



Exclusively  
**inclusive**



Annual Report 2015





## Exclusively **inclusive**

**At Biocon**, we are driven by a vision to develop specialty biopharmaceuticals that address the global need for effective, safe and affordable biologics.

We have made consistent and significant investments in research to strengthen our exclusive positioning.

Our commitment to be inclusive in our reach is reflected in our patient-centric approach towards providing affordable medicines for chronic diseases to billions across the world.

This 'exclusive and inclusive' combination has reinforced our relevance as a sensitive corporate citizen engaged in a humanitarian business with a focus on creating value for diverse stakeholders.

EXCLUSIVELY **INCLUSIVE**

Our 'Exclusively inclusive' approach is aimed at making a difference to global health.

Biocon is developing novel biologics and biosimilars for addressing chronic diseases like cancer, diabetes and autoimmune conditions for patients across the globe.

EXCLUSIVELY **INCLUSIVE**

# We believe our biotechnology business is a humanitarian engagement.

Our BIOMAb EGFR<sup>®</sup>, a novel biologic, has benefited thousands of patients as an affordable therapy for head and neck cancer.

CANMAb<sup>™</sup>, introduced in 2014 as the world's first affordable follow-on Trastuzumab for HER2-positive metastatic breast cancer, is making a significant impact.

EXCLUSIVELY **INCLUSIVE**

**We are driven by our passion to develop pharmaceuticals which can potentially benefit a billion patients.**

As Asia's largest insulins producer, we are making a difference to diabetic patients the world over with our most affordable rh-Insulin and Insulin Glargine. Biocon's Insugen® is the largest generic insulin brand in India. For decades, our global scale in statins has benefited millions of patients. Our commercial footprint extends to over 100 countries.

EXCLUSIVELY **INCLUSIVE**

# Biocon: Reconciling an exclusive business model with an inclusive social commitment.

Our efforts are targeted at affordable innovation that enables us to develop complex biopharmaceuticals at lower costs, thereby benefiting larger patient pools.

Our Oral Insulin under development has the potential to transform diabetes management the world over.

Our Itolizumab is a 'first-in-class' novel biologic that aims to change the treatment paradigm for autoimmune diseases.

## Our Value Proposition

ETHICAL GLOBAL CONVENIENT  
AFFORDABLE  
EXCLUSIVE  
AVAILABLE  
PIONEER  
DIFFERENTIATED  
BEST-IN-CLASS  
ACCESS  
INNOVATIVE





# Exclusively inclusive: **Biocon**

WE ARE DRIVEN BY THE QUEST TO DEVELOP AFFORDABLE BIOPHARMACEUTICALS FOR PATIENTS ACROSS THE WORLD, ENHANCING ACCESS TO OTHERWISE EXPENSIVE THERAPIES. WHEN WE STARTED OUR PHARMACEUTICAL JOURNEY, WE HAD A CHOICE TO DEVELOP LOW-COST GENERIC PHARMACEUTICALS OR COMPLEX CAPITAL-INTENSIVE PREMIUM PRODUCTS. WE CHOSE THE LATTER AND OPTED FOR BIOPHARMACEUTICALS THROUGH DISRUPTIVELY INNOVATIVE PROCESS ENGINEERING THAT COULD DELIVER AFFORDABLE PRICING AND MAKE A DIFFERENCE TO GLOBAL HEALTHCARE. A STRATEGY OF BEING PROFITABLY SMART AND SOCIALLY GOOD.





Biocon has since focused relentlessly on chronic disease spaces like diabetes, cancer and autoimmune conditions, marked by unmet needs. We have consistently invested nearly 10% of our biopharma revenues in research and development. We have made long-term investments in creating 'best-in-class' complex biologics manufacturing capabilities. We have commissioned operations in locations where we can leverage the advantages of cost, scale and knowledge. Over time, we have emerged as a highly innovative biopharmaceuticals enterprise that operates across the value chain comprising small and large molecules.

Our steadfast commitment to innovation has enabled us to develop novel biologics and complex, yet affordable, biosimilars for chronic diseases. The success of our core brands Insugen®, BASALOG®, BIOMAb EGFR®, Abraxane®, CANMAb™ and ALZUMAb™ is an outcome of our 'patients-first' strategy and a differentiated portfolio.

We are making a huge difference globally through affordable insulins, statins and monoclonal antibodies. We seek to extend our presence in niche areas where we see the potential to moderate costs and widen patient access. We aim to transform the approach to killer diseases by developing affordable blockbuster drugs with the potential to benefit a billion patients.

**Through this 'Exclusively inclusive' business model, we strive to rationalize healthcare spends, enhance access to affordable bio-therapeutics and make a significant impact to global health.**

## Key Highlights

REVENUE

31,429  
₹ Million

PAT

4,974  
₹ Million

EBITDA MARGIN

24%

R&D SPEND (GROSS)

3,287  
₹ Million

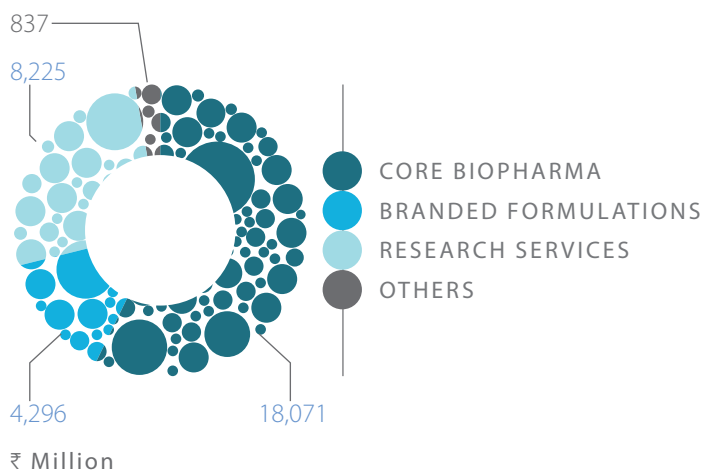
EPS

24.8  
₹

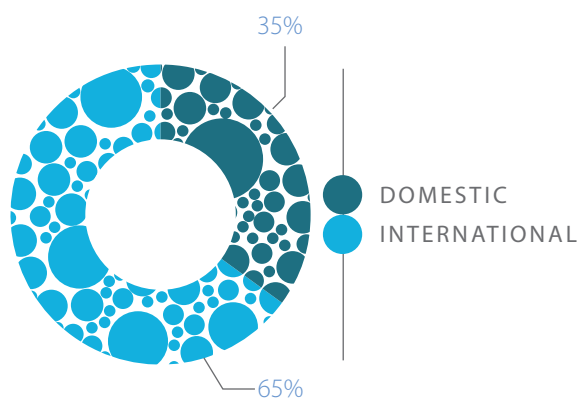
EMPLOYEES

7,500+

### BUSINESS REVENUE MIX



### GEOGRAPHIC DISTRIBUTION



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# Chairperson's **Review**



Ms. Kiran Mazumdar-Shaw,  
*Chairperson*



Dear Shareholders,

### Global Biopharma Trends

The global pharmaceutical industry is under immense pressure to sustain growth and profitability. Sub-optimal drug innovation, imminent loss of patent protection of mega drug brands and pricing pressure from governments, insurers and payers are key challenges. These difficult dynamics are driving inorganic growth through a spate of mergers and acquisitions at unrealistic valuations.

Whether it will deliver synergistic growth and value added profitability remains to be seen. However, one thing is clear: Big Pharma is beginning to realize that global priorities are shifting from providing exclusive and expensive drugs to more affordable drugs which can help enhance access. There is also a realization that the opportunities are in the fast-growing emerging markets, where the old business model of expensive medicines targeted at niche populations of affluent patients will not work.

### Biocon: Exclusively Inclusive

Biocon has been driven by its strategy to provide affordable access to advanced biopharmaceuticals for global patient populations. Through our 'Exclusively inclusive' approach, we are developing a speciality portfolio of products that can benefit millions of patients the world over. Towards this end, we have set out to build global reach and economies of scale. We are steadfastly investing in developing a range of affordable therapies for diabetes, cancer and autoimmune diseases, most of which, were previously unaffordable and hence inaccessible to many.

### Biosimilars: The Next Bolus of Growth

Growing pressure on healthcare expenditure is compelling governments,



Today, Biocon probably has one of the largest generic insulin analogs and biosimilars portfolio in advanced stages of development.

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the world over, to adopt generics and now biosimilars. As global consensus builds around modified regulatory guidelines, the biotech industry is fast approaching its own patent cliff. Some recent biosimilars approvals are beginning to make a difference by increasing accessibility for a larger patient population.

Globally, 57 biosimilars programs are in an advanced clinical development phase. With 10 approvals in the EU, one in the US and 37 programs in pivotal trials, the biosimilars opportunity has started unfolding (*Source: Bernstein report*).

Biocon, with its rich pipeline of biosimilars under development, is at the right place at the right time. As the number of biosimilars increase and the confidence in their safety and efficacy gains broader acceptance, we are seeing our biosimilars strategy playing out with greater credibility and traction.

The global market opportunity for biosimilars is estimated to reach ~US\$24 billion in 2019 (*Source: Frost & Sullivan Global Biosimilars Report*).

Today, Biocon probably has one of the largest portfolios of generic insulins and biosimilar protein therapeutics in advanced stages of development with six molecules in Phase III clinical trials, viz. rh-Insulin, Glargine, Pegfilgrastim, Adalimumab, Bevacizumab and Trastuzumab.

Biocon is confident that, together with our partners around the world, we can build a strong global presence in biosimilars to address the huge need for affordable access to these life-saving and life-enhancing biologics.





Biocon has, over the years, built global-scale and cost-competitive complex manufacturing capabilities to address the needs of patients worldwide.

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The unfolding biosimilars opportunity in emerging markets in the near term and developed markets subsequently, will provide Biocon with the next big bolus of growth.

### Building Global Scale

Biocon has, over the years, built global-scale and cost-competitive complex manufacturing capabilities to address the needs of patients worldwide. Today, we already have leadership in microbial fermentation-based products like statins, immunosuppressants and insulins. We are confident that we can build similar leadership in mammalian cell culture.

#### Insulins: Strong Leadership

We are the largest producers of insulins in Asia. Over the past decade, more than a million patients have benefited from Biocon's inclusive diabetes management portfolio.

The on-time commissioning of the Malaysia plant, designed as Asia's largest integrated insulins manufacturing facility, has put us on track to become one of the world's largest insulin producers.

**Our aim over the next 10 years is to provide Biocon's Insulin products to one in five diabetic patients in need of insulin-based therapy, anywhere in the world.**

#### Oncology: Making Cancer Care Affordable

Biocon's contribution to bringing affordable oncology therapeutics like BIOMAb EGFR®, NUFIL™ and CANMAb™ to the Indian market has already made a significant impact in the realm of cancer care. Our expanding portfolio has gained us recognition as a leading Oncology Company. In less than a decade since the launch of our Oncotherapeutics division in India, we have made a



Biocon's contribution to bringing affordable oncology therapies like BIOMAb EGFR®, CANMAb™ and Abraxane® to the Indian market has already made a significant impact in cancer care.

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difference to the lives of over 20,000 cancer patients and have built significant brand equity across our customer base.

CANMAb™, our Trastuzumab for treating HER2-positive metastatic breast cancer, has been one of the most successful launches of an oncology product in India.

Currently, patient recruitment is in progress across more than 100 sites in several countries for global Phase III trials of our Trastuzumab.

**Our goal is to make Biocon's Trastuzumab available to at least one in 10 HER2-positive breast cancer patients globally.**

By capturing a sizeable and profitable share of the biosimilars market, Biocon aims to unleash accelerated growth in a sustainable manner over the foreseeable future.

### Transformational R&D

We have been consistently scaling up our investments in research and development. On an average 10% of our biopharma revenues are invested in R&D every year. As an innovation-led company, high R&D spends are inherent to our business. Our growing investment in developing cutting-edge novel molecules is now generating encouraging and exciting data. The ultimate success of these programs will bring transformational growth to our business.

### Oral Insulin

I am happy to share with you that we have completed the first set of clinical trials with our Oral Insulin candidate IN-105 in the US. The data from these studies are compelling and we intend to rapidly progress to the next phase of clinical development of this game-changing molecule with the hope of delivering commercial success in the near future.



On an average, 10% of our biopharma revenues are invested in R&D each year. We spent over ₹3.29 billion in R&D in FY15.

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As a prandial insulin IN-105 can prove to be a powerful weapon in the battle against diabetes, especially considering that the number of patients is expected to increase from almost 387 million in 2013 to 592 million by 2035 (Source: World Health Organisation).

#### **Itolizumab**

We continue to explore partnerships for Itolizumab, a path-breaking novel monoclonal antibody, as we concurrently develop this asset further. We are extremely confident of the unique benefits of this anti-CD6 targeting molecule and have begun exploratory development work for rare neurological indications which have a significant unmet medical need.

Itolizumab's mechanism of action is a powerful differentiator as it provides an enhanced safety and remission profile that gives it a distinct and superior edge over competing drugs. This has been validated through the use of ALZUMAb™ for the treatment of psoriasis, benefiting nearly 500 patients till date. Our understanding is that our Itolizumab has a unique immune modulation effect that delivers slower but long lasting and safer efficacy, which subscribes to the growing hypothesis that rapid response is not necessarily safe.

#### **Unlocking Value: Research Services**

Over the years we have built a robust Research Services business through Syngene. I believe it is the right time for us to unlock the value of this business and generate funds that can accelerate Biocon's pursuit of innovation.

Syngene has championed the 'Exclusively inclusive' philosophy of Biocon by offering niche services to a large and diverse clientele. It has also established exclusively dedicated R&D centers for some of its anchor clients like Bristol



**Biocon's 'Offer for Sale' of an 11% stake in Syngene through an IPO is an important event, which sets the stage for significant value creation for the Research Services business.**

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Myers Squibb (BMS), Abbott and Baxter.

The Company has a proven track record of providing high quality discovery, development and manufacturing services for both small and large New Molecular Entities (NMEs). The strength of its business model has been well-recognized through equity participation from reputed investors earlier this year.

Biocon's 'Offer for Sale' of an 11% stake in Syngene through an IPO is an important and much-awaited event and sets the stage for significant value creation for the Research Services business.

Syngene has built a strong reputation of being the 'innovation partner' for many of its clients and is well-positioned to tap the US\$67 billion global Contract Research Organization (CRO) opportunity for discovery and development services (*Source: Frost & Sullivan Report*).

### **Strengthening the Board**

As a Company committed to innovation and excellence, Biocon has strengthened the composition of its Board through the induction of two eminent life sciences experts as Independent Directors.

Prof. (Dr.) Vijay K. Kuchroo, who is the Samuel L. Wasserstrom Professor of Neurology and Director of Evergrande Center for Immunologic Diseases at Harvard Medical School, joined us as Additional Independent Director in January 2015. Dr. Kuchroo has been a part of our Scientific Advisory Board and has been providing us valuable inputs for our novel programs in autoimmunity. His presence on the Board will help us immensely in charting the future direction of our novel programs.

Dr. Jeremy M. Levin, former CEO of Teva Pharmaceuticals and Chairman



**Biocon delivered a commendable consolidated performance in FY15 despite geopolitical challenges and capacity constraints.**

of Ovid Therapeutics Inc., a New York-based private company developing novel medicines for orphan diseases, also joined Biocon as an Additional Independent Director this January. His experience of having worked with leading companies like BMS and Novartis, driving business development and company strategy to bring effective treatments to patients worldwide, augurs well for Biocon. At BMS, he successfully led the 'String of Pearls' strategy that helped transform the company's R&D pipeline.

### Financial Highlights

Biocon delivered a commendable consolidated performance in FY15 despite geopolitical challenges and capacity constraints. The topline grew 7% to reach ₹31.43 billion, driven by strong growth in research services revenues (15% Y-O-Y). Our bottomline increased 20% to reach ₹4.97 billion. Adjusting for an exceptional income from the sale of Syngene shares by Biocon to a strategic private equity investor, the Profit After Tax stood at ₹4.02 billion. Our EBITDA for the year rose marginally to reach ₹7.49 billion, with a healthy margin of 24%. We managed to hold on to our margins despite the huge increase in R&D spends in the year. Biocon's R&D spends at a gross level doubled to ₹3.29 billion during the fiscal.

### Beyond Business: CSR

Our underlying ethos of access and affordability goes beyond our business. It represents the focus of the initiatives by Biocon Foundation, our Corporate Social Responsibility (CSR) wing, in the areas of health, education and infrastructure.

The Foundation is addressing the 'Right to Health,' the 'Right to Education' and the 'Right to Sanitation' through its numerous outreach programs for the benefit of the economically weaker sections of Indian society, especially in



WHO India recently recognized Biocon Foundation as a 'Public Health Champion' for providing sustainable solutions in the area of public health.

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impoverished rural areas of Karnataka.

I am proud to say that the Foundation's CSR initiatives are receiving considerable recognition. WHO India has recently recognized Biocon Foundation as a 'Public Health Champion' for providing sustainable solutions in the area of public health with a focus on cancer, diabetes and hypertension. Biocon Foundation's mobile-based program for early detection and prevention of oral cancer was awarded a 'Certificate of Appreciation' at the NASSCOM Social Innovation Forum 2015.

Biocon Academy, our flagship CSR initiative aimed at developing high-end talent for the Indian biotech industry, is already delivering on its intended objectives. Over 90 young biotech professionals have benefited from an intensive 16-week 'Biocon-KGI Certificate Program in Biosciences' and have readily found employment in various biotech companies. The feedback from employers is extremely positive.

### Looking Ahead

In FY16, we are likely to see a rebound in sales that were muted last fiscal largely because of capacity constraints and geopolitical challenges emanating from the Middle East and North Africa (MENA) region. We are lowering our dependence on the MENA region by shifting focus to other emerging markets. Moreover, contract manufacturing arrangements and investments in capacity enhancement will help Biocon realize greater revenues this fiscal.

A stellar performance by Syngene last fiscal also positions the Research Services business for robust growth. A stable business, differentiated services as well as contract manufacturing opportunities that are coming on stream,



Our technology platforms built on the core values of quality, affordability, reliability and innovation have differentiated us in the marketplace.

will help the business outperform in FY16 and onwards.

Finally, I am proud to say that our technology platforms built on the core values of quality, affordability, reliability and innovation have differentiated us in the marketplace. Our philosophy of affordable innovation, which goes to the core of ensuring a global right to healthcare, has helped us reap rich rewards thus far. It is also opening up a wealth of new possibilities for the future.

We believe we are well aligned with the emerging paradigm where drug innovation and therapy costs interact effectively in a new financial matrix. This will enable us to drive long-term value creation for our shareholders.

Before I conclude, I would like to place on record my deepest appreciation to our retiring directors: Prof. Charles Cooney, Mr. Suresh Talwar and Dr. Bala Manian. Their insights and advice have greatly contributed to the advancement of the Company.

In closing, I would like to thank all our stakeholders for believing in our innovation story and extending their unstinted support to us which has truly enabled Biocon to pursue the path of differentiation, in its quest to be 'Exclusively inclusive.'

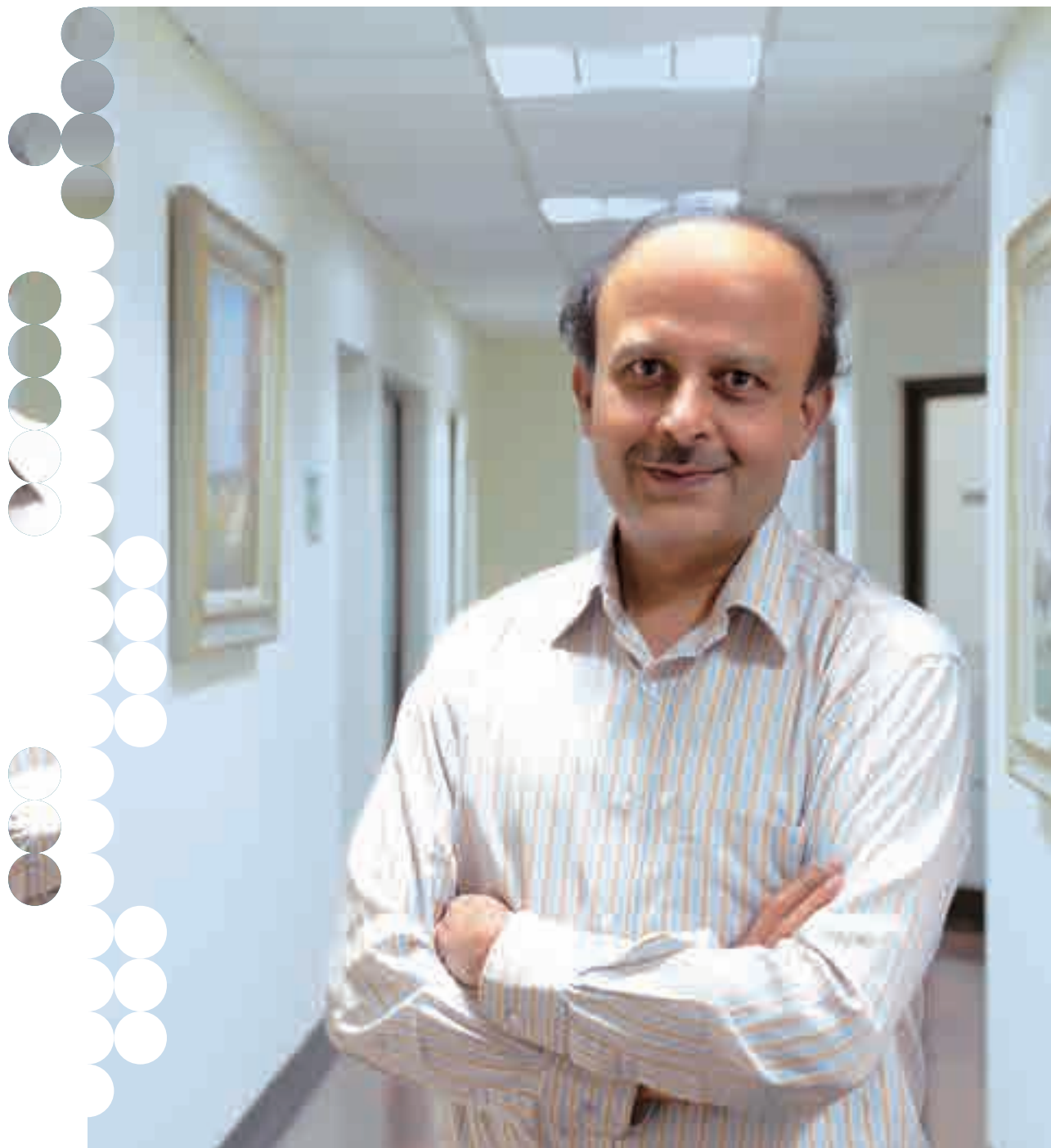
Best Wishes,

**Kiran Mazumdar-Shaw**

*Chairperson*

May 20, 2015

# Operational **Review**





## Q&A with the CEO

**Dr. Arun Chandavarkar,**  
Chief Executive Officer and  
Joint Managing Director

Q

Can you delineate key elements of Biocon's performance in FY15?

A

At ₹31.43 billion, our overall revenues grew by 7%, while Profit After Tax (PAT) at ₹4.97 billion reported a 20% jump. Excluding the exceptional gain on sale of Syngene shares, our PAT was at ₹4.02 billion. Earnings Before Interest Taxes Depreciation Amortization (EBITDA) margins were steady at 24% despite a 29% increase in R&D expenses to reach ₹1.69 billion. In fact, gross R&D spends almost doubled over the previous fiscal to ₹3.29 billion reflecting the progress made in our various R&D programs. We closed the year with a stronger performance in the fourth quarter wherein revenues grew by 15% despite several challenges.

From a segmental perspective, the Biopharmaceuticals segment showed muted annual growth of 5% to ₹22.37 billion impacted by the reasons cited above. Our Research Services subsidiary, Syngene, continued to make good progress with an annualized growth of 15% to ₹8.23 billion driven by the growth in the second half of the fiscal accelerating to 23%. Within the Biopharmaceuticals segment, our Branded Formulations business grew by 10% for the year to ₹4.30 billion. This was lower than our historical growth rate on account of a conscious effort at pruning the product portfolio to focus on profitable specialty products.

Q

How have you progressed on the key priorities identified by you last year?

A

I had outlined four key priorities for our Biopharmaceuticals business in the FY14 Annual Report:

### 1. Moving up the value chain in Small Molecules by filing our own dossiers.

This nascent business made a good beginning in FY15 with Biocon filing the initial set of Abbreviated New Drug Applications (ANDAs) in the US and Marketing Authorization Applications (MAAs) in the EU. We will continue to build momentum in this area with a focus on specialty molecules in chronic therapy segments. We also initiated the design of our first oral solid dosage facility to be located in Bangalore to support our future ANDA filings.

Our innovation-led strategy is aligned with the trends in global healthcare wherein biologics are playing an increasing role in addressing unmet medical needs.

**2. Growing our insulins franchise through timely commissioning of our Malaysia facility.**

We successfully commissioned our greenfield generic insulins facility in Malaysia, one of Asia's largest, to cater to our global ambitions in this space. We have now commenced technology transfer and process qualification activities that are necessary to seek facility and site approvals from local and international regulatory authorities. We expect this effort to span the course of FY16.

**3. Progressing our biosimilar antibody and generic insulins programs through the clinic.**

We have progressed our generic insulin analogs and biosimilar antibody programs that are partnered with Mylan. Two molecules, Pegfilgrastim and Adalimumab, entered global Phase III clinical trials. The global Phase III trial for Trastuzumab initiated previously is progressing in more than 100 sites around the world. An initial emerging market focused Phase III trial for Bevacizumab is also underway. Two global Phase III clinical trials for generic Insulin Glargine have also progressed well with patient recruitment in Type 1 diabetes already completed and in Type 2 diabetes expected to be completed soon.

**4. Focus on operating margins.**

We have managed a healthy operating margin despite lower offtake of a key specialty API and temporary setbacks in the MENA region. Our EBITDA margin was steady at 24% despite a sharp 29% increase in R&D expenses. This is a result of a conscious effort at product portfolio rationalization especially in Branded Formulations, a continued focus on operational excellence, debottlenecking capacities and cost optimization. We hope to continue to benefit from an improved product mix comprising fermentation-based APIs and our biologics portfolio. We will continue these efforts in FY16 including evaluating alternate energy sources as a part of our sustainability efforts.

Q

**What were some of the challenges faced by the Company during the year under review?**

A

During the year, we were constantly challenged with capacity constraints for meeting the growing demand of insulins on one hand while on the other we had to deal with the reduced demand for one of our specialty API. Geopolitical uncertainties in some of the markets further impacted our business in that region. We have put in place measures to overcome these temporary setbacks which we hope will yield desired results over the course of FY16.

Q

Our conscious decision to rationalize our product portfolio in Branded Formulations impacted topline growth in this business. However, this rationalization is in line with our focus on specialty molecules in chronic therapy areas and has resulted in a substantial improvement in profitability.

A

### What provides you optimism about Biocon's strategy and operating model?

We believe that our differentiated product portfolio with a focus on access and affordability is in tune with the 'Exclusively inclusive' approach of our business. Our innovation-led strategy is aligned with the trends in global healthcare wherein biologics are playing an increasing role in addressing unmet medical needs. This has resulted in increasing demands for affordable biosimilars and other generic protein drugs to mitigate the pressures on healthcare budgets.

Although R&D costs are significant and gestation periods for biologics development are longer than small molecules, we have managed the risks prudently through a judicious mix of partnering and phasing of capital investments. We have also focused on revenue generating opportunities in emerging markets whilst working towards approvals in the developed markets. Our declared intent of unlocking value in Syngene through an 'Offer for Sale' by Biocon is largely geared towards resourcing our maturing R&D programs.

Each of our biosimilars R&D programs that have advanced into the clinic address potentially large commercial opportunities as reflected by the cumulative current market size of about US\$60 billion for the reference products. Our small molecule portfolio comprises of specialty, largely fermentation-derived or complex generics wherein we believe the competitive intensity may be lower.

We have laid a strong emphasis on quality as reflected in our successful completion of regulatory inspections from the US, the EU and other jurisdictions. Our facilities, including those of Syngene, met all cGMP expectations of the regulators.





# Vision

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



# Mission

To be an integrated Biotech enterprise of global distinction.

Essential to this mission is Excellence in:

- Intellectual asset creation through discovery, research and development
- State-of-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 behavior
- Performance driven work culture
- Value creation through innovation and differentiation
- Quality through compliance and best practices
- Collaboration, team work and mutual respect



## Awards & Accolades

Biocon's strong brand equity, commitment to address unmet patient needs, steadfast pursuit of affordable innovation and a keen sense of responsibility towards the society and the environment are reflected in the awards and accolades conferred upon the Company. Our efforts have been recognized in areas ranging from business management to talent engagement to technology implementation as well as CSR. We are humbly proud of our achievements that continue to motivate team Biocon to pursue new challenges every day.

1. Biocon won the **Thomson Reuters India Innovation Award 2014** for focus on innovation in drug affordability.

2. Biocon was conferred the **Excellence & Leadership Award** presented by the World CSR Congress for 'Best Corporate & Financial Reporting' for Annual Report 2014, centered around the theme of 'Tryst and Trust.' The award, endorsed by the Asian Confederation of Businesses and World CSR Day, recognized the report for comprehensive presentation of financial, corporate, sustainability and governance related information.

3. Biocon was recognized as the '**Most Caring Company**' by the World CSR Day for its commitment towards enhancing access to

### Brand Biocon



affordable healthcare.

4. **Sir J. C. Bose Memorial Award** (Institutional category) was conferred on Biocon by Indian Science Monitor

(ISM) for the Company's contribution to the field of biotechnology with special reference to the launch of **ALZUMAb™** (Itolizumab), the world's first novel anti-CD6 antibody.

5. Our Environment Management Best Practices reflecting in our exemplary operations and systems were recognized with the **Greentech Environment Gold Award** conferred by Greentech Foundation, Kolkata.

6. Biocon's API facility at Hyderabad won two prestigious Awards for EHS Practices from **Confederation of Indian Industry (CII)– Southern Region**. We were the only pharma company in the region to receive this award in the last eight years. We also secured a '**4 Star Rating**' from among over 130 players across sectors.

7. Biocon received several awards for information technology initiatives: **EDGE (Enterprises Driving Growth and Excellence Using IT)** from **Information Week**. Two Business Technology Awards from **Dataquest** for **'Unified Communications'** and **'Mobility'**. The **'Pioneer Investor in Cloud Services & Solutions'** Award from Microsoft. Syngene received the **SAP ACE Award 2014** for 'Complex SAP Implementation'.

8. Biocon was conferred with the **A.P. Chowdappa Memorial Award** for

**Excellence in Communication** in the Corporate PR category at the 9th Global Communication Association (GCA) Conference, recognizing the strong reputation of Brand Biocon and its achievements in the corporate sector.

9. Biocon was conferred with the **Most Engaging Talent Brand in India** award recognizing the brand's ability to engage and attract talent on LinkedIn, at the ConnectIn Awards, Singapore.

10. Biocon received Pharmexcil's **Bulk Drugs – Gold Patent Award** for two consecutive years in recognition of the commendable contribution to developing pharmaceutical patents.

11. The **SCALE (Supply Chain And Logistics Excellence) Award 2015** for exemplary performance in pharmaceuticals category by CII in recognition of our specialized Supply Chain capabilities and logistics practices.

## Corporate Social Responsibility



Biocon Foundation has been recognized for the integrated healthcare initiatives through which it is constantly engaged in improving the quality of life of several thousand communities in India.

1. **Golden Peacock Award - 2014** for **'Corporate Social Responsibility'** awarded by the Institute of Directors, India, for the relentless efforts to drive social change and empowerment of rural communities through public health, civic infrastructure and education programs.

2. The prestigious **WHO India Public Health Champion Award 2015** for our various initiatives in the area of public health.

3. Asia's Best CSR Practices Award 2014 by CMO Asia at World CSR Congress for our 'Community Cervical Cancer Screening Program.'

4. Certificate of Appreciation from NASSCOM Foundation at the NASSCOM Social Innovation Forum 2015 for introducing 'Mobile Early

Detection and Prevention of Oral Cancer Program' under the category ICT led Social Innovations by a Corporate (CSR).

1. She was ranked **Second** among the **100 Most Influential People** across the globe in the **field of Medicine** in the **Global Medicine Maker Power List 2015** published by a top UK-based medical publication, The Medicine Maker.

2. She was awarded the most coveted **2014 Global Economy Prize for Business** by the Kiel Institute for World Economy, Germany.

3. She was also conferred the **Othmer Gold Medal 2014** by the Chemical Heritage Foundation, Philadelphia, PA, for her outstanding contribution to the Indian biotech sector.

**Kiran Mazumdar-Shaw** Chairperson, Biocon, was conferred with several prestigious global awards and recognitions during FY15. Key among them were:

4. The Huffington Post positioned her at No. 14 in the global list of '**Top 30 Social Influencers in Biotech and Biopharma**.'

5. She also featured in Fortune magazine's list of '**Top 25 Most Powerful Women in Asia-Pacific 2014**' and Forbes magazine's '**100 Most Powerful Women in the World**.'

6. Foreign Policy magazine, a US publication, has named her among the '**100 Leading Global Thinkers of 2014**.'





# Research & Development



At Biocon, our Research & Development (R&D) programs are anchored around the overarching vision of being 'Exclusively inclusive.' With a focus on universal access to healthcare, we have taken the lead to address unmet patient needs through affordable innovation. Over decades, we have expanded our investments in building a robust scientific talent pool, cutting-edge infrastructure, deep regulatory knowledge and creation of intellectual assets.

As spending on pharmaceutical and R&D continues to increase in step with our vision of enhancing patient reach to affordable bio-therapeutics, there is a growing priority to enhance returns from research investments.

With five of the world's 10 largest R&D budgets coming from pharma companies, the industry takes the lead in research (Source: *EU R&D Scoreboard*). Between 2004 and 2013, the total industry expenditure on

R&D has risen from US\$88 billion to US\$135 billion and is expected to reach US\$149 billion by 2018 (Source: *EvaluatePharma*).

As an extension of this reality, the estimated cost of bringing a new chemical or biological product to market has more than trebled from US\$451 million in 2004 to US\$1.5 billion in 2013 (Source: *J. Mestre-Ferrandiz, J. Sussex and A. Towse, 'The R&D Cost of a New Medicine'*). While the R&D expenditure has been on the upswing,

the average number of annual US Food and Drug Administration (FDA) approvals for New Molecular Entities (NMEs) has declined from 31.5 in 1990 to an average 22.9 from 2001-2010 (Source: *FDA*).

At Biocon, research and development is the foundation of our business model. In line with our commitment to innovation, we doubled our gross research investment to ₹3.29 billion in FY15 as compared to the previous year.



**Our Four-Pronged R&D Focus:**

- Operate across the oncology, diabetes and autoimmune spaces.
- Leverage our expertise in fermentation to drive novel and biosimilar programs.
- Create a differentiated pipeline that stretches across the biopharma value chain.
- Leverage strategic alliances and partnerships for better outcomes.

Biocon's discovery-led R&D practice focuses on the full drug development pathway - from process development to non-clinical and clinical research. Our highly qualified scientific team drawn from various parts of the world is a part of the best-in-class innovation ecosystem offered by Biocon. The depth and breadth of our technological and scientific pool empowers us to engage in cutting-edge research to develop innovative yet affordable bio-therapeutics for the world's most debilitating diseases.

Under the remit of our R&D, our 'Exclusivity' is anchored around the therapeutic focus on select chronic diseases and quest for novel and follow-on biologics,

leveraging the India advantage. The 'Inclusive' element is reflected in our commitment to drive affordable access to expensive biopharmaceuticals for patients, partners and healthcare systems across the world.

Our proprietary fermentation technology for manufacturing affordable rh-Insulin, helping millions of patients across the globe in diabetes management, reflects our pursuit of inclusivity. This 'Exclusively inclusive' approach has enabled us to improve patient compliance, widen the patient pool and expand the market, thus enhancing access and making a difference to global health.

**Strengths**

Our R&D principally focuses on novel molecules, biosimilars and complex small molecules. We leverage our world-class infrastructure, India's cost competitiveness and our access to world-class talent. While bolstering our ability to address our R&D objectives, these advantages also enable us to maximize the productivity of R&D investments. The fact that we operate one of South East Asia's largest biologics facilities adds to our strengths. Our inspiring work environment built on the foundations of a world-class R&D ecosystem attracts the best global talent.

Over the decades, we distinguished our offerings through our deep fermentation capabilities complemented by world-scale capacities and analytical skills. Our high-end talent, equipped with the best international experience in the areas of research, development, regulatory and manufacturing, helps ensure seamless movement of the targeted product from lab to market.

**Developing Novel Biologics for Cancer, Diabetes and Autoimmune Conditions:**

- Seven novel molecules under clinical development: Two in Phase III/ IV; three in Phase II and two in Phase I/ early discovery.
- Once approved, our Oral Insulin is likely to usher in a paradigm change in treating diabetes.

**Key Developments**

The year FY15 marked the initiation of global Phase III trials for Insulin Glargine, which has global sales of over US\$8 billion. Over the next few years, we expect to commercialize Glargine in partnership with Mylan. This will address the currently underserved and growing diabetic population. The market for biosimilar insulins, which stands at

### Developing Biosimilars to Introduce Critically-Required Drugs at Affordable Prices:

- Six molecules across generic insulins, MAbs and recombinant proteins undergoing Phase III clinical development.
- Three under preclinical development

~US\$20 billion, is growing annually in double-digits.

We also made significant headway in the development program of our portfolio of monoclonal antibodies (MAbs) and recombinant proteins.

- Two molecules, Pegfilgrastim and Adalimumab, entered global

Phase III clinical trials.

- Phase III global clinical trial for Trastuzumab is progressing in over 100 sites around the world.
- An initial RoW focused Phase III trial for Bevacizumab is also underway.

### Intellectual Wealth

In our pursuit of innovation, we have consistently created intellectual wealth through our incisive IP strategy. This strategy has provided us a distinct competitive edge in biopharmaceuticals. Today, Biocon has filed over 1,150 patent applications and holds over 530 patents.

During the year, over 35 new patent applications were filed while we received over 20 patent approvals.

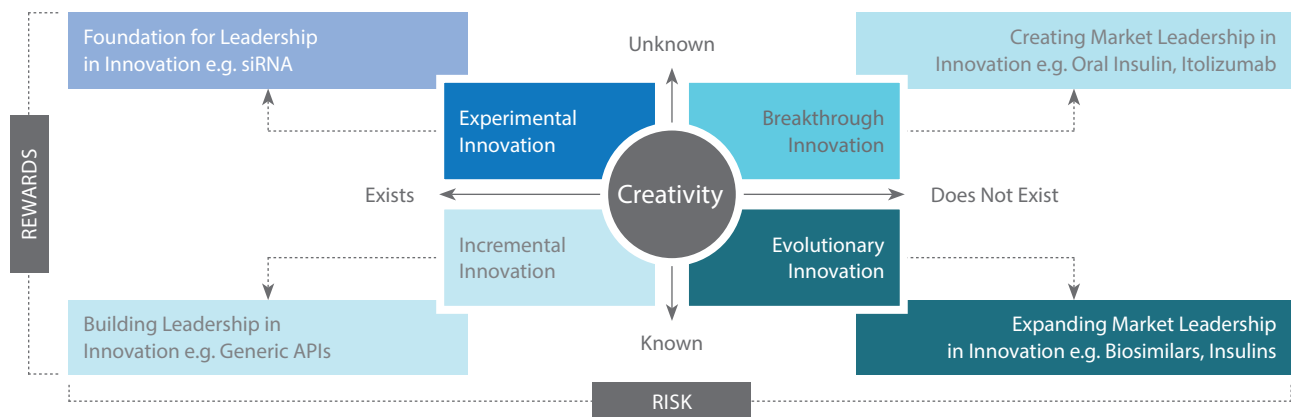
### Quality & Regulatory

Biocon is committed to bring high-quality drugs to patients globally.

Our operations are guided by stringent quality controls in compliance with global standards, thus enabling us to achieve the highest quality standards for all our products. A consistent and spotless track record on quality is essential for validation of processes, data review by regulators and final qualification and approval of facilities. During the past year, we successfully underwent 10 audits by some of the leading global health regulators without any adverse observations.

Our deep commitment to innovation and cutting-edge research is reflected in our achievement of becoming 'Exclusively inclusive'.

## Our Innovation Matrix





#### Developed and Commercialized Differentiated Products in Challenging Therapeutic Spaces:

- Making a difference to thousands of cancer patients through our 'best-in-class' anti-EGFR MAb, Nimotuzumab, which has significantly better efficacy and superior safety profile.
- Brought to market 'first-in-class' anti-CD6 MAb, Itolizumab, which is a pipeline within a product for various autoimmune diseases.
- Introduced the world's most affordable Trastuzumab in India, currently under Phase III trials for global markets.
- Addressing the large need for affordable insulin therapy through India's first indigenously-produced rh-Insulin and Insulin Glargine.

# Board of Directors



Standing from left:

Mr. Daniel M. Bradbury, Dr. Jeremy Levin, Mr. Russel Walls, Dr. Bala S. Manian, Prof. Charles L. Cooney, Ms. Kiran Mazumdar-Shaw, Mr. John Shaw, Dr. Vijay Kuchroo, Ms. Mary Harney, Mr. Peter Bains, Prof. Ravi Mazumdar, Mr. Suresh N. Talwar, Dr. Arun Chandavarkar and Prof. Catherine Rosenberg.

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

First generation entrepreneur with nearly 40 years' experience in biotechnology + Well recognized global business leader + Independent Member of the Board of Infosys + Chairperson of the Board of Governors of the Indian Institute of Management, Bangalore + Recipient of 'Othmer Gold Medal 2014' by the U.S. based Chemical Heritage Foundation + '2014 Global Economy Prize for Business' by 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' + Recipient of two most prestigious national awards, the Padma Shri and the Padma Bhushan.

**Mr. John Shaw***Vice Chairman*

Foreign promoter and a whole-time director + Master's degree in Arts (Economic hons.) in History and

Political Economy from Glasgow University, United Kingdom + Served in senior corporate positions at various locations 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 25 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.

**Dr. Bala S. Manian***Non-Executive, Independent Director*

Chairman and Founder, Reamatrix Inc. + Expert in the design of electro-optical systems + Authored several peer-reviewed scientific publications + Holds more than 40 patents, many of which have resulted in successful commercial products + Recognized through numerous awards for contributions as educator, inventor and entrepreneur, including Technical Academy Award in Digital

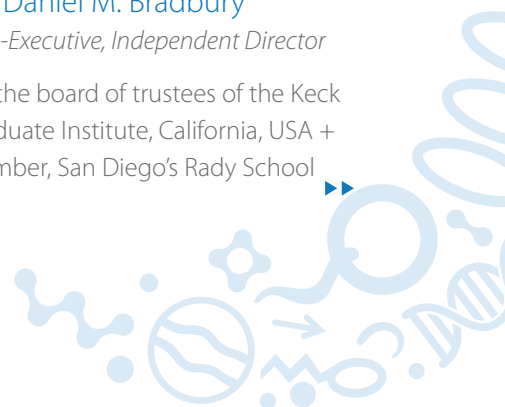
Cinematography by Academy of Motion Pictures, Arts and Sciences.

**Prof. Charles L. Cooney***Non-Executive, Independent Director*

Director, Mitra Life Sciences, Pronutria Inc. and LS9 Inc. + Professor, Chemical & Biochemical Engineering, MIT, USA + Research interests include biochemical engineering and pharmaceutical manufacturing + Recipient of prestigious awards, including Gold Medal of the Institute of Biotechnology Studies + The James Van Lanen Distinguished Service Award from the American Chemical Society + Food, Pharmaceutical and Bioengineering Award from the American Institute of Chemical Engineers + US FDA's Advisory Committee Service Award + Bachelor's degree in Chemical Engineering from the University of Pennsylvania, Master's degree and a Ph.D. in Biochemical Engineering from MIT.

**Mr. Daniel M. Bradbury***Non-Executive, 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 + Honored with the Corporate Directors Forum Director of the Year Award for Enhancing Economic Value (2012) + The Ernst & Young's Entrepreneur of the Year Finalist (2012) + 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.

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### Ms. Mary Harney

*Non-Executive, 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.

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### Prof. Ravi Mazumdar

*Non-Executive, Independent 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.

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### Mr. Russel Walls

*Non-Executive, Independent Director*

Chairman, Aviva Life Holdings Ltd.

Experience of more than 45 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.

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### Mr. Suresh N. Talwar

*Non-Executive, Independent Director*

Board of several leading companies such as Merck Ltd., Blue Star Infotech Ltd., Larson & Toubro Ltd., Johnson & Johnson Ltd. + Founder Partner of Talwar Thakore & Associates + Specialization in corporate law and related fields + Legal counsel to numerous Indian companies, multinational corporations and Indian / foreign banks + B.Com from the University of Mumbai, LL.B. from the Government Law College, Mumbai and is a solicitor of the Incorporated Law Society, Mumbai.

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### Dr. Vijay Kuchroo

*Additional 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 + Received the Fred Z. Eager Research prize and medal for his Ph.D. research work at the University of Queensland, Brisbane, where he specialized in pathology.

#### Dr. Jeremy Levin

*Additional Independent Director*

Chairman of Ovid Therapeutics + 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, Masters of Arts 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.

#### Mr. Peter Bains

*CEO & Director, Syngene*

Director of Sosei, a Tokyo-listed Japanese biotechnology company + Extensive track record of achievement as a senior pharma and life sciences executive + Non-Executive Chairman, Fermenta Biotech Ltd. and Director and Member of Audit Committee, Kromek Group Plc.

#### Prof. Catherine Rosenberg

*Director, Syngene*

University Research Chair Professor and Chairman, Department of Electrical and Computer Engineering, University of Waterloo, Canada.



# 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





# Core Committee



**Ms. Kiran Mazumdar-Shaw**  
*Chairperson & Managing Director,  
Founder - Biocon Limited*

**Mr. John Shaw**  
*Vice Chairman,  
with Biocon since 1998*

**Dr. Arun Chandavarkar**  
*Chief Executive Officer  
& Joint Managing Director,  
with Biocon since 1990*

**Mr. Ravi Limaye**  
*President, Marketing,  
with Biocon since 2014*

**Mr. Siddharth Mittal**  
*Chief Financial Officer,  
with Biocon since 2013*

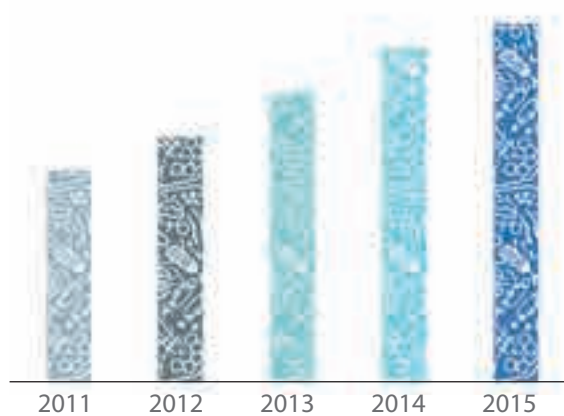
**Mr. Amitava Saha**  
*Sr. Vice President, Human Resources,  
with Biocon since 2013*

# Financial Highlights

## Total Revenue

(₹ mn)

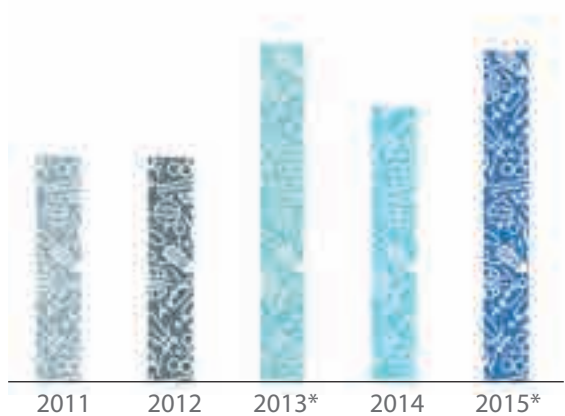
18,576   21,483   25,380   29,332   31,429



## Profit

(₹ mn)

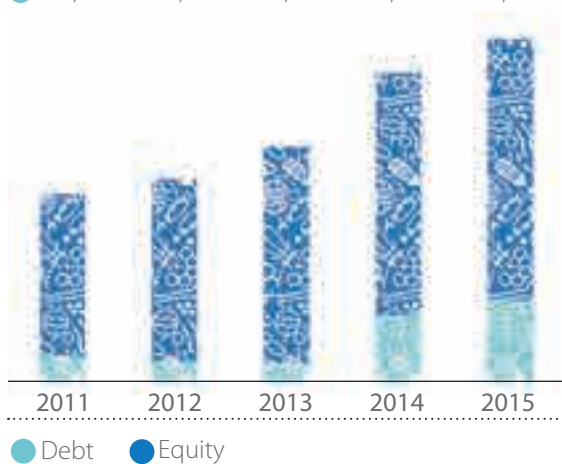
3,399   3,384   5,089   4,138   4,974



\* PAT includes exceptional income

## Debt : Equity

● 20,328   22,724   26,946   30,267   32,706  
● 3,341   2,709   2,488   8,497   10,306

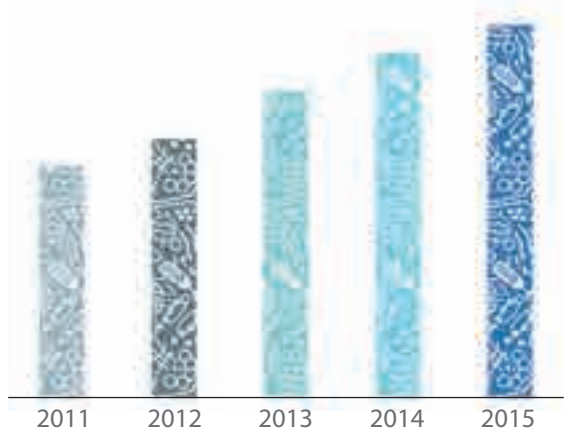


● Debt   ● Equity

## Net Worth

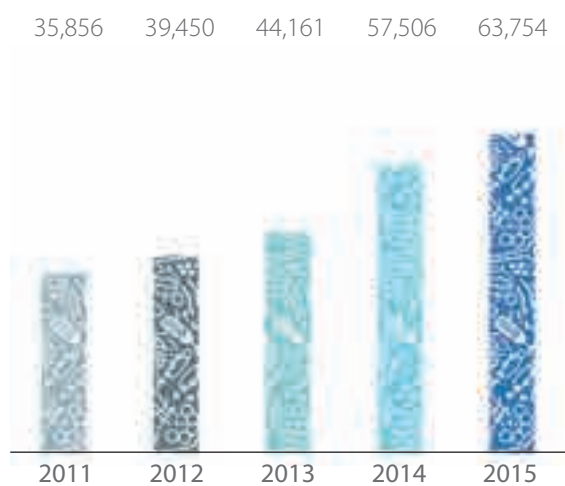
(₹ mn)

20,328   22,724   26,946   30,267   32,706



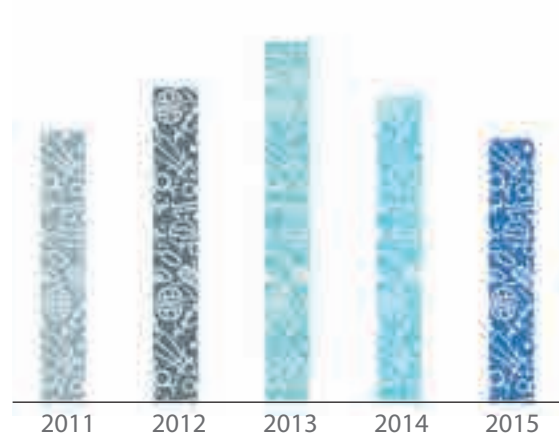
## Total Assets

(₹ mn)



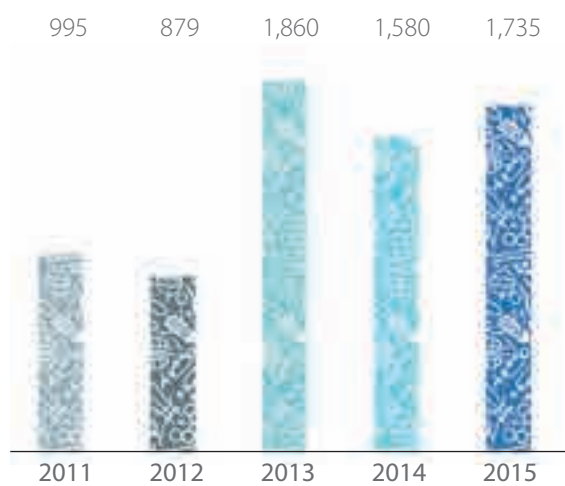
## Current Ratio

1.70 1.97 2.26 1.91 1.65



## R&amp;D Spend\*

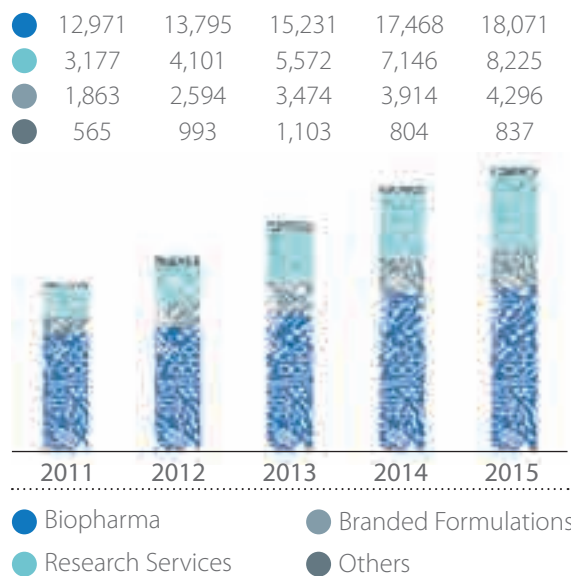
(₹ mn)



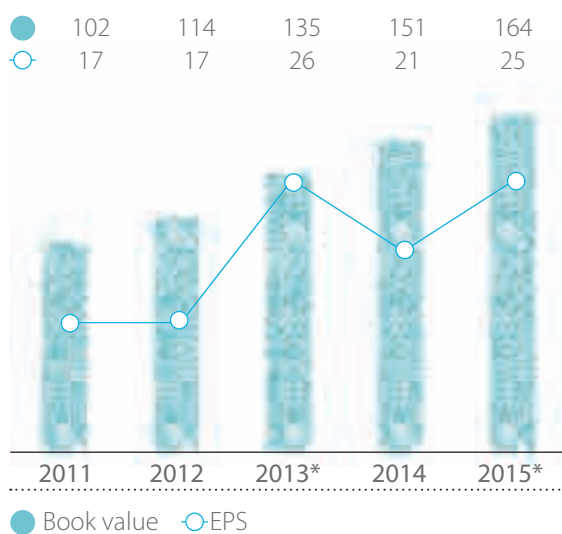
\* Includes revenue &amp; capital R&amp;D

## Revenue Break-Up

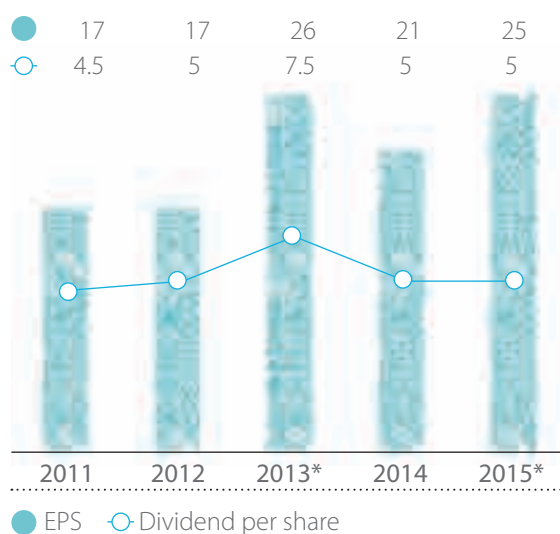
(₹ mn)



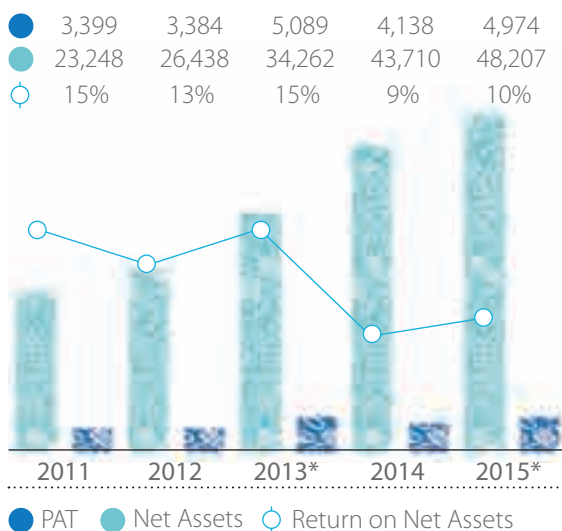
### EPS and Book Value per Share



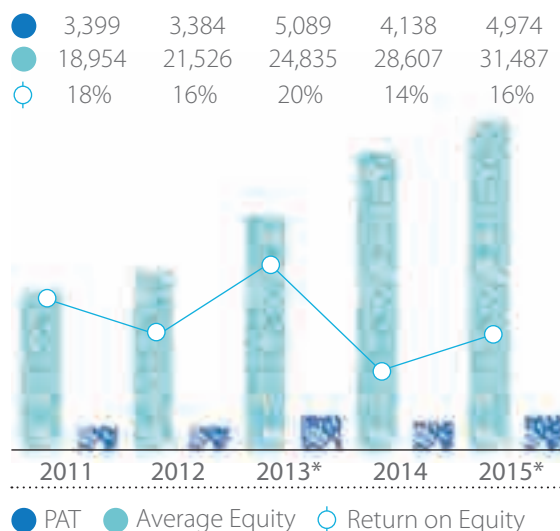
### EPS and Dividend per Share



### Return on Net Assets



### Return on Equity



\* PAT includes exceptional income



## Performance-Business Units

Novel Molecules

Biosimilars

Branded Formulations

Small Molecules

Global Marketing

Research Services

# Business Units



## Novel Molecules

The 'Exclusively inclusive' approach is the bedrock of Biocon's innovation strategy. By translating breakthrough innovation into affordable therapy, we are addressing the challenge of unmet medical needs in cancer, diabetes and autoimmune diseases. Biocon, which identifies itself as an 'innovator from the developing world', has leveraged India's value advantage and scientific excellence to accelerate new and differentiated therapies to market.

Our quest for exploring newer treatments for addressing debilitating diseases has led to the development of two novel monoclonal antibodies (MAbs). India's first indigenously produced

monoclonal antibody for head and neck cancer, Nimotuzumab, introduced as BIOMAb EGFR®, is helping meet the cancer treatment challenge. The world's first anti-CD6 monoclonal antibody, Itolizumab, brand named ALZUMAb™, has made psoriasis management easier for thousands of patients in India. We are currently developing the world's first orally delivered insulin which is expected to revolutionize diabetes treatment and management.

### Market Trends

Over the next few years, several new drugs are expected to be launched, benefiting patients the world over. According to IMS, over 40 New Molecular Entities (NMEs) are likely to

be approved annually, going forward. Drugs for cancer and neurological disorders, anti-infectives and anti-virals comprise nearly half the pipeline of NMEs in late-stage clinical studies. In parallel, risk-sharing models based on co-development of novel drugs have emerged as the new paradigm. Our state-of-the-art infrastructure combined with the best global minds and our R&D competence position us as ideal collaborators for both large pharma innovators and small biotech firms. Our efficient and cost-competitive asset development capabilities also make us attractive strategic global drug development partners.



**S**o far, over 400 people including Type 1 diabetics, Type 2 diabetics and healthy volunteers have participated in IN-105 clinical studies.

### Core Strengths

- In-house expertise along the drug value chain
- Pipeline includes proprietary and partnered programs
- R&D strategy covers early, mid and late-stage assets
- Exploring early-stage assets that leverage our expertise
- Demonstrated expertise in taking novel biologics from lab to market
- Translated breakthrough innovation into affordable therapy

### Key Developments

Given the basket of seven novel assets under clinical development, Biocon's pipeline is an interesting combination of early and advanced stage assets. With the completion of the first set of clinical trials in the US in April, the Oral Insulin program, IN-105, made substantial progress. These trials pave the way for the next phase of development, which is key to unlocking the enormous potential this asset offers. The US studies, conducted on about 100 subjects under a US IND, can be classified as Phase-Ib/IIa trials. These were aimed at answering questions around pharmaco-dynamic impact on drug absorption, intra-subject variability and effects of food. So far, over 400 people including

Type 1 diabetics, Type 2 diabetics and healthy volunteers have participated in IN-105 clinical studies.

Biocon continues to be in discussion with potential partners for the joint development of its novel asset Itolizumab, a 'first-in-class' novel anti-CD6 biologic, for regulated markets. The Cuban origin of this product requires the potential licensee to obtain additional regulatory clearances from the US government, leading to delays in the process. While we hope that the thaw in US-Cuba relations will help overcome regulatory barriers, we continue with the development of the asset. Our priority currently is getting proof-of-concept data in rare neurological indications which have significant unmet medical need.

We had expanded our novel pipeline through collaborations with Quark Pharma and Advaxis in FY14. During the year, we made progress on the two high potential novel assets we are developing on the small interfering RNA (siRNA) platform with Quark Pharma for rare indications of ophthalmology and organ transplant. These molecules could change the treatment paradigm for such orphan indications.

The innovative immunotherapy technology we licensed from Advaxis has been truly exciting. Biocon was among the first companies to

identify the potential of this unique technology in the area of cancer immunology. Our strong belief in the science associated with this technology has been validated by multiple collaborative partnerships signed by Advaxis with major global players over the past 12 months. This asset has tremendous potential in treating HPV-associated cervical cancer, a devastating disease seen primarily in developing countries. In targeting a huge unmet medical need, this asset epitomizes our 'Exclusively inclusive' R&D philosophy.

### Outlook

Bringing path-breaking proprietary products to global markets is Biocon's long cherished objective. As drug development becomes an expensive and high-risk endeavor, we are leveraging our robust R&D engine to deliver affordable innovation. Our global competitive edge rests on our high-quality talent, process innovation and high-value licensable research assets. Going forward, we expect R&D spends to continue to be between 8%-10% of biopharmaceutical sales, reflecting our investments in pipeline expansion as well as advances in novel and biosimilars programs.

### Oral Insulin: Novel MOA

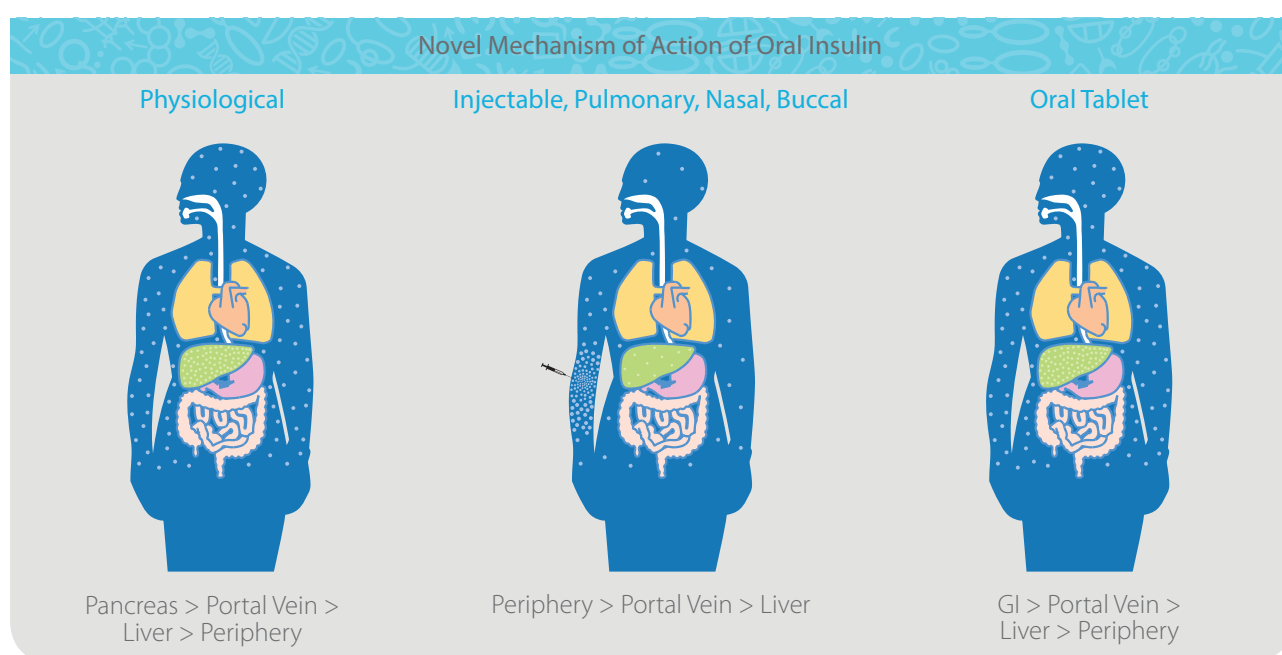
Biocon's Oral Insulin has a novel mechanism of action (MOA). IN-105, absorbed from the gastro-



intestinal tract, directly reaches the liver and re-establishes normal physiological, portal to peripheral gradient of insulin. By targeting the liver, an organ central to glucose

metabolism, IN-105 mimics the natural physiology of the body. This results in lowering the risk of hypoglycaemia when blood sugar levels fall to abnormally low levels

and also prevents weight gain. No other non-invasive insulin delivery mechanism has the ability to achieve such results.



#### Novel Assets Under Clinical Development

		Therapeutic area	Molecule
Phase III/IV	Two Molecules	Oncology Autoimmune	BIOMAb EGFR® (Nimotuzumab) ALZUMAb™ (Itolizumab)
Phase II	Three Molecules	Diabetology Ophthalmology Oncology	IN-105 QPI-1007 ADXS-HPV
Phase I	One Molecule	Oncology	Anti-CD20
Early Discovery	One Molecule	Oncology	Fusion Proteins

With Itolizumab, Biocon has taken the lead in demonstrating the critical role that Th17 cells play in autoimmunity.

### Itolizumab: Novel MOA

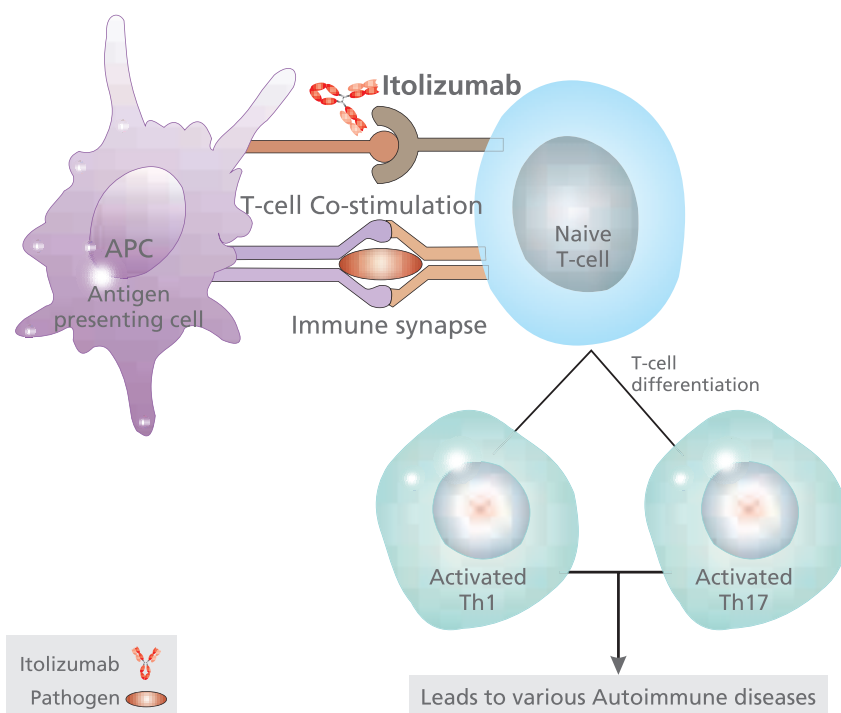
Itolizumab has a unique MOA that inhibits CD6-mediated co-stimulation of T-cells and down-regulates production of multiple pro-inflammatory cytokines. Significantly, since T-cells in circulation are not depleted, the general immunity is not compromised and the body continues to fight infection.

Traditionally, pathogen activated

naive T-cells were recognized for differentiating into different subsets with distinct effector functions: Th1 and Th2. Recently, this paradigm evolved to incorporate the highly exciting discovery of a third subset of T-cells - Th17. With emerging data demonstrating the critical role that Th17 cells play in autoimmunity, there is increased focus to design ongoing research around Th17. Itolizumab has taken the lead in this

area. It targets CD6, a cell surface receptor expressed T-cell, shown to reduce proliferation of Th1 and Th17 cells. Biocon is among the few companies with a validated MOA and clinical data involving the Th17 pathway and is probably the first company to take such a product from lab to market. We launched this product as ALZUMAb™ for chronic plaque psoriasis in India in 2013.

### Evolving Science Validates Novel Mechanism of Action of Itolizumab (ALZUMAb™)



Itolizumab prevents T-cell co-stimulation and further differentiation of activated T-cells which acts as a potential therapeutic in autoimmune diseases like Psoriasis, Rheumatoid Arthritis and Multiple Sclerosis



*State-of-the-art integrated insulins manufacturing facility in Malaysia commissioned*

## Biosimilars

In keeping with our 'Exclusively inclusive' philosophy, we have leveraged our core strength of fermentation technology to develop a wide portfolio of generic Insulins and Analogs, biosimilar Monoclonal Antibodies (MAbs) and recombinant proteins. We have emerged as a significant global player by reinforcing our scale, competence and pioneering technology capabilities. With a view to enhance drug affordability for patients, partners and healthcare systems,

we focus on affordable innovation and deliver high-quality, world-class products across the globe.

### Market Trends

The articulation and implementation of biosimilar guidelines in developed and emerging markets are picking up pace. The month of March 2015 witnessed a milestone announcement when the US FDA approved the sale of a Filgrastim follow-on product, the first-ever approval for a biosimilar granted by them. Earlier in 2013, European

Medicines Agency's nod for biosimilar Infliximab marked the introduction of the first biosimilar monoclonal antibody in Europe. Going forward, a shift is expected towards targeted therapies for life-threatening conditions such as cancer and autoimmune diseases. This will be catalysed by a growing preference for such therapies as well as their progressive genericization with the first set of biologics losing their patents. From US\$1.3 billion in 2013, the biosimilars market is

**B**iocon's rh-Insulin today has marketing approvals in 60 countries. Our Insulin Glargine is approved in 20 countries.

expected to reach ~US\$24 billion in 2019 (Source: Frost & Sullivan Global Biosimilars Report) as a higher number of products penetrate North America, Europe and Asia.

#### Core strengths

- Global-scale, complex biologics manufacturing capabilities
- Facilities accredited by international regulatory agencies
- Extensive physico-chemical and biological characterization capabilities
- Decade-long experience and demonstrated expertise in developing MABs and other biologics
- Global strategy led by initial commercialization in emerging markets
- Strong portfolio of generic insulin analogs and biologics in advanced stages of development
- Strategic global and regional partnerships

#### Key Developments

##### Generic Insulins & Analogs

At Biocon, we are developing a range of affordable basal, rapid and intermediate acting generic insulins for patients worldwide. The portfolio comprises Recombinant Human Insulin (rh-Insulin), Insulin Glargine, Insulin Aspart and Insulin Lispro. Our

generic insulins portfolio targets a US\$20 billion market opportunity as per 2014 sales of innovator reference products.

Biocon has been recognized for its proprietary fermentation technology that enabled it to produce rh-Insulin efficiently and cost-effectively. Over the years, we have leveraged this advantage to provide affordable access to rh-Insulin to patients and partners across the world. In 2004, we introduced the first indigenously developed and produced rh-Insulin, Insugen®, in India. Since then, millions of diabetics have benefited from this product and have lived a better life. Today, our Insugen® is the largest generic insulin brand in India.

Biocon is probably the largest insulins producer in Asia and our rh-Insulin today has marketing approvals in 60 countries. In FY15, it became the first generic insulin to be introduced in Malaysia, a country with a very high incidence of diabetes. We hope to make a significant difference in Malaysia by providing diabetics access to an affordable generic insulin.

In line with our global ambitions, we have been pursuing a harmonized clinical development strategy for the launch of rh-Insulin in developed markets including the EU and the US. Our Malaysian facility, once

commercially operational, will enable us to meet the growing demand for insulins and analogs in these markets.

#### Clinical Development

Our strategic collaboration with Mylan is focused on the global development and commercialization of generic versions of three insulin analog products: Glargine, Lispro and Aspart.

Glargine, an important basal insulin, is a global opportunity pegged at ~US\$8 billion in 2014, as per innovator sales. Two global Phase III clinical trials for generic Insulin Glargine, initiated in 2014, have made significant progress. Patient recruitment for the Type 1 diabetes study has been completed while the recruitment for the Type 2 diabetes study is expected to be completed later in 2015. Phase III clinical trials on both Type 1 and Type 2 diabetes are quite significant in the development process of this important therapy for diabetics. This is a non-inferiority study to compare the efficacy and safety of Biocon and Mylan's Insulin Glargine with the innovator product.

Currently, our Insulin Glargine is approved in 20 countries. We are gearing up to capitalize on this opportunity in the emerging markets. Our Glargine brand, BASALOG®, has benefited thousands of patients in India since its launch in 2009.



During FY15, our product became the first Insulin Glargine to be approved in Mexico under the new Biocomparable Approvals Pathway defined in 2012. This will provide access to a generic basal insulin, thus expanding the diabetes management therapy portfolio in Mexico, a country with over 9 million diabetes cases.

Insulin Lispro and Insulin Aspart are in different stages of pre-clinical development. From a strategic standpoint, a rapid-acting insulin analog will add significant value to our overall insulins portfolio.

## Insulin Devices

Our generic insulins business is complemented by a comprehensive device basket. During FY15, we introduced a second-generation affordable device by developing a cost-effective reusable pen. We are also developing a next generation disposable product in keeping with the growing need for such devices in India.

## Malaysia Plant Commissioned

Our most sophisticated insulins manufacturing facility was commissioned in Malaysia as scheduled. This is probably the largest integrated insulins manufacturing facility in Asia. It is well-equipped to manufacture drug substances and drug products and has full-fledged R&D capabilities. As we move ahead in FY16, we are preparing for the regulatory filings that will trigger qualification and approval by various international regulatory agencies. These approvals will pave the way for commercialization and will enable us to meet the growing need for affordable insulins in the developed markets of the US and Europe. Meanwhile, the facility will augment our existing capacities to meet the demand for insulins and analogs in emerging markets where our

products are already registered.

## Outlook

Over the next 10 years, our aim is to provide Biocon's insulin products, either rh-Insulin or insulin analog, to every one in five diabetic patients in need of insulin, anywhere in the world.

## Monoclonal Antibodies & Other Biologics

One of the fastest growing segments, MABs are revolutionizing the treatment landscape by offering a targeted therapy for life-threatening conditions like cancer and autoimmune diseases. Biocon has gained global recognition for being one of the key players in developing MABs and recombinant proteins. We have made significant investments in clinical development and manufacturing and strategic partnerships over the years.

Biocon and Mylan have one of the longest-standing partnerships in the global biosimilars space with a strong position in a promising industry. Since 2009, we have been developing a high-value portfolio of three MABs (Trastuzumab, Bevacizumab, Adalimumab) and two recombinant proteins (Pegfilgrastim, Etanercept). The innovator product sales of this portfolio stood at ~ US\$40 billion in

Our global Phase III clinical trial for Trastuzumab is progressing well in over 100 sites around the world.

2014 (Source: Company reports).

### Clinical Development

In FY15, we made considerable clinical progress in our portfolio of biosimilars that include MABs and recombinant proteins.

Clinical trials are in progress for four different Mylan-partnered programs, of which three are cancer therapies. Our global Phase III clinical trial for Trastuzumab is progressing well in over 100 sites around the world. A global Phase III trial for Pegfilgrastim is also underway. We are also conducting a Rest of World (RoW) focused clinical trial for Bevacizumab in metastatic colorectal cancer as part of our overall global development strategy for this

molecule. In the autoimmune space, a Phase III trial for Adalimumab has also been initiated.

The advancement of these programs in the clinic represents significant progress towards providing high-quality follow-on biologics to patients across the world.

Trastuzumab, introduced as CANMAB™ in India in FY14, is an important milestone in the collaborative biosimilars development program. It is the first non-innovator Trastuzumab approved anywhere in the world and we believe it is also the most affordable\* globally. Overall, CANMAB™ has helped increase patient access to Trastuzumab by

nearly 30% in India.

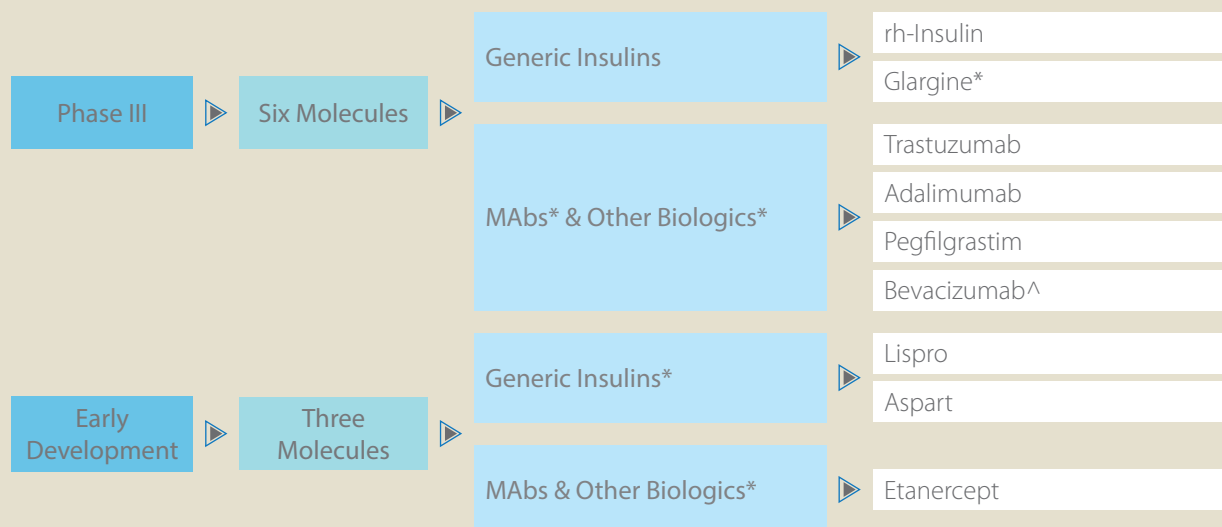
Biocon has licensed Trastuzumab in a few emerging countries and we are in the process of securing marketing authorizations.

### Outlook

We aim to deliver affordable biosimilars by building global manufacturing scale. Being ahead of the curve, we are among the few early players in this space, focusing both on developed as well as regional markets. Our goal is to make Biocon's oncology biosimilars available to at least one in 10 breast cancer patients globally.

(\* As per May 2015 MRPs)

### Biosimilars & Generic Insulins Pipeline



\* Biocon-Mylan partnered product

^ RoW-focused Phase III clinical trial





*Our Key Brands*

## Branded Formulations - India

In our Branded Formulations business in India our 'Exclusivity' is reflected in our differentiated approach to create a premium perception for ourselves as India's largest biologics-led, branded pharmaceutical company. Our specialty portfolio targets diabetes, cancer, end-stage renal disease,

immune disorders, sepsis and other life-threatening conditions. What makes us 'Inclusive' is our ability to develop these world-class biopharmaceuticals cost-effectively and offer them to millions of patients in India at a price they can afford. Beyond enhancing access to these differentiated therapies, we

have been 'Inclusive' in introducing patient-centric initiatives for disease awareness, prevention and management. We also engage with physicians through targeted educational programs related to best treatment practices for complex medical conditions. This combination of products, patient and physician



 CANMAB™ has enhanced patient access to this affordable critical therapy by nearly 30%.

support programs is enabling us to enhance the pool of patients we reach out to, thus making a difference to millions of lives.

### Market Trends

Ranked as the third largest globally in terms of volume and 13th in terms of value, the Indian pharmaceuticals market is expected to emerge as one of the Top 10 global markets by 2020 (*Source: PWC*). This robust growth will be fuelled by increased purchasing power, improved diagnosis, growing investment in healthcare infrastructure, deeper health insurance penetration and access to better healthcare. Changing lifestyles are leading to a rise in non-communicable diseases and subsequent demand for therapies to treat conditions such as cardiovascular diseases, diabetes, cancer, depression, among others.

The Indian pharma market, which is dominated by branded generics, has recovered after a general economic slowdown and trade issues related to the government's new drug pricing policy stymied sales growth in 2013. We believe much of the market turbulence has subsided and the future augurs well. The domestic pharmaceutical market reached

~₹864 billion (US\$13.8 billion) in FY15 (*Source: AIOCD MAT*).

### Core Strengths

- Portfolio approach focused on chronic disease segments
- Nearly 50% of revenues accrue from biologics
- Key products feature among Top 10 brands in diabetes, cancer, cardiovascular, nephrology segments
- Emerging as a specialty franchise
- Targeting in-licensing opportunities to drive specialty portfolio growth
- Enjoy trust of doctors, patients owing to proven scientific expertise
- Product range that is 'Made in India' and 'Made for India'

### Key Developments

Leveraging a portfolio of 60 differentiated brands across multiple therapy areas, the Branded Formulations-India business reported revenues of ₹4.30 billion growing at 10% Y-o-Y. It accounted for about 14% of Biocon's total revenues for FY15.

In keeping with our aspiration of

emerging as a specialty franchise, we continued to optimize portfolios with an intent to focus on select anchor brands and streamlined the sales force to support these brands. This strategic shift has resulted in a modest topline growth compared to previous years, but operating profit for the business has more than doubled from a year ago. Our Top 10 brands have grown over 30% in FY15, while the Indian pharma market reported an overall growth of 12% (*Source: IMS*).

Given our commitment to introduce innovative therapies at an affordable price to patients across India, Biocon entered into an agreement with Gilead Sciences to license its chronic hepatitis-C blockbuster product, introduced as Cimivir™ (Sofosbuvir) by Biocon. New brands such as CANMAB™ (Trastuzumab) in Oncology, BIONESP™ (Darbepoetin) in Nephrology and CytoSorb® in Critical Care have also delivered on Biocon's promise of increasing accessibility to critical therapies in India.

The launch of CANMAB™, the world's most affordable Trastuzumab, has enhanced patient access to this critical therapy by nearly 30% in India.



## Branded Formulations - Divisional Review

### Metabolics

The Metabolics division, which is a combination of brands in diabetes and cardiovascular therapies, has created a complementary portfolio resulting in a holistic treatment for co-morbid diabetes, hypertension and dyslipidemia.

During FY15, we introduced a second-generation, low-cost, reusable insulin pen, INSUPen® EZ, which provided diabetic people in India a user-friendly and affordable

device for effective management of diabetes.

Also during the year, our flagship brands Insugen® and BASALOG® reported remarkable growth, becoming the fastest growing brands in their respective categories. Insugen® continues to be the biggest Indian brand of insulin.

#### Patient-Centric Programs

During the year, the Metabolics division implemented several patient

outreach initiatives around screening, compliance and adherence. The 'Decade of Excellence of Insugen®' was celebrated to mark 10 years of the introduction of an affordable insulin in India. As a part of this program, a unique multi-stakeholder event 'Winning Together' was also organized to promote patient-doctor engagement and help raise awareness about managing diabetes through diet, exercise, foot care, among others.

**O**ncotherapeutics division crossed a significant revenue milestone of ₹1 billion in FY15.

Our Insulin Therapy Assistance Program (iTAP), a structured visit plan that involves counselling by Diabetes Care Advisors (DCAs) to improve patient compliance to insulin therapy, has led to significant positive outcomes. More than 450 patient education programs were conducted during the year that translated into 99% patient satisfaction and improved retention on therapy, up to 88%.

"I have controlled my diabetes with the help of insulins and medical support. Now I am fit and extremely happy with Biocon's patient services."

– A patient who participated in 'Winning Together' initiative

### Physician Education Programs

ABIDE, our novel diabetes education initiative for medical practitioners, has been doing extremely well. It has the unique distinction of being the first and only academic program to be recognized and accredited by the Endocrine Society of India, a premium academic society comprising top endocrinologists of international repute.

ABIDE is now gearing up to launch an online portal that will

enable physicians to share patient management experiences with their mentors and peers, thus enabling cross learning.

"The academic content of ABIDE was very precise and the speakers were highly competent. It was one of the best academic programs I have attended so far"

– A participant in one of the ABIDE programs

### Outlook

The division will continue to focus on diabetes therapies while offering affordable treatment options for associated cardiovascular diseases.

"Biocon needs to be congratulated for introducing this innovative program, ABIDE, which is transformational and path-breaking."

– A faculty member at the ABIDE program

### Metabolics: Our Inclusive Approach

**Top Brands** Insugen®, BASALOG®

**Patients**

- Nearly 120,000 patients registered on INSUPen®
- Over 40,000 patients have undergone iTAP program
- Over 1,600 patient-centric activities conducted so far
- Nearly 174,000 patient visits made by Diabetes Care Advisors

**Doctors** Conducted over 50 courses involving more than 2,000 physicians across 150 cities under the ABIDE initiative

### Oncotherapeutics

Launched in 2006, the Oncotherapeutics division is making a meaningful impact in cancer care in India with its niche portfolio of drugs, thus contributing significantly to our objective of bringing affordable and innovative medicines to the market. Biocon

has emerged as a leading oncology company and our Oncotherapeutics division crossed a significant revenue milestone of ₹1 billion in the year. Our top oncology brands performed exceptionally well, with BIOMAb EGFR®, CANMAb™ and Abraxane® catalysing the division to report exemplary growth in FY15.



CANMAB™, a convenient, affordable and new life-saving therapy option for HER2-positive metastatic breast cancer patients launched in FY14, has made a tremendous impact with thousands of patients undergoing treatment in the first year. It has been by far the best launch in the history of the Branded Formulations-India business, based on the number of lives it has touched.

#### Patient-Centric Programs

The division organized a 'Free Oral Cancer Screening Week' in collaboration with Indian Cooperative Oncology Network (ICON) and Indian Dental Association (IDA) during which over 8,700 people

were screened. It also offered free HER2 testing for metastatic breast cancer patients. It also joined hands with the Indian Cancer Society to raise breast cancer awareness in rural areas under the 'REACH HER2SAVE HER' program.

#### Physician Education Programs

Continuing medical education programs aimed at helping oncologists keep abreast with the latest developments in the field of oncology were held during the year. 'CONVERGE 2014', an exclusive summit, was held during the year to deliberate on breast cancer. It was well-attended by key oncologists from all over the country. A special book on breast cancer, authored by 125 oncologists, was also released during the event.

#### Outlook

As an extension of its mission to help cancer patients, the division is exploring other therapy options that will address unmet needs in cervical cancer, metastatic head & neck cancer and oesophageal cancer in India.

#### Oncotherapeutics: Our Inclusive Approach

Top brands	CANMAB™, BIOMAb EGFR®, Abraxane®
Patients	Over 20,000 patients treated since launch
Doctors	Coverage of over 1,400 oncologists

Hundreds of psoriasis patients, including a few from overseas, who underwent treatment with ALZUMAb™ in India have benefited immensely.

## Immunotherapy

The Immunotherapy division, established in 2010, has a niche portfolio of oral and topical immunosuppressants and our flagship novel biologic ALZUMAb™ (Itolizumab), the world's first anti-CD6 monoclonal antibody launched in India for acute psoriasis in FY14. The team has been engaged in bringing to the market its portfolio of safe, efficacious and affordable drugs for a wide range of immune-related disorders.

ALZUMAb™ is a new line of treatment for psoriasis, hence the team is focusing on market shaping through seminars aimed at educating the medical community on the benefits of using biologics for autoimmune diseases. The product has expanded the market. Hundreds of psoriasis patients, including a few from overseas, who underwent treatment with this innovative product in India have benefited immensely.

### Patient-Centric Programs

Besides regular patient outreach programs, special awareness campaigns on psoriasis were run on radio and print media for the benefit of patients and caregivers. A compassionate care program,

'Kiran: A Ray of Hope', has also been introduced for underprivileged patients who are unable to afford treatment with ALZUMAb™.

### Physician Education Programs

A high-impact, in-clinic communication program related to brand ALZUMAb™ was launched to get medical practitioners to understand the role of biologics in treating psoriasis.

An exclusive scientific session was held for key specialists with Dr. Vijay Kuchroo, a globally-renowned immunologist and an Independent Director on the Board of Biocon. Dr. Kuchroo provided deep insights into the evolving science of immunology and the role of Th17 in autoimmune diseases in the backdrop of ALZUMAb™ launched by Biocon for patients in India.

Biocon stepped up its outreach program through scientific presentations at international, national and zonal dermatology events like EULAR, the Annual Meeting of British Association of Dermatologists,

DERMACON and CUTICONS, as a part of its overall strategy to educate medical practitioners.

Several other programs targeted at dermatologists were also organized to increase awareness on the benefits of treatment with brands like TBIS® and PSORID™. The underlying objective was to improve the knowhow of the doctors and thereby enable them to upgrade the line of psoriasis treatment from topicals to methotrexate to cyclosporine to biologics.

Immunodermatology workshops covering the entire spectrum of available treatment options were conducted across India. These provided us the opportunity to strengthen our relationship with over 500 doctors who participated in these workshops.

### Outlook

The division seeks to be a leader in the immunodermatology segment with a comprehensive portfolio of topical, systemic and biologic therapies.

### Immunotherapy: Our Inclusive Approach

Top brands	ALZUMAb™, PSORID™ and TBIS®
Patients	Over 20,000 patients treated since launch
Doctors	Coverage of nearly 5,000 dermatologists





## Nephrology

The Nephrology division has been focusing on providing a comprehensive and innovative range of therapies for chronic kidney disease patients. TACROGRAF™, which is now the No. 2 Tacrolimus brand in India, emerged as a power brand in our transplant portfolio in FY15. In the anemia management space, ERYPRO safe™ (Erythropoietin) has differentiated itself by offering

an innovative safety solution. We successfully launched BIONESP™ (Darbepoetin) in FY15 to provide better compliance with anemia management in early-stage patients.

### Patient-Centric Programs

The Nephrology division played an active role in educating people across the nation about kidney disease through a special campaign on All India Radio on World Kidney Day. The importance of organ donation was conveyed through the 'Pledge Your Organ' initiative aimed at the general public to commemorate World Organ Donation Day. We also partnered with healthcare trusts and hospitals across India to organize chronic kidney disease screening camps and distributed patient starter kits for better anemia management.

### Outlook

This division with its Top 3 brands – TACROGRAF™, ERYPRO™ and RENODAPT® - has been able to consistently cater to various patient needs. With a de novo patient penetration of 30% through our immunosuppressants portfolio, we are progressing towards our vision of touching the lives of every transplant patient in India.

## Comprehensive Care

Launched in 2010, the Comprehensive Care division of Biocon is playing a crucial role in the critical illness segment with an existing anti-infective portfolio and the introduction of novel therapies in surgical trauma and sepsis management.

Biocon expanded its strategic partnership with CytoSorbents in FY15 for CytoSorb® to treat Systemic Inflammatory Response Syndrome (SIRS), which can be caused by a wide range of life-threatening conditions inside an intensive care unit (ICU) as well as post-surgical complications.

### Patient Education Programs

Besides regular patient assistance programs, a special information booklet Cytosorb® Dialysis Technician Guide was published to aid the usage of Cytosorb®.

### Physician Education Programs

During the year, a Cytosorb® Advisory Board was constituted and under its guidance the team organized several information and knowledge sharing events, including a CytoSorb® International Speaker Program, Cytosorb® Poster Presentation events at international symposia, Cytosorb® Knowledge Sharing Program and Cytosorb® Users and Non-users Meet.

An IMICELUM™ In-Hospital Experience (IIHE) Study was also

### Nephrology: Our Inclusive Approach

Top Brands	ERYPRO safe™, TACROGRAF™, RENODAPT®
Patients	Nearly 15,000 patients treated since launch
Physicians	Coverage of nearly 1,500 doctors

As a leading biologics company we constantly challenge ourselves to make branded biopharmaceuticals affordable and accessible.

conducted during the year. The brand is one of the most widely used therapies in sepsis management. Most of the doctors covered by the study said a majority of patients treated with IMICELUM™ showed early response i.e. within five days of therapy. Moreover, it reduced hospital/ICU stay without compromising patient safety. IMICELUM™ therapy was unanimously recommended by clinicians for managing infections in critically ill patients.

The In-Hospital Experience with PENMER™ (INHEP) Study underlined the effectiveness of PENMER™ in the management of serious bacterial infections. It has shown the best results within 72 hours of therapy initiation. PENMER™ provides

comprehensive improvement in clinical symptoms and can be used effectively with other anti-bacterials safely, as per the study.

Several other monthly campaigns like 'Beat the Bug,' 'Scale Down Medication Error,' 'Surviving Sepsis Campaign,' 'Paint Pancreas Pain-Free Happy' and paramedic engagements like 'Healthcare Training Program for Cytosorb®' and 'Nightingale Activity for Nurses' were also conducted during the year.

### Outlook

A high prevalence of certain viral and bacterial infections among the Indian population coupled with a dramatic increase in resistance of certain microorganisms towards conventional antibiotics have warranted the need for the introduction of new anti-infectives in the market. We are gearing up to capitalize on this opportunity and position Biocon as a reliable partner for critical care.

### Comprehensive Care: Our Inclusive Approach

<b>Top brands</b>	Cytosorb®, IVNEX™, BiopipertZ™, PENMER™
<b>Patients</b>	<ul style="list-style-type: none"> <li>Access to over 1,000 key hospitals across the country</li> <li>CytoSorb® has helped treat over 400 patients since its launch</li> </ul>
<b>Doctors</b>	Around 10,000, including specialists such as intensivists, nephrologists, gastroenterologists, surgeons and neurologists among others

"CytoSorb® has given a new kidney and a new life to my mother."  
- A patient's son

### Doctors on CytoSorb®

"A New Paradigm : Blood Purification in Sepsis."  
- A Critical care specialist from Mumbai

"Successfully treated critically ill sepsis patients."  
- Intensive care specialist from New Delhi

"A novel therapy to address sepsis."  
- A Critical care specialist from Pune

"A predominant therapy for Sepsis."  
- An Intensivist from Chennai

### Branded Formulations India - Outlook

Overall, Biocon's Branded Formulations business in India has been progressing well and with a strategic focus on niche therapies and anchor brands it is poised to do even better. Going forward, we will

strengthen the specialty segments of metabolics, oncology, immunology and nephrology, with the objective of establishing Biocon as a market leader in each of these areas.

We will also step up our investments in new verticals such as virology and

will increasingly target in-licensing opportunities to drive the growth of our specialty products portfolio.

As a leading biologics company we constantly challenge ourselves to make branded biopharmaceuticals affordable and accessible.





## Small Molecules

Biocon's 'Exclusively inclusive' journey began with our Small Molecules business, which is built on the back of our unique strength in fermentation technology and entrenched presence in the chronic therapies space. Our differentiated portfolio spans complex molecules ranging from cardiovascular and anti-obesity agents to immunosuppressants and narrow-spectrum antibiotics. Our varied portfolio has enabled us to build a commercial footprint across the globe, providing affordable access to patients and partners. Our state-

of-the-art manufacturing facilities and strict quality compliance to rigorous regulatory requirements have made us a preferred partner for Active Pharmaceutical Ingredients (APIs). Building on our core expertise in APIs we are developing value-added generic formulations for both emerging and developed markets.

### Market Trends

Global spending on medicines is forecast to grow to nearly US\$1.3 trillion in 2018 (*Source: IMS*), with generic drugs making up 50-60% of this pie. About half the sales of generic drugs will be in

highly regulated markets such as the US, the EU and Japan, with the US projected to grow at a CAGR of 5%-8% through 2018 (*Source: IMS*). While emerging markets like Asia, Africa, East Europe and Latin America are expected to account for a smaller share of the generics opportunity, sales are expected to grow faster at a CAGR of 8%-11%. A large percentage of growth in drug spending is expected to be driven by the oncology, autoimmune, respiratory, anti-virals and immunosuppressant therapy areas, which also augurs well for Biocon.

**W**e continue to be one of the largest statins and immunosuppressants manufacturers in the world.

### Core Strengths

- Expertise in fermentation technology
- Leadership in statins
- Growing leadership in immunosuppressants
- State-of-the-art manufacturing capabilities for complex molecules
- Facilities conforming to highest quality and regulatory standards
- Forward integration of fermentation-based APIs into finished dosages
- Robust product pipeline of 'difficult to make' technology intensive molecules for emerging and developed markets

### Key Developments

#### Small Molecule – APIs

The Small Molecules business across regulated and emerging markets was stable, reporting a flat growth resulting from the geopolitical turbulence in the Middle East and North Africa (MENA) region and slow offtake of the novel API, Fidaxomicin.

We continue to be one of the largest statins and immunosuppressants manufacturers in the world, and the business benefited from a good performance in both these products portfolios.

With a strong focus on R&D in the Small Molecules business, we

built a robust pipeline of complex generic products. We maintained the momentum of regulatory filings with over 20 new Drug Master Files (DMFs) being filed in various countries.

In FY15, our manufacturing sites successfully underwent 10 audits by health regulators, including those from US, EU and Mexico. Our uncompromising compliance with stringent quality and regulatory requirements formed the foundation of our success in these audits. The API facility in Hyderabad was qualified by the US FDA, Mexico's COFEPRIS and the Danish Health and Medicines Authority.

Our Hyderabad facility was also awarded by CII-Southern Region for its Environmental, Health and Safety (EHS) practices. It is the only pharma facility from Hyderabad to have received this award in the last eight years.

#### Generic Formulations

The Generic Formulations business, established in 2012, filed its first set of Abbreviated New Drug Applications (ANDAs) in the US and Marketing Authorisation Applications (MAAs) in the EU during FY15. These filings are in line with our strategy of reducing the threat arising from the commoditization of APIs, by moving up the value chain to develop generic finished dosages for global markets.

Forward integration of complex fermentation-based APIs, expertise in producing large-scale sterile injectables and manufacturing capabilities for device-based products are our key differentiators in the competitive generic formulations space. To strengthen this business further we are also setting up a greenfield oral solid dosage facility.

#### Outlook

While immunosuppressants and statins continue to be the mainstay of the Small Molecules business, Biocon is building a pipeline of complex new generic products in segments such as oncology, neurology and ophthalmology.

We are also in the process of obtaining regulatory approvals in newer geographies to redeploy sales from the troubled MENA region and offsetting the pressure on the business.

In Generic Formulations, we continue to evaluate the attractiveness of new molecules to add to our nascent pipeline with the intention of manufacturing complex products that provide profitable vertical integration opportunities.

The Small Molecules vertical, a significant contributor to Biocon's revenue, is currently positioning itself to contribute effectively to our aspirational revenue target of US\$1 billion by 2018.

# Global Marketing



Biocon's Global Marketing team is taking safe, efficacious and affordable drugs to countries challenged with a rising incidence of non-communicable diseases (NCDs) like diabetes, cancer and autoimmune disorders. The treatment costs of NCDs are simply unaffordable in many developing economies where the 'standard of care' is equivalent to several months' wages for a majority of the population. In keeping with our 'Exclusively inclusive' ethos, Biocon's APIs and generic formulations are helping individuals

lower their out-of-pocket spend and governments bring down their per capita expenditure on healthcare. We leverage our marketing alliances to extend our reach into North America, South Asia, Latin America, the Middle East and Africa.

## UAE

NeoBiocon, our subsidiary based in the UAE, has a robust portfolio of differentiated formulations for cardiology, diabetology and oncology. It operates in a regulated and insurance-dominated pharmaceutical market. The

Company engages with a strong network of over 2,500 oncologists, cardiologists, internists, pediatricians, gastroenterologists and general physicians in the Middle East and the GCC countries. A majority of our brands are ranked among the top generic brands in their respective therapeutic segments.

The US\$1.6 billion branded generics market in the UAE, growing at 11% annually, is characterized by stiff competition from Big Pharma and local generics companies. NeoBiocon, ranked 22nd, has carved

**N**eoBiocon is the No. 1 generics company in cardiovasculars with a 4.7% share of the UAE market.

out a 1.3% market share within just three years despite a challenging environment. (Source: IMS)

NeoBiocon's Branded Generics division caters to the high incidence of lifestyle diseases in the UAE. The prevalence of cardiovascular disease and diabetes in the UAE, at over 15%, is higher than the global trends. Our targeted therapeutics are the first generic brands offering reliable levels of efficacy, safety and quality in a market dominated by innovator brands. NeoBiocon is the No. 1 generics company in cardiovasculars with a 4.7% share of the UAE market. Overall it is ranked No. 6 in a space dominated by Big Pharma. With several cardiovascular and diabetes management drugs in the pipeline, NeoBiocon is poised for long-term growth in this market. (Source: IMS)

Our Oncology division offers innovative, life-saving products to patients and partners in the region, where cancer care is a fast-growing therapy area. Biocon's Abraxane® is the second largest chemotherapy brand in UAE with a 31% share of the taxane market in the Gulf region. In a market with high entry barriers, NeoBiocon features on the list of the Top 15 oncology companies. (Source: IMS)

A few of our brands have also gained entry into hospitals, which typically use innovator brands.

NeoBiocon has reported a strong growth, doubling its turnover over a period of two years. Several partnering agreements were inked for a range of biologics, which will strengthen our portfolio and enhance patient access.

### LATAM, CIS and Africa

During the year, we concluded several partnering arrangements for a wide range of our products in the LATAM, CIS and African countries, which will widen our commercial footprint in the emerging markets.

In the LATAM region, we identified strategic partners for biosimilars in key markets and also expanded existing partnerships in Argentina, Chile and Colombia.

The partnership for our biosimilars and generic insulins with a prominent player in Russia will help strengthen our presence in the region. We expect good growth from our existing product range as well as a new statin which is in the process of being commercialized.

Biocon's successful registration of Glargine and another immuno-modulator in some of these markets will catalyze regional expansion. The registration of key generic formulations in Brazil and Argentina is expected to generate reportable outcomes in FY16.

### APAC

Biocon has made further progress with product filings in Japan in FY15 which will help in product introduction soon. We have stepped up our focus on China and are working on strengthening our

### Biocon's Commercial Footprint Across the World in Over 100 Countries



position as a preferred partner for complex small molecules and biologics. We are also exploring licensing opportunities for insulin analogs and biosimilars in key APAC markets.

### North America

The North American operations, comprising the US, Canada and Mexico, are significant contributors to our global sales. Successful alliances for a complex portfolio that includes immunosuppressants and peptides, high quality products and responsive client services have made us a sought-after partner in the region. Our clients for these products comprise Big Pharma companies, generic pharma players, biotech companies and startups.

The ongoing consolidation of North America's pharma sector in FY15 has led to the emergence of a vertically-integrated customer base in the region. The increasingly vigilant

approach of regulators related to GMP compliance has enhanced the importance of quality-conscious companies like Biocon. In order to enhance our value proposition we continued to invest in developing a strong ANDA portfolio.

During FY15 we advanced our business in the region by partnering for a range of biosimilars, insulins and generic formulations. In Mexico, Biocon along with its partner, PiSA Farmaceutica, has played a significant role in enabling access to generic rh-Insulin over the last eight years. Over 70% of Mexico's population is overweight and prone to developing diabetes. Last year, over 9 million cases of diabetes were reported. The approval of Insulin Glargine in Mexico through our partner, who will market the product as Galactus, will further enhance access to an affordable insulins portfolio in the country.

Our outlook for the North America region is positive and major value

creation is expected as the market opens up for our biosimilars and ANDAs.

### Europe

A number of generic companies focused on the developed markets have tied up with Biocon for API supplies. These customers are gearing up to introduce key generic formulations of Sirolimus, Rosuvastatin, Mycophenolate Sodium and Everolimus over the next two to four years. We are positioning ourselves to be their preferred source of APIs for these new products as well as working on a set of Drug Master Files (DMFs) for products expected to go off patent in Europe between 2020 and 2025. Good product development traction among leading Indian generic companies with our APIs is becoming increasingly visible, which bodes well for our growth in this region.



# Research Services



As a leading India-based Contract Research Organization (CRO), Syngene is extending its parent Biocon's 'Exclusively inclusive' promise to R&D focused organizations across the world. Syngene offers an array of integrated discovery and development services with a distinctive cost advantage to enable novel molecule R&D. We offer attractive variable cost alternatives to the traditionally fixed cost, in-house, resource intensive business models of pharma innovators. In FY15, our flexible and customized business model enabled us to support nearly 200 clients, ranging from start-ups to mid-sized enterprises as well as eight

of the Top 10 global pharmaceutical companies (*Source: IMS 2014 sales data*). We leverage India's large, high quality, low-cost scientific talent pool to contribute to our partners' R&D programs, helping them bring innovative products, biosimilars and generic molecules to patients across the world.

## Market Trends

CROs are increasingly accounting for a larger share of the life sciences R&D dollars being spent today. The global R&D expenditure for the pharmaceutical industry in 2014 was estimated at ~US\$139 billion, of which US\$105 billion could

have potentially been outsourced (*Source: Frost & Sullivan Report*). IQ41 Research estimated the outsourcing penetration of CRO discovery services in 2013 to be 51.9% of the global pharmaceutical and biotech industry. This is now poised to grow to 65.7% by end-2015, reflecting a CAGR of 12.5%. The global CRO market for discovery services, Syngene's core focus area, was estimated at US\$15 billion in 2014 and is expected to reach US\$23 billion in 2018, reflecting a CAGR of 11.5%.

Increasingly, small virtual pharma and biotechs including PE-backed



firms with sizeable intellectual property are outsourcing R&D work to third party service providers. Externalization of R&D has emerged as the centre piece of the radical business model deployed by these pharma and biotech start-ups. The trend is reinforced by increasing R&D outsourcing in Asia, with clients looking beyond cost arbitrage, to R&D productivity and innovation. Moreover, large pharma and biotech clients now prefer to work with a select group of CROs with either

an integrated service platform or differentiated capability.

#### Core Strengths

- One-stop offering for discovery and development requirements of NMEs
- Integrated discovery (from hit to candidate selection), development (preclinical, clinical, analytical, bioanalytical, formulations, stability) and pilot manufacturing (scale up, preclinical, clinical) platforms for small and large molecules
- New differentiated service platforms including antibody drug conjugates and oligonucleotides
- Flexible and customized business models ranging from FTE to FFS
- High quality scientific talent with over 90% scientists holding a Masters or a Doctoral degree
- Strong focus on IP protection, data confidentiality and quality

#### Key Developments

With its integrated offerings and the India cost advantage, Syngene is well-positioned to benefit from the global CRO market growth. We closed FY15 with sales of

₹8.23 billion, reporting a growth of 15% on the back of a strong fourth quarter during which our sales grew by 27%.

Our performance was driven by good traction across services supported by capacity and capability expansions and a strong order book. We expanded our current small molecule manufacturing facilities in Bangalore and are expanding our large molecule manufacturing capabilities with a new unit in Bangalore. We also established new capabilities including a 75,000 square feet, GMP-certified, multi-product Stability Centre, which supports stability studies for early stage IND to commercial programs.

A key highlight of FY15 was the extension of our discovery and development partnership with BMS till 2020, reflecting the strength of the existing collaboration that has delivered many successful outcomes. The scope of our engagement has expanded over time to encompass a broad range of integrated service offerings across drug discovery and development.

Our manufacturing facility successfully underwent a pre-approval inspection by the FDA – the



**S** Syngene intends to evolve from a CRO into a full-fledged CRAMS company providing additional forward integration opportunities to its clients.

first such audit of our facilities by the US regulator – underpinning the high quality of our systems and processes.

We are expanding into Viral Testing Services and foraying into commercial scale manufacturing of New Molecular Entities (NMEs).

#### Outlook

Our strong revenue momentum is underpinned by growing revenues from existing customers and addition of new ones. We intend to evolve from a CRO into a full-fledged Contract Research and

Manufacturing Services (CRAMS) company providing additional forward integration opportunities to our clients. In line with this ambition, we recently entered into a long-term contract with an existing client for commercial manufacturing of a novel small molecule API, which is currently under late-stage development. This model can be replicated with many of our clients with programs in late-stage clinical development. We have commenced the establishment of a new large scale facility in Mangalore to

manufacture novel small molecules for innovator companies in pharmaceutical, agrochemical and other industrial sectors.

Syngene with a combination of high-end scientific talent, global accredited systems, R&D infrastructure and continued focus on IP protection is well-positioned to capture a robust share of the growing CRO market.

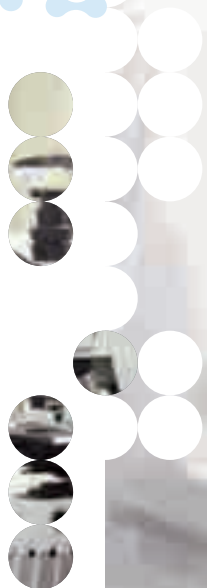
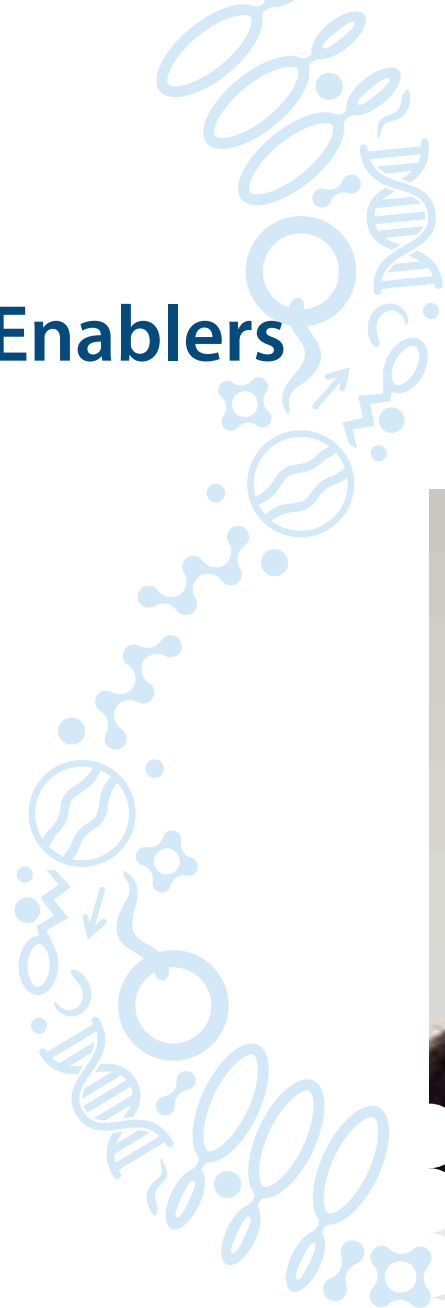
We are preparing to list Syngene on the Indian stock exchanges subject to regulatory approvals.

**In a post-Balance Sheet development, Syngene filed its Draft Red Herring Prospectus with regulators on April 22, 2015 seeking approval for an IPO.**

#### Key features of the scheme are:

- Listing is an Offer for Sale (OFS) by Biocon
- Sale of up to 22 million equity shares (including a reservation of 10% of the issue to retail investors of Biocon)
- OFS constitutes 11.0% of the post-offer paid-up equity share capital
- Issue type: 100% Book Built Issue
- Face value: ₹10 per equity share
- Listing on: BSE Limited (BSE) and National Stock Exchange of India Limited (NSE)
- Book Running Lead Managers: Axis Capital Limited, Credit Suisse Securities (India) Private Limited and Jefferies India Private Limited
- Legal Counsels: Amarchand & Mangaldas & Suresh A. Shroff & Co., AZB & Partners and Sidley Austin LLP
- Biocon (along with subsidiary BRL) holds 84.5% equity stake in Syngene

# Enablers





## Human Resources

Biocon is well-recognized as India's most preferred biotech employer and is highly regarded by the scientific community in the US and Europe. Our HR initiatives aimed at attracting the best talent, nurturing and building an engaged workforce and harnessing a performance-driven culture have been instrumental in building this image. We pride ourselves on creating an ecosystem that encourages a collegial atmosphere conducive to free flow of ideas and collaborative research. These efforts have helped build a 7,500-strong global team motivated and committed to delivering on our 'Exclusively inclusive' promise.

### Key Developments

During FY15, we focused on inculcating and strengthening best-in-class people processes and practices. The successful growth of the Biocon Academy, implementation of SAP, identification of critical talent and a suite of talent enhancement programs have been some key achievements.

### Attracting the Best & Brightest

During the year under review, we recruited 300 employees by deploying innovative talent acquisition strategies including hiring through social media platforms such

as LinkedIn and Facebook and the internal referral program. We won the 'Most Engaging Talent Brand' award among Indian companies at the LinkedIn Talent Excellence Awards held at Singapore.

With a view to bridge the gap between industry and academia, we invited several groups for industry visits and further refined our internship program.

We reached out to prominent academic groups, both international and Indian, by inviting them to our campus. Among the various institutions who visited our campus were the National University of Singapore, Sri Satya Sai Institute of Higher Education (Puttaparthi), Mepco Schlenk Engineering College (Sivakasi), MS Ramaiah Institute of Technology (Bangalore), BIT (Mesra) and SIES (Mumbai).

The internship program engaged over 450 students from international institutes including the Yong Loo Lin School of Medicine (Singapore), Kingston University (UK), University of Manchester (UK), University of Aberdeen (UK), University of Borås (Sweden), New York University (US) and Newcastle University (UK). We also attracted talent from premier Indian institutes like IIT, BIT, NIT, Delhi School of Economics, NIPER and

Tata Institute of Social Sciences. Our interns worked on projects across functions spanning Quality, R&D and Operations.

### Malaysia: Growing in Strength

Biocon Malaysia today has more than 300 employees. The year witnessed a keen emphasis being laid on attracting best-in-class talent from the industry, formulating learning and development exercises and fine-tuning HR operations. We recruited talent with both local and international experience most of whom were put through intensive training at our facilities in India.

### Effective Performance Management

Our leadership in innovative science is built on a philosophy of constant performance augmentation supported by a culture of competencies, values and collaboration. Our robust performance management program is designed to encourage and reward talent that harmonizes achievement of organizational goals with personal aspirations and milestones.

### Developing Competencies

Our Learning and Development team implemented various learning platforms, including 'Train the Trainer' networks, 'E-Learning,' 'Communities of Practice' and 'Leader Networks'

benefiting over 2,500 employees.

ISURGE, our leadership development platform, implemented several initiatives aimed at integrating multiple levels of leaders to build synergies. Being an integral part of our talent strategy, ISURGE includes coursework, assessments, action learning projects and talent reviews.

We built on our strong association with reputed institutions to continuously deliver technical programs to enhance the biopharma-related technical knowledge of our talent pool.

### Reinforcing a Gender Diverse Ecosystem

Gender diversity is a key focus area at Biocon, where women make up over 14% of the workforce. We endeavour to bridge the gender divide by giving women the opportunity to pursue successful careers in an environment of mutual respect. From middle management to the Board of Directors, women are well represented in the Company. To reinforce our longstanding commitment to advancing and empowering women at the workplace, Biocon signed up for the Women's Empowerment Principles (WEP), an initiative of the UN Women and the United Nations Global Compact.

### Harnessing the Power of Youth

Our employee age profile is testimony to Biocon being the preferred destination of young, aspiring biotech professionals. Over half our human capital is under 30 years of age making Biocon an incubator of exciting new ideas.

### Fun at Work

Employee engagement is critical to the motivation and effectiveness of an employee. With a view to building an engaged organization, we conducted several cultural and sports events, giving employees a platform to interact in an informal environment. Awareness on important topics like Workplace Health and Safety, Cancer Prevention etc. were highlighted through quizzes, poster-making competitions and other fun activities all aimed at increasing employee participation.

### Connecting with the Society

Biocon is a strong proponent of socially-conscious living. Our values were reflected across a number of CSR activities that encouraged employee participation.

- Wish cards from several NGOs were placed at various locations during this year's 'Joy of Giving Week,' encouraging employees to contribute and make a difference.
- A blood donation camp was

**G**ender diversity is a key focus area at Biocon where women make up over 14% of the workforce.

organized in association with Victoria Hospital and Bowring Institute.

- Biocon employees donated through the CUPA Shelter website during an animal care event organized along with CUPA.
- To mark Biocon's 36th Founder's Day on November 29, 2014, a fun-filled carnival was organized for children. The painting competition, nutritional camp and a heart-warming performance by the children of Adwaya Foundation were the highlights of the celebrations. To express gratitude for being a part of the Biocon journey, each family was honoured with a 'bountiful tree,' planted by 'Grow Trees' at Chintamani, Karnataka.
- While celebrating Women's Day we also tried to make a difference

to the lives of the less privileged by sourcing gifts for our women colleagues from NGO Sabuj Sangha.

### Biocon Academy: Addressing the Skill Deficit

The Biocon Academy, a Center of Excellence for Advanced Learning in Applied Biosciences, completed its first year with 90 students graduating successfully. In keeping with its goal of addressing the skill deficit in the country's biotech sector, the Biocon Academy is gearing up to launch a new course in Management of Bio Sciences in FY16.

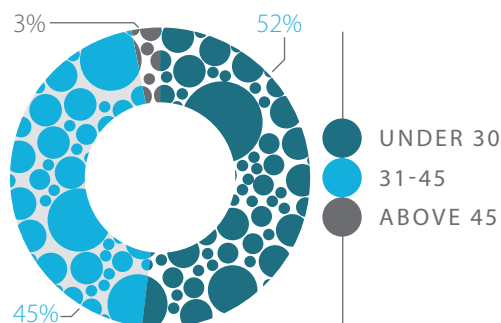
### Setting Priorities for FY16

- Strengthen our image by enhancing the employee value proposition to make Biocon the most preferred employer in the industry.

- Establish a robust competency framework making it the foundation for talent management and succession planning exercises and enable a transparent merit-based reward and recognition process.
- Initiate special programs for grooming critical and high-potential employees.
- Impart skill-based training in clusters and build a reward mechanism around the same.
- Enhance focus on competence-based hiring.
- Enhance the current curriculum and introduce new courses for technical as well as behavioral skills.
- At Biocon Malaysia, move all people-based processes to the online platform.

Company	No. of Employees as on March 2015	No. of Employees as on March 2014
<b>Biocon</b>		
India	4555	4775
Malaysia	307	251
Syngene	2666	2262
<b>Total</b>	<b>7528</b>	<b>7288</b>

### EMPLOYEES' AGE PROFILE





## Supply Chain Management

The Supply Chain Management (SCM) function has helped Biocon deliver on its 'Exclusively inclusive' promise by arming us with a competitive edge in a space characterized by complex manufacturing processes and stringent regulatory norms. An integrated SCM function enables the end-to-end management of products ranging from fermentation-derived small molecule APIs to recombinant proteins and monoclonal antibodies. Careful planning, smart sourcing and continuous monitoring have improved operational efficiency. Seamless supply chain processes

encompassing business verticals, manufacturing locations and a diverse product portfolio have helped ensure timely product delivery, cost optimization, better compliance and ultimately, increased customer satisfaction.

### Key Developments

#### Building a Competitive Supply Chain Function

Our process improvement programs and key partnerships with external stakeholders have supported the rapid growth of our business. Our consolidated supply chain structure resulting from investments in resources and a responsive team aligns various functions to our

aspiration of achieving US\$1 billion in revenues by 2018.

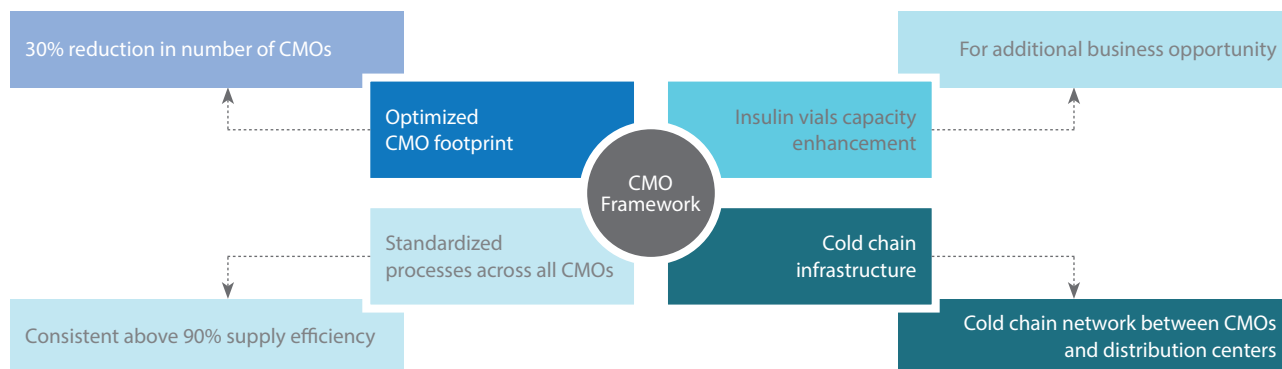
#### Driving Operational Efficiencies

Our integrated demand and supply planning has led to inventory optimization across the supply chain. Customized supply chain solutions are supporting business growth in various products and regional markets. Process standardization and simplification have facilitated consistent reproducible productivity and error minimization. Real-time data is also being used to improve analytics and monitor Key Performance Indicators (KPIs).



An integrated SCM function enables the end-to-end management of products from small molecule APIs to monoclonal antibodies.

### Strategic CMO Framework Established



### Implementing Scalable & Secure IT Strategy

Implementation of SAP is providing real-time data visibility across the extended supply chain. In addition, a barcode-based Warehouse Management System (WMS) functioning across warehouses has led to error-free tracking.

### Building Trust & Transparency

We collaborated with strategic partners including suppliers, contract manufacturers, logistics providers and customers to build trust. Information centralization has helped

us continuously review progress in tracking, monitoring and aligning our Supply Chain operations. Risk profiling was also one of the many strategic initiatives undertaken with key vendors.

### Improving on Our Strengths

In an effort to create a lean, responsive and customer-led value chain, we continuously improved our SCM. Our efforts helped us better handle operational complexity, make more accurate demand forecasts and enhance our cold chain capabilities.

### Functioning with Responsibility

In pursuit of the highest standards of EHS, we integrated our efforts by training our people and adopting greener and sustainable logistics.

### Performance Orientation

During the year under report, we also worked on developing a diverse talent pipeline and leadership that matches the organization's growth ambitions. We emphasized a performance culture that respects organizational values and leverages

### SCM: Capability Development

#### Scalable IT Systems

- ▶ ○ SAP implementation with the key focus on real-time data visibility
- ▶ ○ Implementation of barcode-based WMS across all the raw material warehouses
- ▶ ○ Established market intelligence platform for commodity purchases

#### People and Processes

- ▶ ○ 30+ team members certified by prominent Indian supply chain institutes
- ▶ ○ Initiated Six Sigma Green Belt certification to enhance functional expertise
- ▶ ○ Cross-functional teams in process improvement programs across business units



the operating framework to build and reinforce competitive advantage.

### Integrating SCM Teams at Malaysia and India

With the core value system firmly imbibed, the Malaysia team was able to rethink, reinvent and rewire themselves to establish a robust SCM system at Malaysia.

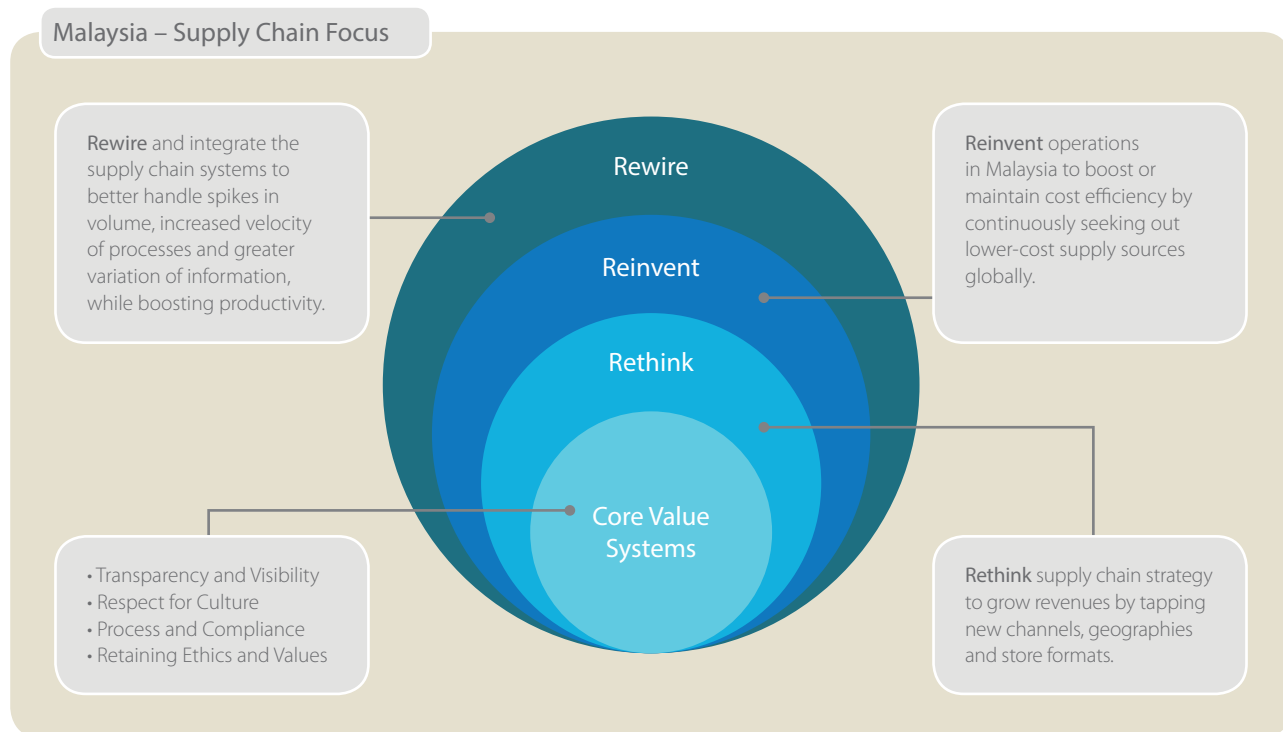
The SCM framework at Malaysia was

structured around the following key pillars:

- **Processes and Systems:** New SAP (ERP) system was implemented to align with India SCM operations.
- **Sourcing Strategy:** Pursuing novel cost reduction initiatives in key Insulin and Glargine materials.
- **Logistics:** Global logistics

partners were engaged to align and synchronize the supply lines, ensuring compliance.

- **Mitigating Supply Risk:** Capabilities of key supply and logistics partners were mapped with long-term growth plans.
- **Focus on Talent:** Leadership and mid-level teams were trained to handle the complex regulatory environment.





## Environment, Health and Safety

Biocon's 'Exclusively inclusive' business philosophy, emphasizing sustainable healthcare solutions, finds resonance in our constant endeavor to adopt the best practices in Environment, Health

and Safety (EHS). These are built on a compliance culture aligned with statutory local, national and international laws. These practices are governed by a Code of Conduct and internal legal and ethical

guidelines. Building on our successful EHS programs, we have incorporated environmentally sustainable practices across our businesses.



### Key Developments

In keeping with our commitment to achieve the highest global standards of EHS and reducing our environmental footprint, we successfully implemented strategies aimed at optimizing, recycling, recovery and reuse of resources. We obtained necessary approvals, consents and clearances from all national and international agencies and complied with the statutory norms.

### Water Conservation, Recycling and Reuse

We achieved our FY15 goals for reducing our carbon footprint, water

use and waste generation. While reducing our own carbon emissions, we also encouraged our suppliers and consumers to reduce these during sourcing and consumption.

Our substantial investments in a zero-liquid discharge system across all manufacturing units resulted in the recycling of recovered water for onward use at in-house utilities.

Using our eco-greenhouse system, we composted 25 tonnes of in-house food waste, thus reducing our environmental footprint.

The 2,500 cubic metres of biogas generated per day by the anaerobic waste treatment plant was used to fuel our boilers and generators, thus saving 60,000 kilowatt-hours of power in FY15. We also installed solar energy systems across our plants.

### Safety and Health Performance

With a view to encourage employees take ownership of making 'safety' core to the organizational culture, we organized a series of training and awareness programs. We also focused on inculcating safety as a basic management function, empowering employees to be independently responsible.

We remained committed to follow

ISO 14001 and OHSAS 18001 guidelines through an ongoing culture of regular internal and external audits. Our efficient systems were validated with our re-certification for ISO 14001, the most reputed environmental management benchmark. In line with Globalized Harmonizing Systems, we embarked on the migration of Material Safety Data Sheet (MSDS) to Safety Data Sheet (SDS). We also conducted an inter-departmental safety competition to enhance employee involvement.

### Safety Training

We rolled out an integrated, module-based safety training program for employees and suppliers. This program covered chemical safety, laboratory safety, EHS systems and legislation, operational safety, emergency safety equipment, emergency response procedures, maintenance activities and other specialized areas.

During FY15, 14,915 person-hours were invested in EHS training through our Biobizapp software.

Safety committee meetings and monthly safety campaigns including 20 mock drills and 12 first-aid trainings were conducted across

**C**arbon dioxide emissions were reduced by 2,700 tonnes in FY15 with the procurement of 3.61 million units of green power.

manufacturing sites. These helped enhance awareness of workplace hazards. In FY15, we continuously upgraded EHS standards across sites and locations as well.

### Procedural Safety Management

An effective Procedural Safety Management program requires a systematic approach. We thus invested in a program to identify procedural vulnerability and established and documented process safety management protocols across our manufacturing operations. Our procedural safety team was equipped with tools like HAZOP, HAZAN, powder characteristic study and reaction kinetics for this exercise.

### Industrial Hygiene Management

We remain committed to industrial hygiene excellence, aligning our practices with global standards and strengthening them further. We defined occupational exposure limits for APIs. We invested every effort to ensure that potential hazards (chemical, physical, biological and ergonomic) were adequately controlled. During the year, we planned new projects to ensure

compliance. Frequent monitoring of Volatile Organic Compound (VOC) levels helped upgrade shopfloor safety as well.

### Energy Conservation

Our energy conservation initiatives led to a marginal increase in power consumption during FY15. This was an outcome of regular monitoring of high-energy consumption areas and power-saving equipment as well

as implementation of energy-saving measures.

Total energy costs declined 4% during FY15, aided by alternate energy procurement and softer global crude prices.

Carbon dioxide emissions were reduced by 2,700 tonnes in FY15 with the procurement of 3.61 million units of green power.



Second position in  
'Best Fuel Efficient Boiler'  
Category

### Awards & Recognitions

During FY15, we received several recognitions at the state and national levels for our progressive EHS practices and initiatives. These included:

- Greentech Safety Gold Award 2014
- 2nd rank in the 'Best Fuel Efficient Boiler' Award category conferred by the Karnataka State Safety Institute
- 4-Star rating to our API facility at Hyderabad for its EHS practices from CII-Southern Region



# Corporate Social Responsibility



## Biocon Foundation

Biocon believes its Corporate Social Responsibility (CSR) lies in promoting social and economic inclusion by ensuring that marginalized communities have equal access to essential healthcare services, educational opportunities, proper sanitation and other civic infrastructure.

India is faced with a pressing need for smart CSR models that are viable and scalable. Since 2004, the Biocon Foundation has been fulfilling this need through targeted, efficient and sustainable programs.

Our constant endeavors are aimed at improving the health status of our communities through the network of our primary healthcare centers and supporting children education through special text books that improve their mathematical skills.

The positive impact created by some of our programs has earned us the recognition of a Public Health Champion, an award we received recently from WHO, India. Our pioneering efforts in the area of preventive healthcare have brought us several other awards and accolades during FY15.

## Healthcare

In the year gone by, we accelerated our efforts in the area of chronic diseases such as diabetes and cancer while continuing our work in the area of basic health. Our path-breaking mobile phone-based health (mHealth) initiative ensured that healthcare reaches remote and underserved communities in a cost-effective manner. Our efforts seek to create a sustainable health ecosystem that can be replicated across Karnataka and the country.

The communities served through the Foundation's programs typically have

**O**ur cervical cancer prevention and control program focuses on early detection and affordable treatment.

limited access to healthcare facilities. For generations they have sought help only in a medical emergency, which often pushes them to sacrifice their life savings. Our preventive healthcare programs facilitate early diagnosis and affordable treatment, potentially averting a lifetime of indebtedness resulting from a catastrophic illness of a family member.

A network of Community Health Workers (CHWs) associated with Biocon Foundation's nine Arogya Raksha Yojana (ARY) clinics take our preventive healthcare programs to these communities. Besides imparting preventive health education, they also promote maternal and child health and raise awareness about personal and environmental hygiene.

CHWs educate and sensitize Influencers, a key family member who can take responsibility of the family's well-being. Under this initiative, the CHWs reached out to over 64,650 key Influencers during FY15.

### Cervical Cancer

More women die of cervical cancer in India than anywhere else in the world. Over 430 million women in India, aged 15 years and older, are at a risk of developing cervical cancer. Despite the disease being

completely preventable, current estimates indicate that nearly 125,000 women are diagnosed with this cancer annually and more than half of them do not survive (*Source: ICO Information Center on HPV & Cancer*).

Our cervical cancer prevention and control program focuses on early detection and affordable treatment to enable better outcomes and improve survival rates in the rural communities we serve.

Our CHWs are trained to provide reproductive health education to women in underserved communities. We also collaborate with tertiary cancer centers to link diagnostic, screening and treatment services.

Easy accessibility of tertiary oncology facilities has helped in the early detection and treatment of cervical cancer. Those having undergone screening have emerged as key Influencers motivating others to participate. During the year under report, the program covered over 28,000 women and created nearly 15,200 influencers.

Over 900 women were screened for cervical cancer and nearly 2% were found to be 'Pap Positive'. They underwent treatment under our recommendation. Our impact in the area of cervical cancer screening was

also recognized by the World CSR Congress.

### Oral Cancer

We have developed and implemented a mHealth technology platform for oral cancer screening and surveillance that enables the creation of electronic health records and facilitates targeted screening. The platform leverages telemedicine to link oral cancer specialists with patients in rural areas and provides opportunities for follow-ups and referrals.

Our CHWs also educate people about the life-threatening effects of smoking and chewing tobacco and counsel them to quit the habit.

Under our community screening program, 5,000 'high-risk' individuals were identified. Over 2,600 people were screened in Kalkunte and Chikballapur and nearly 6% of them were recommended for biopsies.

We also identified factory workers as a 'high risk' population given that they get into the habit of tobacco chewing because of their monotonous jobs. Over 5,240 of them were screened at various industrial establishments during the year. Of these, nearly 300 were recommended for biopsies; however only 25% actually underwent the procedure. This reflects the challenges faced by our CHWs.





We are developing a non-invasive, point-of-care diagnostic tool, a salivary biomarker, to help identify oral cancer among tobacco users. Such a technology would render biopsies unnecessary, thus improving patient participation. Along with KLE Dental College, we have collected 550 saliva samples for this study.

We are proud to share that in our follow-up survey on those screened for oral cancer in Huskur and Mangalgudda in FY12, we did not find a single case of malignancy.

The oral cancer program won us a Certificate of Appreciation at the NASSCOM Social Innovation Forum 2015 in the category of 'ICT-led Social

Innovations by a Corporate (CSR)' as well as the 'CSR Program of the Year' Award at the NGO Box India CSR Summit 2014.

#### **Diabetes and Hypertension**

Our efforts aimed at increasing diabetes awareness have led to an increase in the number of patients visiting our clinics for regular follow-ups. Of the 5,000 visits to our diabetes camps during the year, nearly 3,700 were follow-up cases. These patients have been provided with a Diabetes Management File to help them maintain their treatment records, improve their understanding of the illness and make disease management more efficient.

Through our diabetes education

program, we reached out to over 8,000 people, including patients and their families. We conducted diabetic foot and diabetic retinopathy screening at regular intervals across our clinics during the year.

#### **Child Malnutrition**

Our child malnutrition program, in partnership with the local administration in District Bagalkot, Karnataka, is progressing well. We work with teachers and supervisors of 389 anganwadi centers and development officers to implement these programs, impacting 30,000 infants and young children.

We provided free nutritional supplements to nearly 2,000 malnourished children. We also worked to ensure greater coordination among the government's Public Distribution System, Health Department and Women and Child Welfare Department to effectively address malnutrition. Weekly community awareness workshops on malnutrition were organized. We also facilitated monthly health check-ups of severely acute malnourished (SAM) children as well as follow-ups in coordination with anganwadi supervisors and workers.

Nearly 2,000 children underwent systematic annual health check-ups

**I**n FY15, Chinnara Ganitha workbooks were distributed to nearly 125,000 children of classes I to VII across 1,542 government schools in Karnataka.

at our paediatric camps to identify congenital and chronic diseases.

Special charts were designed to provide a reliable documentation of immunization dates for children, especially those under the age of three, who do not regularly visit anganwadi centers. Overall, over 9,500 children were treated in FY15.

## Education

During the year, Biocon Foundation continued its efforts to improve the quality of education for children in rural areas.

### Chinnara Ganitha

Our program of distributing special Chinnara Ganitha mathematics workbooks, in collaboration with Macmillan Publishers India, continues to fill a critical gap in imparting numeracy skills to children in a language familiar to them. These activity-based workbooks are closely aligned to the Directorate of Secondary Research and Training Curriculum for standards I to VII. In FY15, Chinnara Ganitha workbooks were distributed to nearly 125,000 children across 1,542 government schools in eight districts of Karnataka.

Some new effective learning initiatives introduced during the year include **Buddhige Thindi**, a comprehensive quiz to assist recall



of key concepts; **Thatantha Uttarasi** test papers that serve as an excellent revision guide of basic concepts; **Saval-Jawab**, question and answer sessions to make mathematics fun and enjoyable and **Reward Stickers** for encouraging and motivating students to perform well.

### Aata Paata Wadi

The Aata Paata Wadi, our after-school resource center in Thithimati, Kodagu, continues to provide an interactive learning platform for children from economically weaker sections of the society. Our innovative techniques help these children develop a good foundation in English with a better sense of phonetics, sentence formation and paragraph writing.

During the year, we initiated interactive digital lessons for imparting computer operating skills created by the Azim Premji Foundation. We also conducted life-skills classes which included lessons on moral values as well as on the rights and duties of a citizen.

### Kelsa+

Kelsa+ provides a platform for low-income support staff at Biocon to learn basic computer skills. Casual and contract laborers are taught how to use the Internet, set up e-mail accounts and read newspapers online. During the year, 30 women received basic computer lessons. Based on feedback from women workers, we now offer them skill development in lamp-making and embroidery.



## Drinking Water

**Project One:** Our investigations into the increased incidence of gastrointestinal cases at our ARY clinic in Huskur village pointed towards the shortage of potable water. In order to address this issue, we implemented Project One, a booth where a water filtration plant using reverse osmosis and ultra-violet technology was installed. Safe drinking water from the booth is offered to over 5,000 villagers daily at a minimal cost of ₹2 for a 20-litre jar.

As an organization, Biocon is cognizant of the fact that we are in a humanitarian business – that of making a difference to human health. Biocon Foundation extends our vision, albeit with a focus on underserved communities, and continuously strives to provide access to affordable healthcare.

## Success Story

From SAM to a healthy 4 year old

Thippava, a 4-year-old girl from Kutukenkeri village in Badami taluk, is leading a healthy and normal life today thanks to timely intervention by the Biocon Foundation.

At a tender age of 1 year and 4 months, she weighed only 6.5 kgs and was diagnosed as a Severe Acute Malnourished child with low cognitive skills and breathing problems. Further physical and systemic examinations recommended by the pediatrician at our camp found that she had developed cardiac complications because of malnourishment.

As Thippava's family was Below Poverty Line (BPL), we counseled the family for the child's treatment and facilitated free surgery at Narayana Health, Bangalore under the Bal Sanjeevani Scheme. Our interventions led to a significant improvement in Thippava's quality of life in terms of diet, IQ, cognitive skills and hygiene.





## Biocon Academy

### Creating a world-class talent pool of biotech professionals

Biocon Academy leverages the industrial leadership of Biocon along with the strong academic and technical expertise of its international education partner Keck Graduate Institute (KGI) in California, US.

The Academy, set up as a learning initiative of Biocon under its Corporate Social Responsibility agenda, addresses the skill deficit in the biotech industry. It has been instrumental in shaping careers of aspiring biotech graduates while

bridging the industry-academia gap.

The 16-week intensive program comprises technical and professional skills modules. In addition, the Industrial Expert Mentorship module is aimed at leveraging Biocon's industry leadership strengths and KGI's academic vigour to make students industry-ready.

India's biotech professionals are fast evolving to align with the growing needs of the global industry. Since it requires 'application of science' in the business context, they need to develop a deeper understanding of the industry and the overall business of science.

The experiential learning methods deployed by the international faculty at the Academy enhance education outcomes. An expectation-setting exercise provides the institute and the faculty insights into student aspirations.

Given its holistic approach, the program includes functional visits thrice a week to institutions like SIT, IBAB and the Biocon Research Centre. Students get hands-on experience in diverse areas including molecular biotechnology, biopharma quality assurance and control, CMC regulations, pharmaceutical development and mammalian cell biotechnology.





From an industry perspective, strong scientific knowledge coupled with business acumen to drive concepts from lab to market play a critical role. Professional attributes such as the ability to work with teams, take decisions and communicate clearly are some defining factors for success. Therefore, the program also includes sessions to sharpen these attributes in students.

The Technical modules range from Molecular Biotechnology to Pharmaceutical Development; Biopharmaceutical Quality Assurance & Control; CMC Regulations of Pharmaceuticals; Introduction

to US FDA & European Laws and Regulations; Fermentation Principles; Mammalian Cell Biotechnology; Bioseparation Engineering & Science.

During the year a talented pool of over 90 students graduated from the Biocon Academy and was successfully placed. The students were a mix of those experienced in research and industrial areas as well as new entrants with a background in biotech and applied biosciences.

Over 20 biotech companies hired the students through campus interviews for functions ranging from Production, Quality Assurance, Regulatory Affairs, Research &

Development and Marketing. All the students were placed in several globally reputed companies, including Biocon.

This innovative program provides deep learning and inculcates professionalism in the students. These industry-ready science graduates are better prepared to serve the global life sciences industry through their knowledge, talent and passion.

Biocon Academy is committed to make a significant contribution by developing such high-end talent through a series of new programs currently under planning.