; Development of In-Vitro assays; 'Proof of Concept' animal model studies in diabetes, autoimmune diseases and oncology



Toxicology

Protocol development for GLP and non-GLP studies; Evaluation of histopathology of animal tissues; Interpretation of PK, PD and IHC in pre-clinical and clinical samples



Drug Discovery and Preclinical

MOA, PK-PD; clinical PD and patient selection markers and assays; Enable pharmacodynamic and response biomarkers; Development of companion diagnostics

## Intellectual Property

Biocon understands the importance of IP in the biopharmaceutical sector. IP assumes a much greater significance as it guides the R&D and commercialization strategy of the company that enables protection of inventions and innovations. It also helps build credibility while enabling a first mover advantage in many cases. IP also enables product positioning, lifecycle management as well as asset monetization and valuation. Biocon R&D has consistently created intellectual wealth through an incisive IP strategy that recognizes the innovative potential of our products and processes. Till date we have filed nearly 1,300 patent applications and hold over 1,050 patents and 555 trademark registrations globally. The IP team has brought recognition for Biocon through various awards. Biocon was the only Indian Biopharma Company to make it to the prestigious Asia IP Elite List, 2016. We were also awarded the 9th National IP Award for 2017 in the category 'Top Indian Company for creating Global Brand' along with the prestigious WIPO Users Trophy.

## Regulatory Sciences

The Regulatory Sciences team has a large number of talented individuals who are the interface between the company and regulators. Understanding the guidelines, rules

and processes of each country is a formidable task. Drug regulators from the US (FDA), European Union (EMA), Australia (TGA), Canada (Health Canada), Brazil (ANVISA), Japan (PMDA), etc. have unique country specific processes which have to be followed mandatorily. With patents expiring on novel biologics, several countries have articulated their guidelines for ensuring biosimilarity. The field is evolving with new regulatory submissions and industry players, regulators, payers, physicians, pharmacists are learning from each other. Biocon's R&D regulatory team is playing a key role in this knowledge exchange and the evolution of the regulatory pathway for establishing comparability, interchangeability and extrapolation of indications among biosimilars.

Strong regulatory capabilities in R&D coupled with a focused team effort resulted in us being the 'first to file' a proposed biosimilar Trastuzumab with the US FDA & EMA. Our regulatory filing for two key biosimilar mAbs, Trastuzumab and Pegfilgrastim, are being reviewed by the US FDA and EMA. Insulin Glargine is under review in Europe. The launch of our Insulin Glargine in Japan has been a major milestone since the country is reputed as a stringent, highly regulated market.

## The Scientific Culture of R&D

The culture of science is in our DNA. We have always valued and cherished our role in being part of a rich scientific ecosystem. At R&D, our employees have access to special clubs for statistics and medical writing, a forum to access international journals and journal



clubs. Our focus on the learning curve has put us 'ahead of the curve'.

### Collaborations

Biocon believes in the strength of strategic partnerships and has invested in various partnerships with global pharma companies like Mylan and Quark Pharma for several projects. Since it is imperative to collaborate with academia and government institutions, Biocon R&D lays a lot of emphasis on establishing relationships with national and international institutions. These collaborations include those with the Trinity College, Ireland, Queensland Institute of Medical Research, Australia and the Indian Institutes of Technology, among others. The scope of collaborative research includes process development, preclinical animal models, exploratory biomarker studies, and fundamental science research projects. These collaborations that happen at different levels are critical to the growth of a robust R&D organization.

## QUALITY

Excellence through Quality and Compliance is at the essence of Biocon's strategy to be 'ahead of the curve'. We rigorously follow Good Manufacturing Practice, Good Laboratory Practice and Good Documentation Practice throughout our operations with no compromise on compliance, which in turn ensures the highest standards of quality at all times.

During FY17, Biocon's manufacturing sites underwent several regulatory inspections by agencies of different countries across the world as a part of the new product approval process and verification of compliance.

Our strong regulatory, quality and manufacturing capabilities have ensured continued global acceptance of our complex small molecules and biosimilar products. The successful conclusion of regulatory audits of our Biologics Drug Substance and Drug Products manufacturing sites has facilitated

product approvals and launches in most of the countries. Our manufacturing facilities for Small Molecule APIs also underwent a number of regulatory audits, including inspection by the US FDA.

During FY17 we underwent more than 10 international regulatory audits to receive respective cGMP approvals. Some of the agencies that approved our sites include ANVISA (Brazil), COFEPRIS (Mexico), MCC (South Africa), Ministry of Industry and Trade (Russian Federation), NPRA (Malaysia) and Ministry of Health, Ukraine.

We expect to see an increase in regulatory inspections on account of new product submissions as well as periodic verification of GMP compliance by agencies in the jurisdictions we supply to. The Quality team is fully geared to meet the intensified quality scrutiny and address the increasingly demanding benchmarks of regulatory agencies from around the globe.



# Supply Chain Management



The Supply Chain Management (SCM) function has put Biocon 'ahead of the curve' by focusing on operational excellence in a space characterized by complex manufacturing processes and stringent regulatory norms. We have built global scale, end-to-end supply chain processes encompassing multiple business verticals, several manufacturing locations and a diverse product portfolio. Meticulous planning, smart sourcing and disciplined monitoring have enabled us to ensure 'on-time' delivery to our customers in over 100 countries.

During the year, the SCM function enabled us to build on our reputation of being a trusted partner to global pharmaceutical companies that rely on our APIs for their formulations. SCM enabled the successful foray of our biologic products into several emerging markets.

### Strengthening SCM Practices

The SCM function focused on building regulatory compliant systems and processes to meet the demands imposed on the supply chain by the increased global

demand for Biocon's biologic products. We also partnered with established global logistic companies to meet the need for effective cold chain systems that ensure shipment safety.

We have created a dedicated logistics team to ensure business readiness for new markets. This enabled us to have shipping channels ready ahead of business initiation in some of the new key markets.

In FY17, we initiated implementation of the C-TPAT (Customs - Trade

## FUNCTIONAL IMPERATIVES

### Strategic

- Leverage supplier positions and global reach to create competitive advantage
- Develop suppliers in new strategic regions
- Lead industry in best-in-class practices
- Focus on supply assurance mapping for critical materials

### Financial

- Cost management initiatives
- Predict market price trends
- Build-up of strategic inventory to address price fluctuations
- Price benchmarking strategies for key cost drivers

### Operational

- Cultivate dynamic planning capabilities to enhance performance
- Reduce transactional complexity
- Identify scope for improvement and extend supplier performance to meet customer satisfaction
- Focus on green initiatives
- Integrated Malaysia on uniform sourcing and operations platform

### Training and Development

- Promote employee engagement
- Encourage disruptive ideas
- Identify and meet training needs for employees
- Certificate programs for high performing employees
- Inclusive talent pool in Malaysia maintaining diversity

Partnership Against Terrorism) guidelines published by the US Customs & Border Protection to ensure that we are aligned with enhanced drug supply security requirements in the key US market. This will simplify logistics procedures and help Biocon obtain

priority Customs clearance.

In Malaysia, we have made good progress in tying up with local vendors. This has helped reduce logistical challenges as well as bridge socio-cultural differences.

To address the rising market diversity

and increased complexity of logistics requirements, we implemented a system of checks and balances in the areas of packaging sustainability, terrain-specific transportation modes, material safety, and delivery efficiencies.



We have also ensured seamless operations for our key products using best in class logistics service providers and packaging vendors. Warehouse facility consolidation at one of our sites has helped enhance capacity by 20% to better align with business requirements.

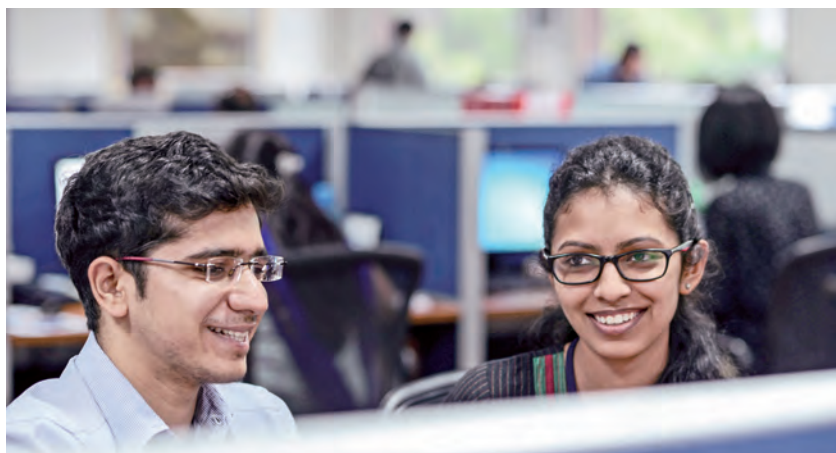
### Functioning with Responsibility

While there is single-minded focus on achieving business goals and targets, Biocon's SCM maintains high levels of ethics, integrity and process orientation. This has enabled us to maintain a spotless record of meeting mandatory compliance levels for our processes during internal and external audits. During the year, the warehouse team supported and facilitated about 30 facility audits, including by the US FDA and EMA, which were completed without any critical observations.

We are also working on continuously improving our operations through Six Sigma practices to ensure better working conditions and improved safety standards.

### Sustainable Sourcing Initiatives

The creation of a stable sourcing platform is critical for our biologics portfolio and SCM has taken steps to ensure long-term supply sustainability in this space. Some of the initiatives we have taken include:



#### i. Sourcing & Vendor Consolidation

To reduce multiplicity of transactions and minimize operational loads we have consolidated vendors for all our plants in Bengaluru. This has also helped in better planning and effective negotiations.

#### ii. Green Supply Chain

Moving from an animal-origin to a recombinant supply base for some of our key products have contributed significantly to our efforts of ensuring an eco-friendly supply chain. Our sourcing team is also focusing on use of 'green solvents' e.g., ethanol at a majority of our business units, thereby reducing our dependence on non-renewable forms of energy. By consolidating vendors for solvents deliveries, we have reduced the fuel cost per unit of solvents consumed at Biocon.

#### iii. Periodic Vendor Evaluation

Biocon has developed a process to periodically evaluate its vendors for all critical materials on the basis of selected metrics.

### Contributing to the Local Economy

Biocon has always strived to create a strong local ecosystem by procuring goods and availing of services from small and medium size vendors based around its manufacturing locations. About 15-20% of our total supplier base are small and medium enterprises. Local sourcing capabilities earn us multiple benefits in terms of shorter turn-around times for delivery and quicker resolution of issues pertaining to material quality. In return, we help these vendors plan long term capacity by sharing forecasts for up to 12 months. In contributing to the local economy we also enhance the sustainability of our own operations.

## GLOBAL SOURCING FRAMEWORK

**Strategic Sourcing**  
 Sourcing processes and compliance  
 -----  
 Cost management and alignment to budgetary constraints  
 -----  
 Cross-functional interface to address long-term supply risks and sourcing constraints  
 Org level - procurement - data analytics  
 -----  
 Identify and mitigate sourcing risks

**Procurement Ops**  
 Execution and operational discipline  
 -----  
 Securing logistics and timely delivery  
 -----  
 Coordinating and supporting global vendor development plans  
 -----  
 Monthly procurement review  
 -----  
 Integrated planning and procurement for operational dynamism

**Vendor Risk Mitigation**  
 Dedicated teams created for managing sourcing risks in Drug Substance & Drug Product  
 -----  
 Geographic risks mapped into vendor development platforms  
 -----  
 Supply assurance and vendor sustainability evaluations built-in  
 -----  
 Cross-functional teams activated to review progress on risk-mitigation activities  
 -----  
 Top of the house risks mapped at corporate level

*Continuous improvement programs through review of performance and compliance*

### Awards

Biocon was conferred with awards for 'Overall Excellence in Procurement & Sourcing' and 'Excellence in Procurement Transformation' at the CPO Forum India.



A YOUNG DYNAMIC WORKFORCE PUSHING THE ENVELOP TO KEEP BIOCON 'AHEAD OF THE CURVE'



# Human Resources



At Biocon, our innovative spirit puts us ahead of our competitors. We believe in employing and fostering the best talent as we believe they are vital to the health of our company. Over the years, we have attracted some of the brightest minds who have challenged the status quo and pushed the boundaries of science to develop affordable therapies that can impact global health. Their skills have helped transform goals into realities, create new models for success and sustain high levels of growth. Through our work culture of unconventional thinking, focus

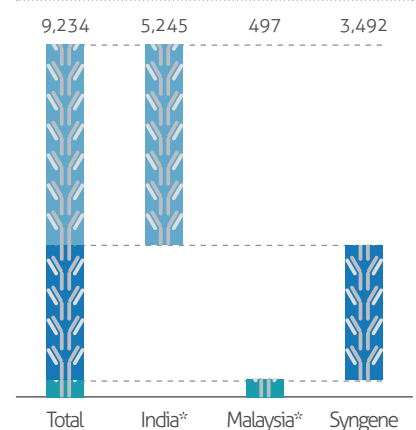
on excellence and high degree of empowerment, we have instilled confidence and a high sense of ownership in our people, which has driven them to make a difference.

These qualities have led to us being recognized among the Top 10 Global Biotech Employers. An annual survey conducted by *Science / Science Careers* magazine ranked us at No. 9 in 2016 up from No. 13 the previous year. We have the distinction of being the only company from Asia to feature on this prestigious list.

In the past 12 months, the HR team has played a significant role

in helping bring some of our key projects closer to realization.

## Global Employee Base



\* Biocon

As on March 2017

### Attracting Talent

During the year, we used social media extensively to attract the best talent from today's tech-savvy generation. We now hold the highest talent brand index on LinkedIn amongst peers, making us the employer of choice. Following the digital integration of our recruitment tools we have been receiving over 2,500 applications per month through LinkedIn. Social media platforms have enabled us to target talent groups at almost zero cost.

Biocon's positioning as a 'world-class employer brand' enabled us to recruit top talent from some of the country's premier institutes. Several candidates from Indian School of Business accepted Biocon's offer on priority during the campus recruitment.

In FY17, we increased our hiring by 30% over the last fiscal. Within the pool of new hires there was a 65% rise in senior-level appointments. To increase workplace diversity, we also recruited from countries like US, Hong Kong, UAE, Germany, and Malaysia.

We modified our internship program this year to target young and promising life sciences talent in international universities. In addition to various Indian academic institutes such as NIPER and IIT, we offered internships to students from the University College Cork (Ireland), University of Glasgow, Imperial College, London, University of California, San Diego, University of Melbourne, and University of Queensland. From among the 650 candidates who interned with us, we offered jobs to nearly 150 in FY17.

Biocon is well-recognized among the top global biotech employers and is highly regarded by the scientific community in the US and Europe. Our performance driven work culture encourages unconventional thinking, incubation of exciting new ideas and the pursuit of excellence, making Biocon an innovation-led organization that is comparable to the best in the world."

*Amitava Saha,  
Sr. Vice President & Head - HR*

### Learning & Development

Learning & Development plays a critical role in a knowledge-driven organization like Biocon. ISURGE, our leadership development program, implemented several initiatives around Business Excellence and Interpersonal Excellence designed

to manage and lead change. Several employees underwent this focussed group training program during the year.

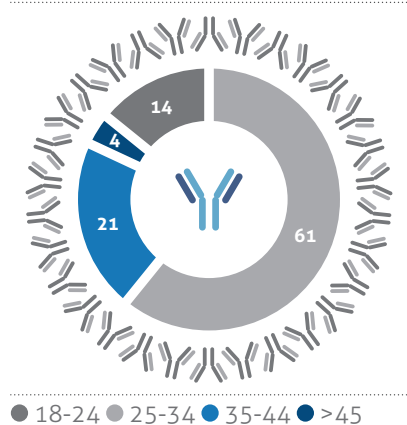
BioWin – ISURGE, our women's leadership program, also conducted a focussed workshop for several women leaders.

In addition to these programs, close to 3,000 employees attended various training programs organized by the Learning & Development team. Over 30,000 learning people hours were clocked during the year.

## A Young Organization

Biocon has been the preferred destination of young aspiring biotech professionals, a fact which is reflected in the age profiles of our employees. Almost half the size of our human capital is under 34 years, which makes Biocon an incubator for exciting new ideas.

### Employees' Age Profile



## Employee Engagement Initiatives

The Employee Engagement Initiatives during the year were aimed at motivating our employees to give their best and stay committed to the organizational goals and values with an enhanced sense of their own well-being.

Apart from our regular employee engagement activities this year, we conducted customized programs aimed at addressing 'early burnout' and 'healthy living' through our wellness initiative - BioPulse. As an extension to our annual health

check-up practice we introduced free thyroid health check-up for the women employees.

With an intent to provide employees a platform to pursue their interests beyond work and connect with like-minded people, we launched the Biocon Adventure and Sports Club (BASC). Various events were ideated and executed by employees which received a good response across the organization.

Invivo 2016, the Annual Day celebrations of Biocon and Syngene, was marked with great fanfare. In the run-up to Invivo 2016, several events were conducted for employees to showcase their talent. Over 250 employees were felicitated for long service while several others were recognized for their valuable contributions to the organization.

## Biocon Malaysia: Growing in Strength

Biocon Malaysia's manpower strength has gone up by 12% to nearly 500 employees in the last year. Learning initiatives have been intensified and we are leveraging Biocon Academy programs to address specific technical and functional training needs.

Through Biocon Malaysia we are also making a significant contribution to build the biotechnology industry ecosystem in the Southeast Asian nation. Three senior leaders from

Biocon Malaysia have joined the industry-academia panel of the Universiti Teknologi Malaysia (UTM) and Universiti Kebangsaan Malaysia (UKM). These industry-academia collaborations enable universities to tailor their curriculum to emerging industry trends and talent requirements. Industrial visits to our new integrated insulins manufacturing facility in Malaysia by students from several public and private Malaysian universities provided them with practical insights into the working of the biopharmaceutical industry.

## Effective Performance Management

Our robust performance management program is designed to encourage and reward talent that harmonizes achievement of organizational goals with personal aspirations and milestones. Our comprehensive talent management framework identifies and develops critical talent crucial to Biocon's growth strategy.

## Awards

Biocon was recognized for 'Best Corporate HR Practices' at the NHRD for its comprehensive talent management framework. The company was also felicitated at the World HRD Congress 2016 for Excellence in Human Resource Management.

# Environment, Health & Safety



For Biocon, staying 'ahead of the curve' extends beyond business to adopting the best global practices in Environment, Health and Safety (EHS). Our comprehensive governance systems are bolstered by best-in-class infrastructure, specialized EHS systems, competent teams and comprehensive programs.

Sustainable thinking is the cornerstone of corporate responsibility at Biocon. It has helped us move beyond statutory compliances to create responsible business practices that guarantee environmental sustainability. Health

and safety are integral parts of a broader environment and the core of our leadership decision process is focused on providing a safe and healthy work environment at Biocon. A single-minded pursuit of this philosophy has ensured that there were no reportable incidents at Biocon during the year under review.

## EHS Management Systems

As a responsible corporate organization, we have established a best in class environment management system to minimize our ecological footprint. In FY17, Biocon

received ISO 14001:2015 & OHSAS 18001:2007 accreditation from TÜV NORD after a successful transition from the earlier 2004 standard. In line with the new Globally Harmonized System (GHS) of Hazard Communication, we have migrated to Safety Data Sheet (SDS).

## EHS Risk Assessment

Our EHS Risk Assessment programs methodically detect and evaluate risks on various parameters ranging from effects on full organization to potential impacts on individual employees. It also helps efficiently

prioritize risks and determine the best ways to remove, transfer, or mitigate those risks. Based on this assessment, we define and document the EHS roles and responsibilities for all employees at each operating facility. In FY17, we conducted comprehensive enterprise risk assessments for all blocks in addition to evaluations in line with business continuity management.

### EHS Training

Our EHS training program emphasizes on safety practices and enables our employees to identify and mitigate workplace safety hazards to ensure zero reportable incidents. During FY17, over 12,000 person hours were invested in EHS training.

Our employees actively participated in several external training programs covering safety aspects in the pharmaceutical industry, prevention of dust explosions, and best practices for storage and transportation of hazardous chemicals onsite. We also organized a lead auditor and internal auditor training for ISO 14001:2015 as well as a symposium on 'Leadership in Safety Management'.

Additionally, we steered various activities and events across Biocon facilities to mark National Safety Week, Fire Service Week and Chemical Disaster Prevention Week.

### Industrial Hygiene Management

We are committed to industrial hygiene excellence, aligning our practices with global standards and strengthening them further. As a part of our new 'Biocon - Integrated Industrial Hygiene Systems Implementation' initiative we carried out product-wise industrial hygiene studies and exposure reduction drives. We also upgraded our existing sewage treatment unit with new bioremediation technology. Further, we introduced DSPA (Dry Sprinkler Powder Aerosol) fire suppression systems in the chemical synthesis blocks.

### Energy Conservation

Our energy conservation initiatives helped us restrict the rise in energy consumption to 10% despite a nearly 20% Y-o-Y growth in business in FY17. The identification of low cost power sources and optimization

of resources have yielded significant cost savings during the year.

In Biocon, we believe that small steps can yield big results. We achieved power savings of 32,900 kW-h in the year through the installation of IE3 motors, switching to LED lights, improving efficiency of filter press and reduction of operation hours. Our project to reduce chemical consumption for effluent treatment led to cost savings during the year.

With multiple plants operating simultaneously round the year it is imperative that we effectively manage our environmental impact and find ways to reduce our carbon footprint. We successfully cut carbon dioxide emissions by 36,000 tons during the year by sourcing 44 million units of green power. Today, green power accounts for 28% of our total energy consumption.





## Awards and Recognitions

During FY17, we received recognitions at the state and national levels for our progressive EHS practices and initiatives. These included:

First prize in 'Best Fuel Efficient Industrial Boiler' category for adopting best safe practices by the Karnataka State Safety Institute.

'4-Star' Rating for EHS Best Practices by the Confederation of Indian Industry.



## Biocon Volunteers to Revive Hebbagodi Lake

Biocon has taken the initiative to contribute to the Lake revival mission of Bengaluru. Biocon Foundation took the lead to sign an Expression of Interest (EOI) for the rejuvenation of Hebbagodi Lake at the 'Bring Back the Lakes' workshop organized by Karnataka Lake Conservation and Development Authority (KLCDA). A detailed project report has been submitted and our teams have been working closely with KLCDA and other relevant administrative bodies like the District Commissioner (Govt. Of Karnataka) and Hebbagodi City Municipal Corporation (CMC) to obtain necessary approvals for implementing the detailed lake revival plan.

Meanwhile, Biocon has cleaned up the area, removed debris and weeds in and around the lake including

dense vegetation in the lake which had resulted in the shrinking of the waterbody. Water inlets have been cleaned and covered and screens included to prevent debris from being washed into the lake. Land has been cleared to make place for children's playground, fencing of the cleared stretch has been undertaken and information board and streetlights have been installed.

As a result of these efforts the water catchment area has grown and we have seen some of the birds return to their habitat. This motivates us to push other stakeholders to enable the full-fledged lake revival plan for Hebbagodi.

We have also engaged with the local communities to sensitize them on the importance of water bodies and their role in preserving them with their best civic behaviour. It is critical for the local community to play an active role in lake conservation and revival.

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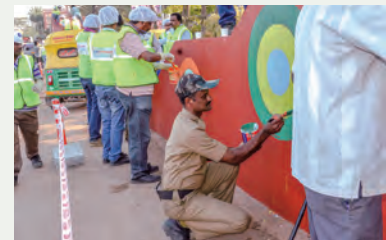


## Community Programs: The Team of Hope

Biocon accords high importance to the health and safety of its stakeholders including its neighboring communities. In FY17, Biocon employees came together under the aegis of Namma Biocommunity, a community connect initiative of Biocon to make a difference to people's lives in urban and rural areas with a focus on ensuring a clean, green, and safe environment.

A 40 member strong team of Biocon volunteers, both men and women, spearheaded several drives during the year to clean up and renovate a number of underpasses around Hosur Road, Hebbagodi, Huskur, Hennagara, Bommasandra etc. which were in a very poor state thus making it impossible for use by public, which added to their safety hazard. Namma Biocommunity encouraged pedestrians in the area to use the underpass to avert road accidents.

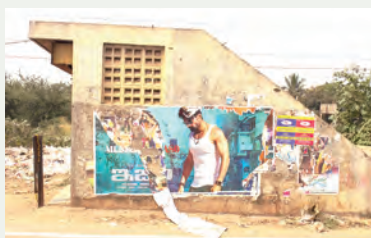
Namma Biocommunity volunteers also helped renovate the Government High School in the neighboring area and encouraged the community to participate in the tree plantation drive.



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# Corporate Social Responsibility



## Biocon Foundation

Biocon Foundation, the CSR arm of Biocon, has been engaged in developing innovative solutions to address critical gaps in healthcare, education and sanitation to make an enduring impact amongst the marginalized communities in India. Through its various initiatives the Foundation aims at empowering and integrating the underprivileged into the social and economic mainstream.

## Healthcare

Our public health initiatives have been successful in providing

sustainable solutions in the area of basic health and addressing the burden of chronic diseases like cancer, diabetes and hypertension.

Given our propensity to stay 'ahead of the curve', we extensively leveraged information & communication technology to develop a unique e-healthcare model in 2015 to bring healthcare services to the doorsteps of those who need them the most. We designed the eLAJ Smart Clinics to strengthen primary healthcare delivery in India by converting Primary Health Centers (PHCs) into a comprehensive single-point

treatment centre with systematic documentation of patient data.

### eLAJ Smart Clinics

eLAJ clinics are technology-enabled, smart clinics equipped with multi-parameter monitoring device, which enables multiple diagnostic tests and generation of Electronic Medical Records (EMRs) of patients. The eLAJ model has been designed to deliver data-based healthcare on the basis of socio-demographic and health indicators obtained from community-based screenings. This innovative health delivery model is facilitating effective preventive



and primary healthcare intervention in the rural areas of Karnataka and Rajasthan for the benefit of communities with poor access to quality healthcare.

These clinics are staffed with doctors, technicians and pharmacists who are trained to handle state-of-the-art diagnostic equipment and clinic management

software, all connected to a secure server. The introduction of the eLAJ model in PHCs can provide access to affordable healthcare services in remote rural areas.

The diagnostic centre in an eLAJ Smart Clinic can perform up to 50 tests and results are available in under an hour. Patient records are digitized and stored on a central

secure server. The eLAJ EMR system is mapped to a unique ID to ensure continuum of care.

By providing clinical consultation and essential diagnostic services at fair prices to all patients, eLAJ clinics reduce out-of-pocket expenses. Improved diagnostics at the eLAJ clinic also reduce the burden on the tertiary hospitals

## Objectives of eLAJ



Continuum of care



Quality of healthcare



Monitor disease profile and trigger alerts in case of disease outbreaks



Protocols for care delivery are followed



Examine prevalence of risk factors to initiate preventive health education



Generation of reports for stakeholders at different levels

## Biocon's eLAJ Model is Addressing Gaps in Public Health Delivery in India

### Infrastructure

Improving and upgrading infrastructure of PHCs.

Renovating toilets & labor rooms.

Installing diagnostic centres in each PHC.

Providing laptops to each PHC for proper documentation.

### Staffing

Recruiting doctors, auxiliary nurse midwives (ANMs), general nurse midwives (GNMS), data entry operators, pharmacists, lab technicians & other support staff.

Ensuring that all the vacancies are filled.

Ensuring that PHCs are running as per Indian Public Health Standards (IPHS) norms on staffing.

### Training and Capacity Building

Training lab technicians to use semi-automatic lab devices.

Training data entry operators to collect health information efficiently.

Training ANMs and health workers in data collection, immunization and antenatal check-ups.

### Electronic Medical Records

Patient records digitized and mapped to a unique ID to ensure continuum of care.

Secure server stores data and patient privacy is maintained.

Multi-parameter monitors installed to record vitals.

Three interconnected modules: Registration, Clinical Consultation & Diagnostics.

Dashboard to capture data on disease profile of a community.

Notifications to help tackle seasonal disease outbreaks.

Dashboards ensure follow-up and disease surveillance of the patients.

### Quality of Care

Ensured that the IPHS norms related to infrastructure, manpower and facilities are followed.

Upgraded labor rooms to ensure institutional deliveries.

Ensured proper power back-up and water supply.

Provided laptops for Pregnancy, Child Tracking and Health Services Management System (PCTS) data entry.

Ensured Water, Sanitation & Hygiene (WASH) practices are followed.

Working with the government to set up biomedical waste disposal protocols.

for treatment and insurance schemes.

The organic workflow pattern starts with baseline indicators and preventive health and culminates in treatment. This enables surveillance, monitoring and evaluation of the health status of the population. Data from individual clinics or from groups of clinics are available to health administrators through live dashboards, which capture patient footfall, vital parameters, disease

profiles of communities, and disease trends. The dashboard sends disease notifications and alerts to the administrator. This enables forward planning for the implementation of need-based healthcare programs. Moreover, notifications help healthcare providers plan for seasonal disease outbreaks.

### eLAJ Smart Clinics – Scaling Up

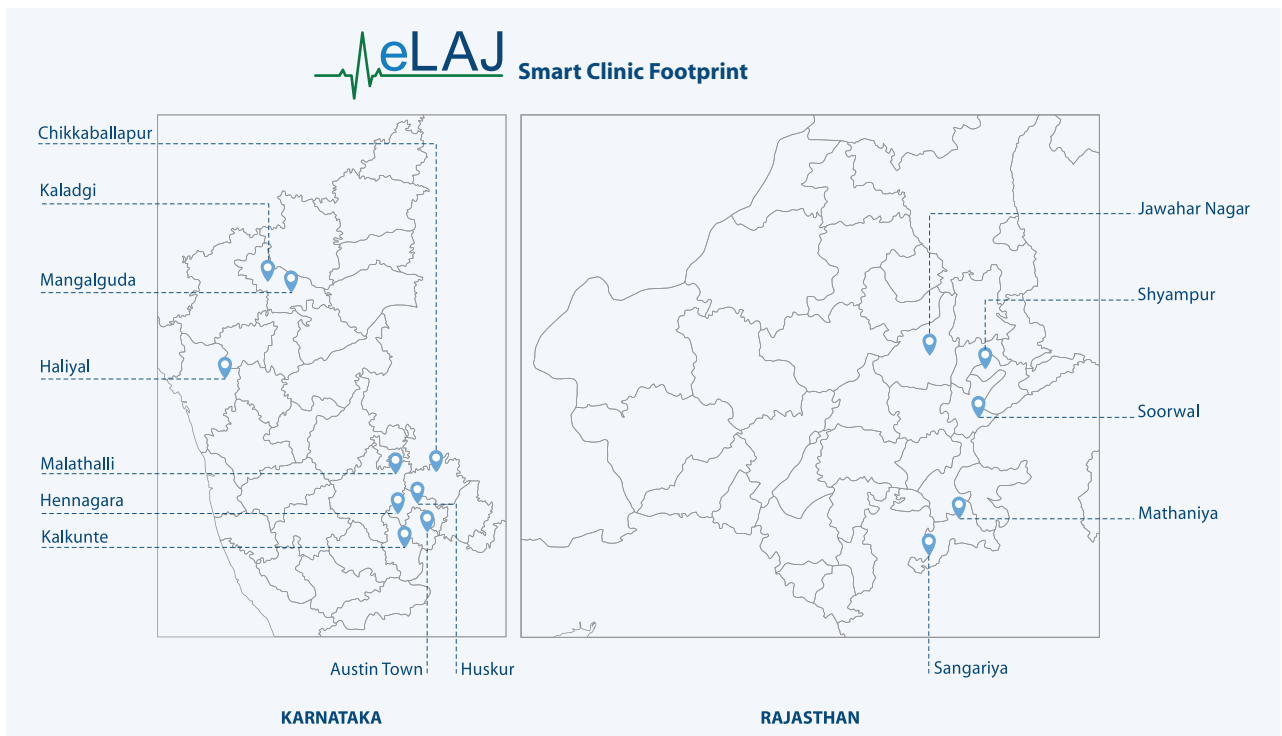
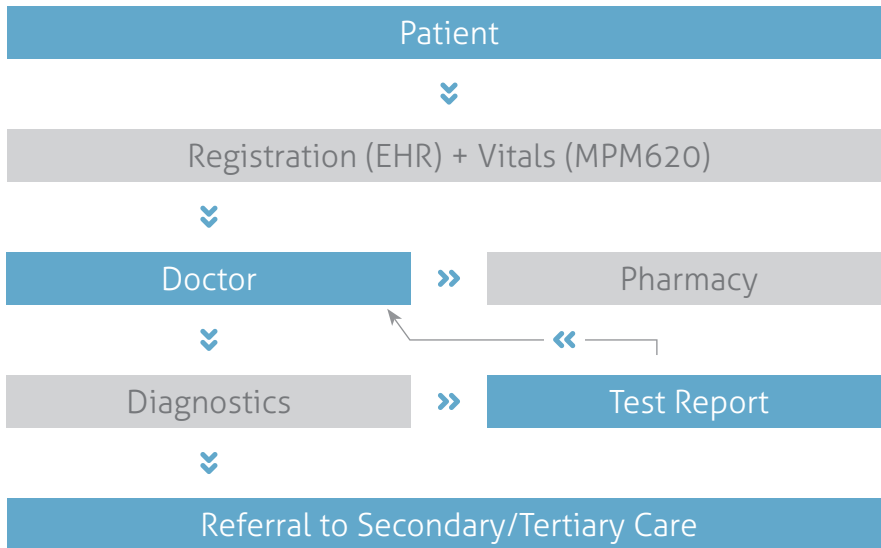
Biocon Foundation set up its first eLAJ Smart Clinic in Huskur in

Bengaluru in 2015.

The pilot at Huskur provided the proof of concept to scale up the model elsewhere. By the end of 2016 the eLAJ Smart Clinic model was installed at eight clinics in Karnataka, run exclusively by Biocon Foundation.



## Patient - Doctor Interface at eLAJ Smart Clinics





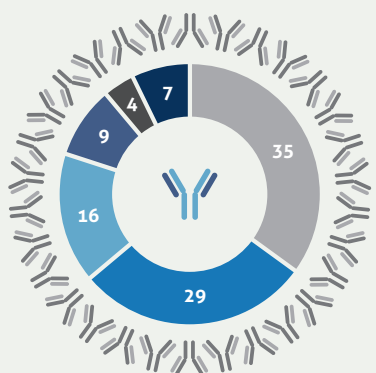
By 2016, Biocon Foundation completed the adoption of five government PHCs in Rajasthan under a Public Private Partnership (PPP) with the Government of Rajasthan.

In January 2017, Biocon Foundation and the Government of Karnataka signed a MoU to install the eLAJ

Smart Clinic model in 15 government run PHCs in Karnataka. The first of these have been flagged off in February 2017. Through this PPP, Biocon Foundation aims at strengthening the present public healthcare system in Karnataka by providing solutions around primary

& secondary healthcare with effective use of technology. Biocon Foundation is recognized widely for implementing innovative healthcare models to create a sustainable health ecosystem. By joining hands with the government, we aspire to benefit many more villages in

### Disease Profile of Patients Visiting eLAJ Smart Clinics in FY17



- Infectious diseases ● Fever / pain
- Non Communicable Diseases
- Trauma & Orthopedics
- ENT ● Others

Over the past year, patient footfall at the eLAJ Smart Clinics has gone up by 50% to more than 9,000 a month. Patient footfall spiked between July and October because of seasonal illnesses, hitting a peak of 13,330 in September 2016. Overall data show that the majority of patient visits to the eLAJ clinics were prompted by infectious diseases (35%) and fever / pain (29%).

Rajasthan, where we run five eLAJ Smart Clinics, also saw a jump in patient footfall in the July-October period. The patients diagnosed at these clinics were mostly suffering from pyrexia (31%) and diarrhoea (27%). We are also seeing good traction in the laboratory tests conducted at the eLAJ clinics in Rajasthan, with numbers soaring 13 times between April 2016 and February 2017.

Karnataka through the eLAJ model that combines good infrastructure, latest technology and the best available medical expertise.

The Foundation currently runs 14 eLAJ clinics covering over 30 gram panchayats across Karnataka and Rajasthan.

### Pradhan Mantri Surakshit Matritva Abhiyaan- ANC Camps

India ranks first in the list of 10 countries that account for 60% of all pre-term births. Yet, India has little more than 50% of antenatal care coverage. In order to tackle the issue of premature births, low birth weight babies and stillbirths, it is essential to increase the coverage of antenatal care in the country. To enable this, the Ministry of Health and Family Welfare, Government of India has launched a program called Pradhan Mantri Surakshit Matritva Abhiyaan (PMSMA).

The aim of the program is to provide a comprehensive package of antenatal care services to pregnant women in their second or third trimester at government health institutions. Biocon Foundation is helping the Rajasthan government implement PMSMA efficiently at the eLAJ PHCs.

How Biocon Foundation is ensuring smooth implementation of PMSMA:

- All eLAJ PHCs use a unique prescription form, designed as

per government requirements, to collect data.

- eLAJ PHCs collaborate with private doctors to be a part of PMSMA.
- All PHCs are provided with Fetal Doppler by the Foundation to check fetal heart rate.
- Glucometers with strips are provided to PHCs to track blood sugar levels of pregnant women.
- Creating monthly action plans for all health centres for smooth management of high-risk pregnancy (HRP) cases.
- As recommended for HRPs in PMSMA guidelines, all eLAJ health centres use red stickers on the high-risk individual's MAMTA card.
- eLAJ PHCs provide vehicles to pick up and drop off pregnant women for antenatal check-ups.
- eLAJ dashboards are given to medical officers and senior

officers from health department to monitor HRPs.

- The dashboards help them monitor HRP cases and ensure that proper preparations are done in case of referral.

In case of high-risk pregnancy cases, eLAJ PHCs follow an action plan:

- Referral to higher institution for delivery: All HRPs whose deliveries are due in the next two months are referred to higher institution.
- Birth and emergency preparedness plan: All pregnant women expected to deliver in the next two months, with a special focus on high risk cases.
- Referral to higher institution for Iron Sucrose: All severe anaemia cases are referred as either inpatient to the PHC if the facility is available or to the higher institution.





- Referral to higher institution for other treatments: All pregnant women identified with some clinical condition for which treatment can't be provided at PHC.

In FY17, nearly 2,500 pregnant women attended the PMSMA camp, of which over 350 were found to be high risk pregnancy cases. Over 34,000 Iron/Folic Acid tablets were distributed to anaemic women. Biocon Foundation also identified about 450 women for family planning counselling.

## Non Communicable Diseases

Non-communicable diseases (NCDs), also known as chronic diseases, are not passed from person to person. They are of long duration and generally slow progression.

India is transiting speedily to lifestyle diseases. NCDs contribute to around 5.87 million deaths that account for 60% of all deaths in India. There is an urgent need to put NCDs at the centre of the country's health policy, plans and programs.

At Biocon Foundation, we believe an integrated community based risk factor management program is a cost-effective and efficient approach to tackling NCDs. We have been conducting population-based screenings for oral, cervical and breast cancers.

### The multipronged approach to NCD management at eLAJ Smart Clinics includes:

- Health promotion and prevention strategies for healthy lifestyles that prevent NCDs and associated risk factors.
- Garner evidence for action through disease surveillance, monitoring and research.
- Psychosocial counselling to meet the emotional, social and mental needs of patients.
- Human Resources and their capacity building for prevention and treatment of NCDs.
- Early diagnosis through periodic/ opportunistic screening of population.
- Treatment and care of NCD patients in special health camps.
- Handholding and referrals as and when required.

### Breast Cancer

Biocon Foundation runs the breast cancer screening program in association with UE Life Sciences. The screening includes clinical breast examination and examination with a handheld device, the Intelligent Breast Examination (iBE), a novel US FDA approved medical instrument for pre-screening of breast lesions. Those who are found to have lesions are then referred for ultrasound/mammography. This device is able to identify high priority patients who require ultrasound or mammography at the first level, therefore reducing their risk of developing breast cancer.

Of the 1,755 persons screened for breast cancer this year, 185 were found to have lesions in the breast. Among them, over 90 underwent mammography.



## Oral Cancer

Early detection and prevention of oral cancer can drastically reduce mortality and the economic burden on the communities. Of the nearly 6,900 patients screened during the year, a third tested positive for potentially malignant lesions. Fortunately, no positive case of oral cancer was detected.

## Cervical Cancer

Cervical cancer can often be successfully treated when diagnosed early. Of the nearly 1,000 women screened, 133 tested positive for reproductive tract infections and 21 for abnormal pap smear. One case of cervical cancer was detected this year.

## Diabetes & Hypertension

Biocon Foundation has developed a comprehensive program for the detection and management of Type 2 diabetes and hypertension through its PHCs. The Foundation routinely conducts surveys for community

risk profiling. The data so generated helps characterize the health status of communities, identify new NCD cases and assess vulnerability to associated risk factors. This year more than 1,200 individuals were screened.

## NCD Health Camps

Biocon Foundation also conducts monthly health camps for Type 2 diabetes and hypertension through its PHCs located across Karnataka. Early diagnosis is carried out along with health screening in these camps. The health check-up is free while medicines and lab investigations are subsidized. This year we witnessed a total footfall of over 8,000 in our NCD Health Camps. Over 2,300 diabetes and hypertension cases were managed through these camps during the year. At these camps, we also provide psychosocial counselling on stress management, blood glucose control and quitting tobacco use.

## Malnutrition

The 2015 Global Hunger Index (GHI) Report ranked India 20th amongst leading countries with a serious hunger situation. One of the major causes for malnutrition in India is economic inequality. Due to the low social status of some population groups, their diet often lacks in both quality and quantity. Women who suffer malnutrition are less likely to have healthy babies. In India, mothers generally lack good nutritional knowledge. Consequently, newborn infants are unable to get adequate amount of nutrition from their mothers.

## Well Baby Clinics

Malnutrition can be prevented with adequate primary healthcare and community education and behavior change. In order to test this hypothesis, Biocon Foundation established a pediatric clinic in Austin Town, Bengaluru in collaboration with St John's Community Health Department in 2016. The clinic provides general pediatric consultative services, follow-ups for ill children and supports both the physical and emotional wellbeing of children and their families.

We have adopted Community-Based Management of Acute Malnutrition (CMAM) approach which enables us to identify and initiate treatment



for children with Severe Acute Malnutrition (SAM) before they become seriously ill. There are four main components of the approach:

**Community Mobilization:** Our Community Health Workers (CHWs) sensitize the community and do child anthropometric assessment to identify acute malnutrition cases.

**Supplementary Feeding Program (SFP):** We provide Ready-to-Use Therapeutic Food (RUTF) to children. RUTF are energy dense and micronutrient enhanced pastes used in therapeutic feeding.

**Outpatient Therapeutic Program (OTP):** We monitor children's

progress through monthly health camps organized in our clinic and also provide home counselling.

**Referrals:** As and when required, children with medical complication are referred for in-patient medical treatment.

This year we organized eight health camps on malnutrition. Out of the 155 cases that were managed in total, five SAM cases were identified.

### Balaspandandana - The Bagalkot Program

Biocon Foundation started nutrition intervention for children below five years in Bagalkot district in

FY13. Our role is supplementary to the government's Integrated Child Development Service (ICDS) program and we have developed a comprehensive strategy to curb malnutrition in the area.

This year we organized a total of 190 health camps and managed a total of 834 cases of malnutrition. Of these, 216 SAM cases showed improvement with an upward growth trend of 92%. We recorded a 14% reduction in anemia cases.

## Education

Biocon Foundation is keenly aware of the fact that the quality of education children receive in school determines the quality of their future. Critical gaps in learning, such as language and numeracy skills, could affect their ability to attain sustainable livelihoods and lead productive, healthy lives. Biocon Foundation has attempted to plug a critical gap in mathematics learning through the Chinnara Ganitha workbook developed in collaboration with Macmillan Publishers India. This workbook approaches mathematics through activities and games in the local language, thereby inculcating

self-reliance in children. They are closely aligned to the Directorate of Secondary Research and Training Curriculum for standards I to VII. Since 2006, we have distributed these workbooks to the most underserved children in various

government schools in Karnataka. During the year, over 100,000 students across 1,400 schools in Karnataka received the workbook. We also trained 1,200 teachers under this initiative.



## Biocon Academy



Biocon took its leadership role in the field of biotechnology forward to establish the Biocon Academy, a premier center of excellence for advanced applied learning in biosciences, in Bengaluru in 2014.

Biocon Academy, a CSR initiative, has leveraged the rich industry experience of Biocon and domain knowledge of international academic partners to empower both experienced as well as recent life science graduates with translational education and industrial proficiency through job-skills development essential to build a promising

career in the biotech industry. It has collaborated with leading global institutes like Keck Graduate Institute (KGI), California, US and BITS Pilani, India, to offer global quality learning to Indian students.

In a short span of three years, Biocon Academy has been instrumental in shaping the careers of more than 300 aspiring bio-scientists by imparting the requisite experiential learning that serves to bridge the existing industry-academia gap.

In doing so, the Academy has contributed immensely to enrich the life sciences ecosystem in India

by producing highly skilled bio-scientists. During the year, a talented pool of over 100 students graduated from the Biocon Academy and all of them were successfully placed in leading life sciences companies. The graduates of the Academy were hired for diverse roles in Production, Quality Assurance, Regulatory Affairs, Research & Development and Marketing.

More than 35 companies participated in the Academy's campus placement programs during the year. While 60% of the graduates found jobs outside

of Biocon the rest were placed in various departments of Biocon and Syngene.

### Biocon KGI Certificate Program in Biosciences

The Academy's flagship program offered in collaboration with Keck Graduate Institute, the premier American school for biosciences education, saw the successful completion of three batches in FY17. The full-time certificate program, spread over 18 weeks, includes classroom sessions on the applications of biotechnology as well as industry assignments and hands-on training.

The classroom sessions involve synchronous transmission of courses and learning material developed and offered by faculty at KGI from California. These sessions are highly interactive and create a personalized learning environment where KGI faculty members and students engage in real time conversations.

The broad-based international curriculum of the program encompasses the domains of R&D, Production, Quality Assurance, Regulatory Sciences & Product Development. Additionally, professional skills training prepares biotech students with the necessary knowledge and skills that make them employable in the industry.

Students undergo functional

training at Biocon's Quality Control and Production laboratories and cGMP training at Biocon. To widen the scope of hands-on training for its students, the Academy collaborated with Bengaluru-based biopharmaceutical services company BiOZEEN and the New Horizon College of Engineering to offer practical training sessions at their facilities.

The Academy also introduced a special mentorship session for students with the faculty and some of the best alumni of KGI, California.

In FY17, 90 students successfully completed the program, including eight from Malaysia. All of them were placed with leading pharma and biopharma companies.

### Alumni Meet

The Biocon KGI Program alumni were introduced to KGI Connect, the alumni portal of KGI students in California. The portal will give Biocon Academy graduates an opportunity to network with KGI alumni as well as provide access to extensive learning resources.

The Academy also organized its second Alumni Meet, which was attended by over 100 graduates. The event, chaired by Kiran Mazumdar-Shaw, Chief Mentor, Biocon Academy and Dr Sheldon Schuster, President, KGI, California, provided interesting insights into the new trends in the

global life sciences industry and opportunities for bio-scientists in India and abroad.

### BITS Biocon Program in Applied Industrial Microbiology

Building on the success of the first batch of BITS Biocon Program in Quality Control Microbiology, the Academy broadened the course curriculum and modified the program to rename it as BITS Biocon Program in Applied Industrial Microbiology.

The exclusive program is designed to enhance the knowledge and skills of aspiring microbiologists, pharmacy and biotech graduates. It seeks to accelerate learning in the fast-growing field of microbiology and boost the job prospects of students in microbiology and biosciences. The program offers experiential learning by combining real world insights with classroom learning on various aspects of microbiology through an intensive curriculum delivered by renowned faculty of BITS, Pilani, Biocon Academy and Subject Matter Experts (SMEs) of Biocon. In addition to honing technical skills, this program also sharpens the professional skills of candidates and provides an opportunity for holistic development.

In FY17, a batch of 20 students completed the BITS Biocon Program and all of them were placed in leading pharma and biopharma companies.



### International Event

Biocon Academy, in association with American Chemical Society Medicinal Chemistry Division and Pharma Innovation Sourcing Center, US, organized the Medicinal Chemistry and Drug Discovery & Development India 2017 (MCADDI 2017), a residential course in medicinal chemistry and drug discovery at its campus in Bengaluru. MCADDI 2017 presented the principles of medicinal chemistry, drug discovery & development in a format designed for industrial and academic participants who are currently working in this area or plan

to do so. The event witnessed the participation of 95 scientists from more than 11 organizations globally.

### New Programs

Biocon Academy has developed two new programs: the Biocon KGI Certificate Program in Clinical Development and the Biocon Academy-Faculty Development Program to expand its offering to the biotech world. The Clinical Development Program has been designed to equip Pharmacy graduates, post-graduates and diploma holders with the skills needed to build a successful career in the realm of clinical development.

The Faculty Development Program will seek to empower biotech faculty from various educational institutes by helping them upgrade their knowledge of emerging industry-specific technologies. These programs will be rolled out in FY18.

Biocon offers scholarships of upto 75% to all the students, which takes care of the major portion of the cost of these expensive international programs.

## Forward Looking Statement

Biocon FY17 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.

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