Biocon

4Ortitude

Four Decades of Pioneering Excellence

Annual Report **2019**

FORTITUDE

It takes immense fortitude to stay the course for 40 years. To be a pioneer. To go against the tide and navigate uncharted waters. To challenge the status quo. To manage risks. To encounter failure and not quit. To stand up for what is right and equitable. To prove to the world that India can be at par with the best.

Our self-belief, commitment and perseverance have stood us in good stead in pursuing this incredible journey of making a difference to patients, people, partners and business. Our 40-year journey of Fortitude has given us the confidence to pursue the next leg of our voyage towards touching a billion lives, co-creating a healthy future.

Enhancing Affordable Access, Touching Patients' Lives

Biocon is driven by the belief that the pharmaceuticals industry has a humanitarian responsibility to enable access to essential drugs for patients who are in need and to do so with the power of innovation.

We have focused on building a new model of innovation that adds the condition of affordability to ensure accessibility. Our goal is to develop affordable blockbuster drugs with the potential to benefit a billion patients.

120+
Countries

We enable affordable access to patients in over 120 countries.

~2
Million Patients

We have served nearly 2 million patients through our biosimilars in FY19.

Our strategy is aligned to the global imperative of improving access to high quality, affordable biopharmaceuticals and specialty medicines in chronic conditions such as diabetes, oncology and immunology.

2004

World's first *Pichia pastoris* technology based rh-Insulin developed and introduced for people with diabetes in India.

Today, concerns about escalating medicine costs are no longer limited to developing countries. Patients in developed markets are also questioning business models wherein life-saving drugs are accessible only to a small affluent section of the population.

As a Company based in a developing country, we have deliberately steered clear of these inherently discriminatory business strategies and chosen to be equitable and inclusive.

Patients are at the heart of our operations. We have used innovative science to bring competition for some of the world's most expensive medicines through our biosimilars. Our biosimilar products have addressed the needs of nearly 2 million* patients in FY19.

2006
India's first indigenously produced novel monoclonal antibody, Nimotuzumab, for head & neck cancer launched.

2014
World's first biosimilar Trastuzumab for breast cancer patients developed and launched in India.

2016
Insulin Glargine pen for people with diabetes launched in Japan as the first biosimilar from India.

2018
First biosimilar Pegfilgrastim launched in U.S. for cancer patients undergoing chemotherapy.

Besides enabling affordable access to biologics through biosimilars, we are ensuring that a larger number of patients are able to afford statins and immunosupressants formulations by supplying our high quality Active Pharmaceutical Ingredients (APIs) to generic drug makers worldwide.

Our 'developing countries first' strategy has led us to deliver key life-saving, advanced biopharmaceuticals for diabetes and cancer patients in India and UAE through our Branded Formulations business. Nearly 400,000* patients have benefited from our insulins portfolio in India since 2004. Through our life-saving oncology portfolio we have impacted over 90,000* patient lives.

Our passion to impact global health has enabled us to touch millions of patient lives. We are committed to impact a billion lives in the years ahead.

**Note: The estimated patient reach numbers have been calculated indirectly based on volume supplied and certain assumptions related to dosage per patient, duration of treatment, units sold, internal data and market research reports.*

Memories
of Yesteryears

40
YEARS OF
BIOCON

1978 1980 1983 1990 1990

2004 2005 2006 2006 2006

2012 2012 2013 2014 2014

2019

Business Evolution
Over the Years

FY1999		FY2004		FY2009	
People	Revenue	People	Revenue	People	Revenue
250	₹318 Mn	700+	₹5,493 Mn	3,500+	₹11,937 Mn

1978-1999

An Enzymes Company

2000-2004

Transforming into a Biopharma Company

Successful IPO, Biocon listed in India (2004)

2005-2009

Building the Base Business and Expertise in Biologics

Enzymes Business Divested (2007)

Global Development of Biosimilars in Partnership with Mylan (2009)

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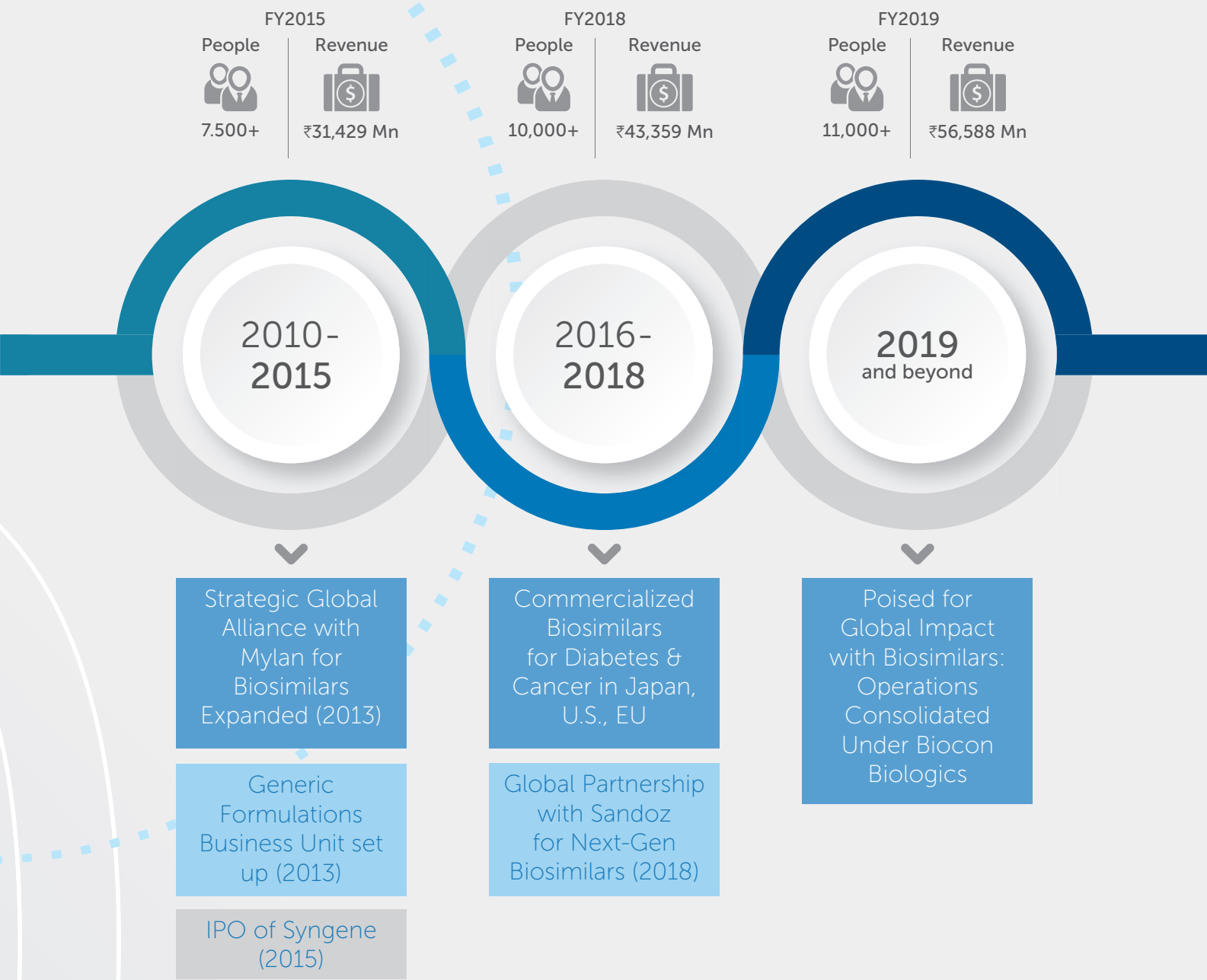
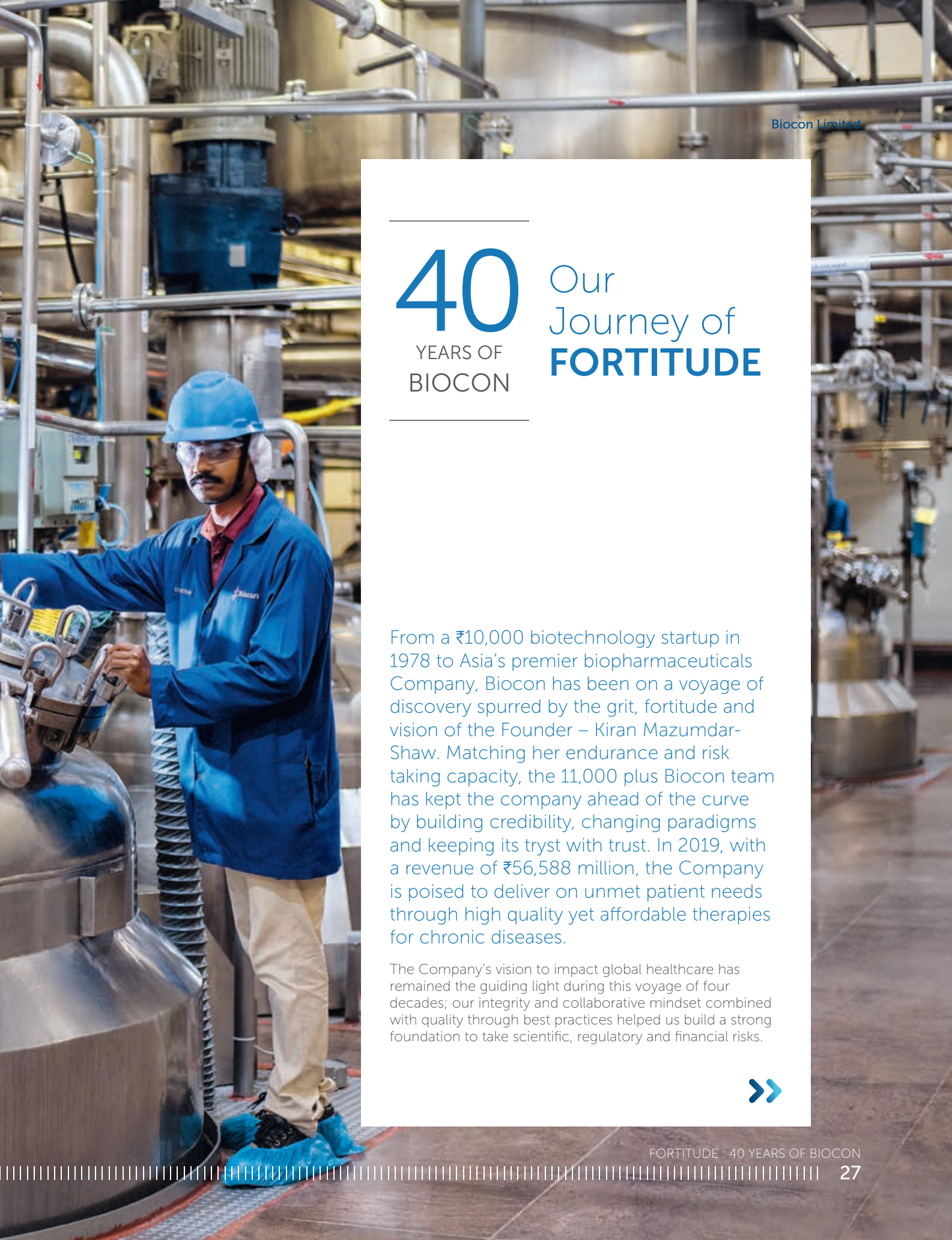
YEARS OF
BIOCON


FY2015
People
7.500+
Revenue
₹31,429 Mn
FY2018
People
10,000+
Revenue
₹43,359 Mn
FY2019
People
11,000+
Revenue
₹56,588 Mn
2010-2015
2016-2018
2019 and beyond
Strategic Global Alliance with Mylan for Biosimilars Expanded (2013)
Generic Formulations Business Unit set up (2013)
IPO of Syngene (2015)
Commercialized Biosimilars for Diabetes & Cancer in Japan, U.S., EU
Global Partnership with Sandoz for Next-Gen Biosimilars (2018)
Poised for Global Impact with Biosimilars: Operations Consolidated Under Biocon Biologics


VENT LINE
VAPOUR LINE



Biocon Limited

40 YEARS OF BIOCON

Our Journey of **FORTITUDE**

From a ₹10,000 biotechnology startup in 1978 to Asia's premier biopharmaceuticals Company, Biocon has been on a voyage of discovery spurred by the grit, fortitude and vision of the Founder – Kiran Mazumdar-Shaw. Matching her endurance and risk taking capacity, the 11,000 plus Biocon team has kept the company ahead of the curve by building credibility, changing paradigms and keeping its tryst with trust. In 2019, with a revenue of ₹56,588 million, the Company is poised to deliver on unmet patient needs through high quality yet affordable therapies for chronic diseases.

The Company's vision to impact global healthcare has remained the guiding light during this voyage of four decades; our integrity and collaborative mindset combined with quality through best practices helped us build a strong foundation to take scientific, regulatory and financial risks.

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YEARS OF
BIOCON

By pursuing value creation through innovation and differentiation we stayed ahead of the curve and leapfrogged into the ranks of the premier biopharmaceutical companies from Asia. Our fortitude helped us stay on course, despite the inherently long gestation periods for product development, the evolving regulatory landscape and large financial outlays for building global scale manufacturing capabilities. Over the last four decades, we have achieved several global and Indian firsts. We have commercialized key biosimilars and novel biologics in developed and emerging markets, making life better for patients by enhancing access to 'best in class' therapies for chronic diseases.

From a Startup to a Global Enterprise

Biocon started by manufacturing specialty bio-enzymes and promoting the application of these enzymes for diverse industries like food & beverages, animal feed, textiles, pulp & paper and leather. Our pursuit of using enzymes-based clean technology, an idea well ahead of its times, threw several development and investment challenges at us, testing our fortitude at every stage. Undeterred, we built on our experience of manufacturing enzymes for the developed markets of U.S. and Europe and our research capabilities for novel enzymes.

In time, we gained recognition as India's leading enzymes company. However, we realized that it was a self-limiting space. Our ambition was to make an impact on global healthcare by making a difference to patients. Hence, we chose to focus on developing biopharmaceuticals leveraging our existing strengths in fermentation sciences. This also enabled us to differentiate ourselves in the overcrowded generic pharmaceuticals space in India.

Further, we incubated the concept of contract research services through Syngene, which was set up as India's first contract research organization (CRO) in 1993. This helped us build additional skills in recombinant technologies and innovative research for new drug development.

From being an entrepreneurial enzymes enterprise, we evolved into an innovation-led, technology-based biopharmaceuticals company. The strong intellectual capital built in the first 20 years provided the foundation for Biocon to capitalize on innovative technologies to develop small molecules like statins and immunosuppressants and recombinant proteins like human

MILESTONES

A Journey of Building Global Scale **Small Molecules**

2000
Commissions first fully automated submerged fermentation plant to produce specialty pharmaceuticals

2001
1st company globally to get U.S. FDA approval for making Lovastatin through solid state fermentation

2003
Submerged fermentation facility to manufacture Lovastatin approved by U.S. FDA

2004
Commercializes a basket of fermentation-derived statins in U.S. & EU, starting with Lovastatin

2007
Divests legacy enzymes business to increase focus on developing, manufacturing biopharmaceuticals

2009
Acquires bulk pharmaceuticals plant near Hyderabad and renovates it to make chemical synthesis-based APIs

insulin and insulin analogs. Our hybrid business model allowed us to balance risk and reward by delivering outsourced research services through Syngene and focusing on novel research at Biocon's laboratories.

Leveraging our internal strengths over the years, we developed into an integrated biopharmaceuticals enterprise of global scale, with a presence across the entire drug value chain.

Driven by our passion and fortitude, we have built one of the largest global biosimilars portfolios across recombinant human insulin, insulin analogs, monoclonal antibodies and other biologics for chronic diseases, and successfully commercialized few of them in the developed markets of Japan, U.S. and EU. We have developed and commercialized two novel monoclonal antibodies for cancer and psoriasis in India, and created a promising pipeline of new biologic entities. We have emerged as a trusted partner for complex, difficult-to-manufacture small molecule Active Pharmaceutical Ingredients (APIs), supplying to over 1,000 customers worldwide. We have carved out a premium niche for ourselves as a biologics-led, specialty products company in India.

Sheer endurance has helped us stay committed to establish Biocon as a credible and reliable player in the highly complex biopharmaceutical sector.

Driving an Affordable Innovation Model

Bringing innovative, affordable healthcare solutions to patients across global markets has been Biocon's long cherished objective. Drug development being an expensive, high risk endeavor, we leveraged our robust R&D engine to introduce an affordable innovation model that could enhance access to complex therapies.

We were acutely aware of the huge burden of chronic diseases like diabetes and cancer. Hence, we chose to develop a recombinant human insulin using our proprietary fermentation technology and introduced it to patients in India in 2004 at a disruptive price point.

We built on this affordable innovation model further to develop a strong portfolio of biosimilars for cancer and autoimmune diseases.

1,000+

Our APIs are supplied to over 1,000 customers in over 100 countries.

2013
Creates new Generic Formulations sub-business unit to forward integrate into finished dosage forms

2015
Acquires potent intermediate facility in Visakhapatnam to enter into oncology segments

2016
Generic Formulations business gets 1st ANDA approval in U.S. for Rosuvastatin tablets

2017
Rosuvastatin is the 1st formulation to be commercialized under Biocon's own label in U.S.

2019
First Generic Formulations plant, commissioned in 2017, receives U.S. FDA approval

+ Read more on Small Molecules Journey : Page 57

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Patient Centric Approach - Impacting a Billion Lives

As a biopharmaceuticals company we are on a mission to make a difference to a billion lives. In the late 1990s, we realized that if we wanted to impact the lives of the largest number of patients across the world, we would have to address their unmet needs by integrating affordable innovation into our business models.

Our proprietary fermentation technology for manufacturing affordable insulins helped expand the market, rationalize prices and improve patient compliance. In several countries, such as Mexico and Malaysia, most insulin dependent diabetes patients take our affordable insulins. Having expanded access to this therapy in several emerging countries, our endeavor is to provide affordable access to this lifesaving therapy to 'one in five' insulin dependent patients across the world.

Driven by our passion to address unmet patient needs, we chose to go beyond insulins. Moving out of our comfort zone, we began exploring opportunities to develop novel biologics in India. In 2002, we collaborated with the Center of Molecular Immunology (CIMAB), Cuba, for a basket of promising, early-stage antibody assets. We leveraged our cutting-edge science and technology capabilities in process development and analytical characterization to develop these humanized antibodies for clinical studies and commercialization.

We decided to push the scientific boundaries to tackle the very high incidence of head & neck cancer in India, which largely afflicted poorer sections of the population, due to excessive use of tobacco.

The result was Nimotuzumab, a humanized anti-EGFR (epidermal growth factor receptor) monoclonal antibody (mAb) targeted at head & neck cancer. Biocon introduced India's first novel indigeneously produced monoclonal antibody, BIOMAb EGFR®, in 2006, at an affordable price point in order to enable patient access to this life-saving biologic therapy. Thousands of patients who previously could not afford the treatment now had an affordable treatment option.

An investigator-initiated study conducted at the Tata Memorial Hospital in Mumbai, one of the largest randomized clinical studies on head & neck cancer patients in India, recently established that Nimotuzumab significantly improved patient outcomes when combined

MILESTONES

A Journey of Self-Belief **Biosimilars**

2000
Leverages fermentation technology strengths to start insulin development program

2003
Begins work on antibodies using mammalian cell-based expression systems

2004
Brings down insulin prices in India with launch of indigenously developed rh-Insulin (Insugen®)

2009
Expands insulins basket with the launch of Insulin Glargine (Basalog®) in India

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Partners with Mylan to co-develop biosimilar monoclonal antibodies & other recombinant proteins

2011
Introduces a reusable insulin pen, INSUPen®, marking a foray into devices

2013
Expands Mylan partnership to include biosimilar insulin analogs

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Our product becomes the 1st biosimilar Trastuzumab to be approved anywhere in the world

with chemo-radiotherapy for the treatment of locally advanced squamous cell carcinoma.

The study conducted with 536 patients proved how the introduction of Nimotuzumab to the existing 'standard of care' led to improved treatment outcomes in terms of progression-free survival, disease-free survival, duration of loco-regional control and overall survival of patients. The results were presented at the annual conference of the American Society of Clinical Oncology (ASCO) in 2018.

Encouraged by our successful launch of Nimotuzumab, we continued the pursuit of our IP driven strategy of differentiation. We developed a novel first-in-class humanized anti-CD6 monoclonal antibody, Itolizumab, in India. The drug was launched under the brand name ALZUMAb™ to treat moderate to severe plaque psoriasis in 2013.

We saw encouraging outcomes in several hundred patients in India. Our research indicated that as the world's first anti-CD6 molecule, Itolizumab held promise in treating several autoimmune conditions. In 2017, we partnered with U.S.-based Equillium Inc. to develop this asset further.

The U.S. FDA in 2018 accepted our partner's Investigational New Drug (IND) application for the asset EQ001 (Itolizumab), which is currently under clinical development for an orphan indication of acute graft-versus-host disease (aGVHD).

Being change leaders in a constantly evolving technological landscape, Biocon stayed ahead of the curve by encouraging innovation, knowledge creation and breakthrough research. We consistently created intellectual wealth through an incisive IP strategy that has led us to file nearly 1,400 patent applications and hold over 1,160 patents and around 700 trademarks globally till March 31, 2019.

Over the last forty years, our fortitude has stood us in good stead, preparing us for the next forty years with a high value portfolio and pipeline of novel biologics and biosimilars to enable affordable access to these therapies for patients across the globe.

Our Dogged Hunt for an Oral Insulin

With India at the epicentre of diabetes pandemic, we decided to go beyond developing generic insulins and embarked on a novel 'oral insulin' program. In line with

2002

Collaborated for a basket of early stage monoclonal antibody assets.

2014

Launches biosimilar Trastuzumab (CANMAb™) for breast cancer patients in India

2016

Insulin Glargine approved & launched in Japan; becomes our 1st biosimilar to be introduced in a regulated market

2017

Expands cancer portfolio with the launch of biosimilar Bevacizumab (KRABEVA®) in India

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Our partnered product Ogivri®* becomes the 1st biosimilar Trastuzumab to be approved by U.S. FDA

2018

Our partnered product Fulphila®* becomes the 1st biosimilar Pegfilgrastim to be launched & commercialized in U.S.

Semglee®* (Insulin Glargine) approved; Commercialized in Europe by our partner

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Partners Sandoz to co-develop next-generation biosimilars

2019

Ogivri®* (Trastuzumab) commercialized in Europe by our partner

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Biologics business crosses USD 200 million annual revenue milestone

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Biologics business addresses needs of ~2 million patients in FY19

* Partnered with Mylan

+ Read more on Biosimilars Journey : Page 62

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this, in 2006 we acquired the IP assets of U.S.-based biotech company Nobex that had a proprietary technology to deliver peptides orally.

We knew it would be a difficult task ahead. Despite decades of research, an effective oral insulin molecule was considered the 'elusive' Holy Grail of diabetes therapy. We plunged ahead driven by the belief that delivering insulin through a pill would potentially usher in a paradigm change in diabetes management by making it convenient for patients to take insulin.

The quest for a game changing insulin therapy led Biocon to invest in the clinical development of Insulin Tregopil, a first-in-class oral insulin molecule that could mimic the natural physiology of the body by targeting the liver, which is a central organ in glucose metabolism. This unique mechanism of action would result in lowering the risk of hypoglycemia, when blood sugar levels fall to abnormally low levels due to injected insulin treatment, and also prevent weight gain.

When an unexpected placebo effect prevented the primary end point from being attained in a clinical trial conducted in India in 2011, we did not give up but continued our quest and partnered with a global pharma innovator and reinitiated the clinical studies. Subsequently, due to a change in their business strategy, our partner had to opt out of this collaboration. However, we decided to continue the development program as we were committed to addressing this critical unmet need. Five years later, clinical studies on Insulin Tregopil in the U.S. concluded that Tregopil provided a novel opportunity for effective postprandial control of glucose metabolism through the physiological route of the portal system.

Our conviction was further endorsed by JDRF, a leading U.S. organization funding Type 1 diabetes research and advocacy worldwide, which came forward to support our plans to study Tregopil in people with Type 1 diabetes in 2017.

Exploring the Next Frontier with Global Partnerships

Affordability is not simple to implement, it requires creative, out-of-the-box thinking to implement new perspectives. Strategic partnerships and collaborations can help harness the kind of innovation needed to attain the dream of ensuring high quality healthcare for all.

While we pursued breakthroughs in therapies, we built strategic global and regional partnerships of a symbiotic nature that over the years allowed us to share risks, lower costs, maximize our efficiencies, expedite development and expand our reach.

Our belief in the strength of collaborations led us to partner with

MILESTONES

A Journey of Differentiation **Branded Formulations**

2004
Diabetology division commences operations with the launch of Insugen® in India

2006
Oncotherapeutics division takes off with the launch of novel biologic BIOMAb EGFR® in India

2007
Sets up JV Neobiocon to provide affordable bio-therapeutics in UAE

Nephrology division starts operations in India

2008
Cardiology division starts with portfolio of products for heart diseases in India

2009
Diabetology division launches Basalog®; offers basal insulin analog option to patients in India

2010
Immunotherapy, Critical Care divisions begin operations in India

global pharma companies such as Mylan and Sandoz in the realm of biosimilars.

Our long-standing global partnership with Mylan started in 2009 to co-develop a portfolio of biosimilar antibodies and other recombinant proteins, which was expanded to include insulin analogs in 2013. Over the last decade, we synergized our frontier science and robust manufacturing capabilities with Mylan's regulatory and commercialization expertise to deliver affordable therapies to patients in both developed and developing countries. Today, we have one of the most extensive biosimilars pipelines under global development. The partnership has started to deliver returns to both partners with three of our biosimilars launched in some of the developed markets like U.S. and Europe.

Our success in biosimilars drew Sandoz, a division of Novartis, to partner with us in 2018 for the development of next-generation biosimilars portfolio for immunology and oncology. This synergistic partnership is providing us an opportunity to scale up our capabilities for an 'end to end' play in the global biosimilars space.

Our co-development partnerships with Mylan and Sandoz, both global leaders, are a recognition of our biosimilar strengths and capabilities in frontier sciences.

In the space of novel assets, too, we have built strong partnerships. We have collaborated with Quark Pharma for siRNA (small interfering RNA) therapeutics, and with JDRF for our novel oral Insulin Tregopil.

We also have technology collaborations with premium institutes across the country such as the Indian Institutes of Technology (IIT) and National Institute for Pharmaceutical Educational and Research (NIPER). We are also working with global academic institutions like Harvard University (U.S.), Trinity College (Ireland), the National Center for Biological Sciences (India) and the Indian Institute of Sciences and others on translational research.

Our marketing alliances have taken the 'Made in India' therapies to over 120 countries, including U.S., Europe, Japan and key emerging markets in Latin America, AFMET, Asia Pacific and CIS regions. With recent regulatory approvals in U.S., EU, Canada, Australia, we are well positioned to make patient lives better in these countries through our high quality, affordable biosimilars.

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Three of our biosimilars co-developed with Mylan have been commercialized in developed markets viz. Pegfilgrastim in U.S., Trastuzumab and Insulin Glargine in EU.

2011

Introduces reusable insulin pen, INSUPen®, for the benefit of diabetes patients in India

2013

Launches ALZUMAb™, a novel biologic indicated for the treatment of chronic plaque psoriasis

2014

Launches world's 1st biosimilar Trastuzumab as CANMAb™ for breast cancer patients in India

2015

Launches Basalog One®, a pre-filled, disposable Insulin Glargine pen, to strengthen insulins portfolio in India

2017

Launches KRABEVA® (biosimilar Bevacizumab) in India for several types of cancer

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Launches biosimilar Insulin Glargine in UAE as Glaricon®

2018

Launches CANHERA as 1st biosimilar Trastuzumab in UAE for breast cancer

+ Read more on Branded Formulations Journey : Page 72

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YEARS OF
BIOCON

Building Scale on a Differentiated Strategy

Very early in our journey, we had realized the importance of building large scale manufacturing capacities to support our ambition of making global impact.

We thus made significant investments in building world class manufacturing infrastructure.

We created large scale fermentation capabilities to support manufacturing of APIs like statins and immunosuppressants. We also built one of India's largest bio-manufacturing facilities for insulins, monoclonal antibodies and devices. We continue to invest in expanding our manufacturing capacities to address the growing market need.

Biocon's insulin manufacturing and R&D facility set up in Malaysia with an investment of USD 300 million is the largest integrated insulins facility in Asia. This is the largest foreign investment in biotechnology in Malaysia and reflects our commitment to serve patients in different parts of the world. Currently, Biocon is addressing the demand for insulins in Europe, Malaysia and several other emerging markets from this facility.

In Pursuit of Quality

Biocon's state-of-the-art manufacturing facilities are qualified by various regulatory agencies from developed and emerging markets. With an unwavering commitment to quality assurance and stringent quality controls, Biocon is on a mission to go beyond compliance and achieve global standards of excellence.

A nearly 1,000 member strong, well-trained Quality team works round the clock to monitor every step of the development and manufacturing process to ensure that each and every product manufactured and distributed by us complies with all internationally accepted good practices and standards of quality, purity, efficacy and safety.

Our Quality Control and Quality Assurance teams ensure that the cGMP guidelines, protocols and SOPs are implemented to deliver high quality products every time. Good Manufacturing Practices, Good Laboratory Practices and Good Documentation Practices are entrenched throughout our operations. The focus is on getting it right the first time.

Robust regulatory and quality systems provide us the platform to develop and deliver complex therapeutics, lending us a significant global competitive advantage.

~1,000

A well-trained Quality team works round the clock to ensure the quality of our products.

MILESTONES

A Journey of Reliability Research Services

1994-2000

Initiates operations as a CRO with services in chemistry and biology

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Receives 100% Export Oriented Unit (EOU) status from Government of India

2001-2007

Forays into chemical development with a dedicated manufacturing facility

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Collaboration with Bristol-Myers Squibb to set up BBRC, Syngene's 1st dedicated R&D center

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Crosses annual turnover of ₹1 billion in FY07

2009-2011

Expands manufacturing services with a new cGMP compliant plant

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Initiates operations in safety assessment and large molecules development services

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Initiates operations in formulations development

Shaping Talent for the Future

At Biocon, a young workforce pursues its innovation dreams, as we pioneer complex biopharmaceuticals, biosimilars and novel drugs development. The depth and breadth of our technological and scientific pool empowers us to engage in cutting-edge research. We have consciously created opportunities for our scientific teams to contribute to science and affordable healthcare. In our journey of 40 years, we pride ourselves in having created an ecosystem that encourages free flow of ideas, collaborative research that motivates the talent to push their boundaries.

From building technical skills of frontline executives to developing leadership capabilities, employees across the spectrum are given opportunities to build capability and participate in Biocon's growth story.

As we continuously expand our talent pool and develop a mix of capabilities to propel us forward in a continuously evolving and complex global biotechnology landscape, we are proud to rank on Science magazine's list of the world's Top Global Biotech Employers every year since 2012.

At Biocon, we are also proud to have contributed to creating a vibrant biotech ecosystem. Inspired by the entrepreneurial passion of our founder and chairperson, Kiran Mazumdar-Shaw, many others have ventured into the biotechnology space, adding to the country's strengths in this sector. Several of our former scientists and employees have spun out as entrepreneurs, bringing to bear their strong foundation of knowledge, skills and value systems.

Value Creation

Even as we continue to develop affordable products, we are also creating value for our stakeholders.

In 2004, Biocon became India's first biotech company to go public. The market's trust in Biocon's intrinsic value was reflected in the IPO being oversubscribed 32 times in 2004. On Day 1 of listing on the stock exchanges, Biocon closed with a market value of USD 1.11 billion, only the second Indian company to have crossed the billion dollar mark on its first day of listing. Given the intrinsically long gestation periods requiring huge investments and an evolving regulatory framework even in the US, our market capitalization remained largely muted till 2016.

Driven by our fortitude and strong determination to make a difference to a billion lives, we continued to develop a pipeline of unique assets. We witnessed an inflection point in our market capitalization post the Insulin Glargine approval in Japan in March 2016, which helped improve investor confidence in Biocon's pipeline for other developed markets. This was further strengthened with the regulatory submissions and approvals of our biosimilars for Trastuzumab, Pegfilgrastim and Insulin Glargine in U.S. and Europe. The confidence of investors in Biocon's current and future prospects is reflected in our current market capitalization of over USD 5 billion (as on March 31, 2019). In 2015, we unlocked value from our Research Services business by listing our subsidiary Syngene on the Indian stock exchanges. The market capitalization of Syngene stood at over USD 1.7 billion (as on March 31, 2019).

We continue to create value for our stakeholders through our key growth drivers.

2012-2015

Partners with Abbott for nutrition R&D center in India, Syngene's 2nd dedicated R&D center

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Crosses annual turnover of ₹5 billion in FY13

Partners with Baxter to establish BGRC, Syngene's 3rd dedicated R&D center

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Successful listing of Syngene as India's 1st 'pure play' contract research services company

2016-2017

Acquires bioinformatics assets of Strand Life Sciences

Partners with Amgen to establish 4th dedicated R&D center

Crosses an annual turnover of ₹10 billion in FY16

Collaborates with Herbalife Nutrition to establish nutrition R&D center

2018-2019

Signs agreement with GSK to advance drug discovery in multiple therapy areas

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Extends Baxter collaboration till 2024

Signs agreement with Biotechnology Industry Research Assistance Council (BIRAC) to set up a Centre for Advanced Protein Studies

+ Read more on Research Services Journey : Page 78

Reliving Yesteryears **Co-creators**

Key Stakeholders

Leslie Auchincloss

1978 onwards

Irish Partner who influenced Kiran to set up Biocon in India

Key Stakeholder in Biocon's 40-year Journey

It is often said that it was an accidental meeting between Kiran and I, that led to establishment of Biocon India. The truth is that I heard about her from a colleague in Australia and sought her out in Baroda. In 1978, I came in search of a partner who could start and run a company in India to manufacture and supply enzymes to my company Biocon Ireland. Kiran was 25, qualified and enthusiastic, yet was not getting a position as a brewer in India because she was a woman! It took some convincing on my part to get Kiran to agree to become a partner and set up Biocon India.

The Indian government had capped foreign equity at 30% at that time, so Biocon India was set up in Bengaluru with Biocon Ireland contributing USD 10,000 to the joint venture. Within two months, Kiran had established operations in a small shed in Bengaluru. We started with making papain and isinglass and soon Kiran was providing a range of bioenzymes for our global clients. That was the start of Biocon India!

Kiran went on to establish a horizontal management style at Biocon India, which was paramount for open communication within the group, sharing of IP and avoiding any politics. Above all, she created a culture of honesty, integrity and trust. Today, I am incredibly proud of all that Kiran has achieved and look forward to the next 10 years of Biocon

When I first met Kiran 35 years back, I was struck by her passion, zeal and determination and instinctively felt that she would succeed in whatever she set about to do. But what she was able to achieve over the next three decades was truly amazing. She was able to build an iconic institution that will stay etched in the annals of India's industrial history. Much of it is due to her sharp business acumen and ability to assemble a very talented team under one roof, but a substantial amount of credit should be given to her emphasis on research, right from the beginning. At a time when everyone was paying only lip service to the concept of linking research to business and industry, she boldly stepped forward and made research a key platform for growth. What Biocon has been able to achieve during the last four decades is truly impressive but what is to follow will pale this into insignificance.

Narayanan Vaghul

1989 onwards

Former Chairman of the Board of ICICI Limited

Key Stakeholder in Biocon's 40-year Journey

Prof. Alan D Cherrington

2009 onwards

Professor, Molecular Physiology and Biophysics, Vanderbilt University
Scientific Advisory Board Member, Biocon

Key stakeholder in Biocon's 40-year Journey

I was fortunate to be working with a biotech company (Nobex) in North Carolina, U.S., when Biocon became a partner in a fledging program to develop an oral insulin. I was struck by the Biocon folks' desire to see the project succeed. When Biocon acquired the asset, I became a consultant to the company. At the time, I was President of the American Diabetes Association and scheduled to visit India for a series of talks. Kiran found out and contacted me to see if I would visit Biocon. I explained to her that my commitments would not allow me to do so, but she would not take 'no' for an answer. She somehow found out that I had a morning free so she arranged for someone to pick me up at my hotel in Chennai and fly with me to Bengaluru for a breakfast meeting with her and her colleagues. By early afternoon, I was back in Chennai. I learned very quickly that Kiran is a strong and determined leader. Further, her example defines the company. She has supported the oral insulin project for many years in the hope that we could develop a new therapeutic approach, which could help in the treatment of patients with diabetes, particularly in India. It has been a pleasure working with the scientists at Biocon. Their hard work, passion and intellect are second-to-none.

I have known Kiran for a long time, since the early years of Biocon. Biocon has become a great national institution because of the outstanding leadership of Kiran Mazumdar-Shaw. Biocon sets an example for picking the right areas and problems of value, and achieving progress by multi-pronged efforts including R&D. I am truly impressed, and congratulate Kiran on her fantastic accomplishments. I wish her and Biocon continued success.

Prof. C.N.R Rao

1978 onwards

Honorary President & Linus Pauling Research Professor, Jawaharlal Nehru Centre for Advanced Scientific Research

Key stakeholder in Biocon's 40-year Journey

Dr. R. A. Mashelkar

1978 onwards

National Research Professor
Formerly:
Director General, CSIR
President, Indian National Science Academy
Chairman, National Innovation Foundation
President, Global Research Alliance

Key stakeholder in Biocon's 40-year Journey

I have been a witness to Biocon's spectacular evolution from an industrial enzymes manufacturing company to a fully integrated bio-pharmaceutical company with a well balanced business portfolio of products and a research focus. I was the chief guest at the inauguration of the Company's subsidiary Syngene (1984), which provided research and development Support Services on a contract basis. I was also present, when another subsidiary, Clinigene was launched in 2000. I had a small role to play, when in 2004, Biocon became the first biotechnology company in India to issue an IPO, which was oversubscribed 33 times!

Kiran represents to me one of World's top most 'biotechnopreneur', who created a thriving world class biotechnological enterprise. she is full of courage and vision, not just a great thought leader but a great action leader.

Biocon's belief in 'innovation with affordable excellence' for the resource pool, itslarge investments in R&D, its conviction in strong IP based growth and finally theprinciple of 'doing well and doing good' through Biocon Foundation are so inspiring! Biocon has had a glorious past, but it has even a more glorious future as it marches towards the golden jubilee.

Reliving Yesteryears **Co-creators**

Business Partners

Rajiv Malik

President, Mylan

Biocon's Business Partner since 2009

Global Development of Biosimilars

We have made significant progress with Biocon over the past decade to increase access to biosimilars for patients. We're proud of all that we have accomplished together, and in particular the strength of our scientific and regulatory teams. Today, these teams have received more than 65 regulatory approvals for several biosimilar products around the world, reaching numerous patients and expanding access to those in need. But we won't stop here. We continue to build on the successes of the collaboration and remain steadfast in our commitment to further patient access to critical biologic treatments and increase competition as healthcare costs continue to rise.

Craig A. Collard

Chief Executive Officer, Veloxis Pharmaceuticals

Biocon's Business Partner since 2006

Small Molecules APIs Business

We would like to congratulate Biocon, who is one of Asia's premier biopharmaceutical companies on their 40 year anniversary. Biocon's vision to make a difference in global healthcare through improved access to high quality, life-saving biotherapeutics has helped Veloxis not only develop but launch a product that is helping to improve the lives of transplant patients across the world. We are privileged to be part of the Biocon history and look forward to an exciting future as our partnership continues to grow.

Stefan Hendriks

Global Head of Biopharmaceuticals, Sandoz

Biocon's Business Partner since 2018

Global Development of Biosimilars

Biocon has proven to be a great complement to our biosimilar capabilities at Sandoz. By working together, we are realizing benefits at nearly every stage of the biosimilar value chain. We are proud that our collaboration with Biocon further strengthens our ability to deliver next-generation biosimilars, ultimately expanding access to high quality and affordable medicines for patients around the world.

Oscar Osorio Arechavaleta

CEO, Laboratorios PiSA

Biocon's Business Partner since 2002

Insulins & Small Molecules

Laboratorios PiSA is proud to have been one of Biocon's earliest partners for human insulin. Mexico has one of the highest prevalence rates of diabetes in the world, and because we recognised early on the importance of Biocon's insulin, we have been able to significantly increase insulin access for diabetes patients in Mexico for over a decade. Today, the vast majority of human insulin patients in Mexico receive the insulin produced through our partnership. We are also proud to have extended our partnership to insulin glargine, small molecules, and to now collaborating to bring a human insulin biosimilar to the U.S. market. Our partnership is built on a shared commitment to provide affordable access to insulins to patients, and we look forward to delivering on that promise together in the years ahead.

Dr. Izumi Sakakibara

Director & General Manager, Business Development FUJIFILM Toyama Chemical Co.,Ltd.

Biocon's Business Partner since 2012

Pharmaceuticals

We, FUJIFILM Toyama Chemical Co., Ltd., sincerely celebrate Biocon's 40th anniversary. Our alliance started in 2012 for the development of biosimilar Insulin Glargine in Japan. Based on the strong partnership and Biocon's innovative technology we achieved the milestone of launching a biosimilar Insulin Glargine pen in the Japanese market. The success of this product sets the stage for the expansion of our biosimilar footprint in Japan through our partnership with Biocon.

Alcebíades de Mendonça Athayde Jr.

CEO, Libbs Farmacêutica

Biocon's Business Partner since 2011

Biosimilar Mabs & APIs

We believe that Libbs has contributed to Biocon's development in the three important areas of regulatory, tech transfer and marketing, in Brazil. Our teams have worked together to build knowledge and wealth for both the companies. Together, we have made a significant impact on public health by improving access to biosimilars in Brazil.

Leonard Ariff Abdul Shatar

Group Managing Director, Duopharma Biotech Berhad

Biocon's Business Partner in Malaysia since 2012

Insulins and MABs

The strategic partnership between Duopharma Biotech Berhad (formerly known as CCM Duopharma Biotech Berhad) (Duopharma Biotech), Malaysia's leading pharmaceutical company and Biocon Limited (Biocon) has brought affordable cancer and insulin therapeutic options to the country. The award of the RM300 million contract to Biocon Sdn Bhd and Duopharma Marketing Sdn Bhd (formerly known as CCM Pharmaceuticals Sdn Bhd) to supply locally produced Insugen (recombinant human insulin) and the recent successful launch of Basalog One (Insulin Glargine pen) as well as Zuhera (Trastuzumab) have positioned Biocon as an innovative and progressive company in Malaysia. The partnership of Biocon and Duopharma Biotech has established both these companies as key players in the diabetes and cancer markets, with the government, healthcare professionals and patients. The supply of insulins in Malaysia has provided a good base for the state-of-the-art manufacturing facility in Johor to operate economically. This provides Biocon with the foundation to explore export opportunities to bring affordable insulin therapies from its Malaysian plant to the rest of the world. It is our hope that the continued future collaboration of Biocon and Duopharma Biotech will bring our companies even closer and 'provide smarter solutions for a healthier life' to patients and customers in Malaysia and neighbouring countries.

Our Business **Journeys**

A Journey of **Building Global Scale**

SMALL MOLECULES

APIs and Generic Formulations

60+

As one of the largest makers of statins and immunosuppressants in the world, we supply these APIs to over 60 countries.

Biocon was among the early movers in developing a portfolio of fermentation derived statins, then referred to as 'the wonder drug of the 21st century' as they helped reduce blood cholesterol and prevent heart disease. Our scientists developed several non-infringing processes for manufacturing statins, which gave us a competitive edge in the global markets.

Most drugs on the market today are small molecules. These are compounds of low molecular weight (less than 900 daltons), which are usually taken orally in the form of a tablet, capsule, or liquid, or can be injected or infused.

India's patent laws in the 1980s had allowed local drug makers to build considerable competencies and offer a large number of small molecule generic drugs legally in the country at a fraction of the price of drugs sold in the Western world. A highly competitive domestic pharma industry ensured the country was self-sufficient in the production of both bulk drugs and finished dosages. Generic pharma producers in India were able to bring down the prices of life-saving drugs for tuberculosis, HIV, hepatitis etc. by as much as 90%. In doing so, India emerged as a vital manufacturer of affordable generic medicines for various acute and chronic conditions and became the world's largest supplier of generic drugs.

At that point in time, Indian vaccine producers were developing vaccines using fermentation which helped them disrupt the market through low-cost yet high quality, vaccines. Biocon, on the other hand, was using this technology to produce high quality bio-enzymes and supplying to the regulated markets of U.S. and Europe. This legacy gave us the confidence to take the unconventional path of producing biopharmaceuticals using fermentation technology. Thus we embarked on the next leg of our journey to develop a range of biopharmaceuticals to address chronic diseases. We set up a large-scale fermentation based manufacturing facility for APIs in Bengaluru and started work on statins and immunosuppressants.

Our move into biopharmaceuticals helped us accelerate revenue growth, from ₹318 million in 1999 to over ₹5 billion in 2004.

2004

Commercialized Lovastatin in the U.S. in 2004.

Statins Frontrunner

Biocon was among the early movers in developing a portfolio of fermentation-derived statins, then referred to as 'the wonder drug of the 21st century' as they helped reduce blood cholesterol and prevent heart disease. Our scientists developed several non-infringing processes for manufacturing statins, which gave us a competitive edge in regulated markets.

We started developing Lovastatin in early 2000 using an innovative solid state fermentation technology. The submerged fermentation process used by the innovator was still under patent protection then. Our novel process helped us obtain our first approval from the U.S. Food & Drug Administration for manufacturing Lovastatin in 2001. We were the only company in the world to use this technology and were one among three players globally with approvals to supply the API to the U.S.

We simultaneously developed the submerged fermentation process for manufacturing Lovastatin for which we received U.S. approval in 2003. We commercialized Lovastatin in the U.S. in 2004, and successfully obtained Certificates of Suitability from the European Directorate for the Quality of Medicines (EDQM), qualifying our drug substances for use in EU member states. We were one of the largest APIs suppliers to leading Indian generics manufacturers for formulations they sold in the global markets.

2000

Biocon developed Mycophenolate Mofetil (MMF) using proprietary fermentation technology in 2000.

Statins went on to become a big growth engine for the company, fuelled by our early mover advantage in products like Lovastatin, Simvastatin, Pravastatin and Atorvastatin. We were among a handful of companies with U.S. and EU-approved APIs for these fermentation-derived statins, which helped lower the competitive intensity otherwise typical of chemistry-based APIs. This competitive edge led us to capture a significant market share for statin APIs in regulated markets by the mid-2000s.

We are now one of the largest statins manufacturers in the world supplying our drug substances to over 60 countries.

Seizing the Immunosuppressants Opportunity

As our expertise in microbial fermentation advanced, we recognized the potential advantages of combining our skills in solid state and submerged state fermentation technologies. Our R&D program to develop a novel hybrid bioreactor combining the two culminated in a patented invention, PlaFractor™. This unique bioreactor enabled solid state fermentation and extraction in the same vessel resulting in a unique containment feature that could be effectively utilised for the manufacture of highly contamination-sensitive products like immunosuppressants.

We quickly scaled up our novel PlaFractor™ technology to plant level and started a facility to manufacture Mycophenolate Mofetil (MMF). Our technology proved a commercial success as Biocon was one of the first companies to make MMF in 2000. We followed up with a full suite of generic immunosuppressants, including Tacrolimus and Mycophenolic Acid (MPA) Sodium using submerged fermentation technology.

Biocon is today one of the largest producers of immunosuppressant APIs globally, with a basket spanning MMF, MPA, Tacrolimus, Sirolimus and Everolimus. We are global suppliers of Tacrolimus and Sirolimus drug substances. Our immunosuppressant APIs are being supplied to leading international as well as Indian pharma companies.

50%

We are a leading producer of the Orlistat API with over 50% share of the global market.

Expanding our API Offerings

Having made an impact with statins and immunosuppressants, our R&D team kept working at new processes and produced more than a dozen difficult-to-make APIs through the 2000s. We developed Orlistat, an anti-obesity drug, using a combination of fermentation and synthetic chemistry techniques. Today, we are a leading producer of the Orlistat API with over 50% share of the global market.

In 2010, Biocon entered into a long-term supply agreement with Optimer Pharmaceuticals for the commercial manufacturing of the API, fidaxomicin, then the first in a new class of antibiotics for the treatment of a potentially life-threatening infection caused by the Clostridium difficile bacteria, which was a major threat in hospitals across the U.S.

Biocon's expertise in fermentation technology and synthetic chemistry gave us a key competitive edge, making us the sole supplier of the drug substance for this proprietary molecule to Optimer for global markets. Optimer is now a part of Merck (U.S.) through a sequence of M&As. Consequently, our supplies of fidaxomicin are now to Merck (U.S.).

Forward Integration Into Generic Formulations

Having built a strong Small Molecules business around a robust portfolio of APIs, which included statins, immunosuppressants and peptides, the natural progression of our technical competencies lay in forward integration to generic finished dosages. For over a decade we had built expertise in complex APIs. Our work in biosimilars had also led us to develop complex characterization, bio-analytical and strong manufacturing skills. We capitalized on these strengths to build a robust pipeline of difficult-to-make niche formulations especially for chronic conditions. We also built a portfolio of potent molecules and early entry opportunities through patent challenges or non-infringement.

Our existing cGMP compliant manufacturing facilities, including our injectable formulations and fill-finish facilities, worked to our advantage in this new endeavor.

In 2013, the Small Molecules business took a big step forward by creating a new Generic Formulations sub-business unit to vertically integrate into manufacturing finished dosage forms. This would help us address an important need in the market – continuity of supply for quality drug products. Our focus was chronic therapy areas, such as metabolics, oncology, immunology and autoimmune indications. We commenced multiple programs to build a robust pipeline of technology-intensive molecules for global markets, primarily the U.S.

We built commercial infrastructure to support this initiative in the U.S. Our brand equity as a reliable API supplier helped us, in a very short time, to build a good network of accounts that includes wholesalers, retailers, Pharmacy Benefit Managers (PBM), Health Management Organizations (HMO) and Group Purchasing Organizations (GPO).

In order to accelerate our entry into the U.S. generic formulations market, we decided to start with formulations for our statins portfolio as these are high volume products and our backward-integration into the API could help us deliver the volumes consistently. We introduced Rosuvastatin Calcium tablets under our own label in the U.S. in 2017. Since then, we have also launched formulations of Atorvastatin and Simvastatin. We also successfully debuted in Europe

by commercializing our Rosuvastatin formulations through a local partner in January 2018.

Biocon has successfully garnered a high-teens share of the market for Rosuvastatin tablets in the U.S. despite competing in a commoditized market with many other players.

Small Molecules Portfolio Holds Bright Prospects

Since the late 1990s, we have emerged as a preferred APIs partner for over 1,000 pharma companies in more than 100 countries and have long-term business relationships with many of them. We now want to leverage and expand upon the reliability we have built over the years to emerge as a key player with our Generic Formulations aimed at niche therapy areas. Potential customers who wish to secure their supply chain from a continuity of supply perspective appreciate our vertical integration across APIs and formulations and consistent track record in quality compliance.

To fuel future growth, we are developing newer fermentation and chemical synthesis-based APIs, which may have technical barriers for entry such as complexity in manufacturing, potent compounds or a mix of both. We are also working on a niche portfolio of finished dosage forms, which includes solid oral and parenteral products in both potent and non-potent categories of compounds.

To support our filings, we had commissioned our first oral solid dosage facility in Bengaluru in 2017. The facility successfully completed several regulatory audits subsequently following our various filings in the U.S. and Europe.

2017

Our first oral solid dosage manufacturing facility commissioned.

SMALL MOLECULES: FY19 at a Glance

Revenue

17,728

₹ Million

Growth 18%

The Small Molecules segment in FY19 recorded good growth on account of APIs as well as ramp up in the Generic Formulations sales. Higher volumes and pricing stability for Statins & Immunosuppressants led the growth in API sales while the Generic Formulations business recorded robust growth, albeit from a small base due to new product introductions in the U.S. market. We successfully commercialized Atorvastatin and Simvastatin formulations in the U.S. and recorded market share gains in the previously launched Rosuvastatin formulations. More launches are expected in the next 2-3 years, which cumulatively provide revenue growth visibility to this segment.

+ Read more on Small Molecules Business : Page 135

A Journey **of Self-Belief**

BIOSIMILARS
Insulins, mAbs and Other Biologics

15+

We have over 15 years of expertise in providing biosimilar insulins to patients globally.

Biocon realized the potential of biosimilars very early on and decided to invest in developing them for global markets at the turn of the millennium. It was early days, India had just approved its first biosimilar, a vaccine for hepatitis B. It took a special kind of fortitude to foray into a complex therapeutic space where the regulatory pathway was still evolving and the international landscape was complex and dynamic.

Biological medicines are playing a critical role in the treatment of serious illnesses such as diabetes, cancer and immune-mediated inflammatory diseases. These innovator drugs, launched in the late 1990s and 2000s, are expensive and hence not accessible to all patients. The top nine branded biologic drugs generated global sales of USD 62 billion in 2018, as per a recent Morgan Stanley research report. As patents on these drugs have either expired or are about to expire by 2025, their biosimilar versions have either hit the market or are currently under development.

As the term suggests, biosimilars possess similar medicinal properties to the original biologics they are referenced to, with similar expected patient outcomes. Targeted as alternatives to existing patented and approved biologics, they have little structural variance, and comparable safety and efficacy to the originator biologic. Unlike small molecule generics, biosimilars require huge investments in research and manufacturing infrastructure as they are more complex, have less-established regulatory pathways and face intellectual property hurdles.

Nonetheless, biosimilars are relatively inexpensive when compared to originator biologics and hence more affordable for patients. Governments and regulatory agencies have recognized the role of biosimilars in addressing issues of access and affordability. They have introduced several measures to support biosimilar development and approval, encourage uptake across multiple indications and foster reimbursement.

The Biosimilars Opportunity

Having realized the biosimilars potential very early on, Biocon decided to invest in biosimilars development for global markets at the turn of the millennium. It was early days, India had just approved its first biosimilar, a vaccine for hepatitis B.

It took a special kind of fortitude to foray into a complex therapeutic space where the regulatory pathway was still evolving and the international landscape was complex and dynamic.

Europe introduced a biosimilars regulatory framework in 2005 leading to the first biosimilar approval in 2006. Since then many biosimilars have received approvals and witnessed good market penetration in the EU region. These biosimilars generated savings of over EUR 1.5 billion in the five largest EU markets alone between 2006 and 2017 *(Medicines for Europe report).*

Biocon, along with partner Mylan, has received approvals for three biosimilars, Trastuzumab, Pegfilgrastim and Insulin Glargine, and commercialized two of them in Europe.

The U.S. was a late entrant in this area, approving its first biosimilar only in 2015. Till June 2019, 20 biosimilars, have been approved by the U.S. Food and Drug Administration (FDA). Biocon is the only company from India to have obtained U.S. approvals for two of its biosimilars, Trastuzumab and Pegfilgrastim, co-developed with Mylan.

With Morgan Stanley estimating the U.S. and EU biosimilar markets to grow at a CAGR of 24% to USD 13.3 billion by 2025 from USD 2.9 billion in 2018, a number of companies worldwide are pursuing biosimilar development despite the prohibitive costs and complexity involved.

An Indigenuous Insulin for Diabetes Patients in India

In the 2000s, India was home to a quarter of the world's then 120 million people with diabetes, and they only had access to expensive imported insulin brands sold by global innovator companies.

Biocon started a biosimilar insulins program in the early 2000s to indigenously develop

2+ Bn

We have cumulatively provided over 2 billion doses of our biosimilar insulins to patients in several countries.

a safe, effective and affordable alternative to this life-saving therapy for Indians who needed insulin to manage their diabetes.

While the product patent on human insulin had long expired, it continued to be protected by strong process patents. Most of the patented processes were using the yeast, Saccharomyces cerevisiae or the bacteria, Escherichia coli to manufacture recombinant human Insulin (rh-Insulin).

As a part of our differentiation strategy, we chose to develop our own proprietary technology based on the methylotropic yeast, *Pichia pastoris,* to produce insulin which was not explored before, hence it was not patent protected.

Pichia as a production system was familiar to us as we had used it in the past to make recombinant phytase, an enzyme used in human health and animal nutrition.

Our rh-Insulin underwent extensive clinical trials in India before we obtained regulatory approval to launch the product as Insugen® in 2004. We compelled the innovator companies to drop prices of their brands by launching Insugen® at a fraction of prevailing insulins prices.

Today, our rh-Insulin is registered in over 40 countries worldwide and has been commercialized in many emerging markets.

Moving to Modern Insulins

The 1990s saw the advent of insulin analogs, which mimicked the body's own insulin production. Insulin Glargine was the first long-acting analog to become commercially available. It allowed better metabolic control, thereby ensuring a better quality of life and improved treatment satisfaction. Having made a difference to people with diabetes in India with our rh-Insulin, we took up the challenge of developing biosimilar Insulin Glargine.

The completion of the process and analytical development, non-clinical and clinical studies for Insulin Glargine in India culminated in its approval and subsequent launch under the brand name Basalog® in 2009, providing diabetes patients with an advanced, affordable insulin therapy.

To take biosimilar Insulin Glargine to people with diabetes worldwide, Biocon initiated a global development program in 2010. The program got a fillip in 2013, after Mylan, a global leader in generic medicines, came forward to partner us for co-developing a basket of insulin analogs, including Insulin Glargine, Insulin Aspart and Insulin Lispro. It was an extension of an earlier agreement to jointly develop monoclonal antibodies and other biologics with Mylan for global markets.

Introducing Patient-Friendly Insulins Devices

As insulins use increased globally, insulin makers across the world began replacing syringe delivery with novel delivery devices like insulin pens, which were less painful and provided people with diabetes an easy-to-use, convenient-to-administer and accurate method of insulin delivery.

2015

Our biosimilar Insulin Glargine was the first insulin to be approved as per the new bio-comparable guidelines of COFEPRIS, Mexico, in 2015.

In 2011, we introduced INSUPen®, a reusable insulin device manufactured with high precision German technology, which offered metered dosing of Insugen® & Basalog®.

Biocon's reusable pens are today available in India, Malaysia and a few other emerging markets, where they have made a significant impact on the quality of life of patients who need treatment for their diabetes.

To take our insulins to the maximum number of people with diabetes we added disposable pens to our portfolio in 2015 since most of the patients on insulin in the Western world preferred this option. We partnered with one of the world's leading medical device makers, Becton Dickinson, to design a pre-filled, disposable insulin pen for both the Indian and global markets. This was the first product to roll out from our Bengaluru-based devices facility set up for manufacturing new generation, patient-friendly insulin devices. The pen, Basalog One®, strengthened our Insulin Glargine portfolio comprising vials, refills and reusable devices.

Making a Difference in Diabetes Management Worldwide

In line with our commitment to make global impact we forged strong regional partnerships in many key emerging markets to provide access to our high-quality yet affordable recombinant human insulin.

For instance, in Mexico, along with our partner Lab PiSA, we have been providing access to our affordable rh-Insulin therapy for over a decade. In 2015, our Insulin Glargine became the first insulin to be approved as per the new bio-comparable guidelines of COFEPRIS, the Mexican Health Authority.

The debut of our insulins in the developed markets happened in 2016 with the approval of our Insulin glargine pen in Japan. This was a landmark achievement for us. While Biocon did the product development, the Japanese partner FUJIFILM Pharma conducted the local clinical studies and commercialized our product.

We had finally entered a regulated market with our own biosimilar, and in doing so became the first company from India to commercialize a biosimilar in Japan.

The approval of our product enabled access to an affordable, world class, pre-filled, disposable pen for the 7.2 million people with diabetes in Japan in 2016 *(IDF)*. Till then, only seven biosimilars had received approvals in Japan, including one biosimilar version of Insulin Glargine. Given Japan's reputation of high product quality expectations and stringent manufacturing standards, the commercialization of our product enhanced our global credibility manifold.

Our partner Mylan submitted a Marketing Authorization Application (MAA) for biosimilar Insulin Glargine with the European Medicines Agency in 2016. It culminated in the approval of Semglee® (Insulin Glargine) in March 2018 and its commercialization in late 2018. Mylan also obtained approval for Semglee® in Australia subsequently.

Our biosimilar Insulin Glargine has been approved in over 60 countries and is commercialized in several key emerging markets like Mexico, Malaysia, South Korea, and UAE, where it is offering an affordable treatment option to millions of people with diabetes.

Even as we make a difference globally with our biosimilars for rh-Insulin and Insulin Glargine, we are working on widening our basket with Insulin Aspart. This rapid-acting insulin analog is currently progressing well in Phase III clinical studies.

Looking to Address the Insulins Crisis in U.S.

We are sensitive to the plight of insulin-dependent diabetes patients in the U.S., where prices of this essential medication have tripled between 2002 and 2013 and many patients are spending hundreds, sometimes thousands, of dollars out of their pockets every month to buy innovator brands *(JAMA)*.

As a company driven by its mission to provide affordable access to high quality, life-saving therapies, we are committed to enable access in the U.S. to our insulins for patients with diabetes.

40+

Our rh-Insulin is registered in over 40 countries worldwide and has been commercialized in many emerging markets.

Our strategy of disruptive pricing helped increase insulin access for diabetes patients in India 15 years ago. Since then we have built one of Asia's largest integrated insulins manufacturing facilities in Malaysia and India to drive economies of scale, enabling us to provide millions of doses of insulin at affordable prices in emerging and developing countries, including Japan and some countries in the European Union.

In fact, we have been providing our insulins in Mexico through our partner for over a decade at a fraction of the price patients pay in the U.S. Through rh-Insulin and Insulin Glargine we have been helping people with diabetes in Mexico manage their condition better by providing affordable access to these critical insulin therapies.

We initiated global development for Insulin Glargine to address patient needs in the U.S. in 2010 and our partner Mylan made a regulatory submission in 2017. However, a 30-month stay was triggered on the approval of the biosimilar due to a patent litigation initiated by the innovator. We believe the final approval of Insulin Glargine is linked to the end of stay period which is expected in March 2020.

Furthermore, we have initiated development of rh-Insulin for the U.S. market. We are greatly encouraged by the positive actions taken by the U.S. FDA in clarifying the path to approval of biosimilar insulins through the transition from the 505 (b)(2) to the 351(k) legislations and in terms of specifying requirements for an interchangeable designation.

Targeting Cancer & Autoimmune Diseases

Our multi-disciplinary technological capabilities combined with a growing expertise in clinical development enabled us to enter the complex territory of mammalian cell culture technology as early as 2003. Mammalian cell culture is key to developing monoclonal antibodies (mAbs), which are complex biomolecules that display specific affinity towards the target antigen or receptor on a tumor cell and initiate a complex set of events that leads to tumor regression and in some patients, complete remission.

Though these molecules stood at the steep end of the learning curve, we leveraged our cutting-edge science and technology capabilities in process development and analytical characterisation to develop in-licenced humanized antibodies for life threatning diseases like cancer and autoimmune conditions like psoriasis. Our path-breaking work in the field led to the launch of India's first novel mAb in 2006. It also drew global attention to our R&D capabilities in the realm of complex biologics. Mylan partnered with us in 2009 to develop a high value portfolio of biosimilars, comprising Trastuzumab, Pegfilgrastim, Bevacizumab, Adalimumab and Etanercept. In 2018, we agreed to expand our collaboration and added two new next-generation biosimilar programs.

Bringing World's 1st Biosimilar Trastuzumab to India

Our collaboration with Mylan witnessed its first success in India in 2013, when our molecule became the first biosimilar

Trastuzumab to win approval anywhere in the world. Trastuzumab was hailed as a path-breaking targeted therapy for HER2-positive breast cancer patients. The aggresive cancer cells spread more rapidly than other breast cancers, putting women with HER2-positive breast cancer at a much higher risk of death.

Successful completion of multi-centric clinical trials in India led to the approval and subsequent launch in 2014 of the biosimilar under the brand name CANMAb™ in India for treatment of HER-2 positive breast cancer.

2017

The U.S. FDA approval of Ogivri®, our biosimilar Trastuzumab, in 2017 was an endorsement of Biocon and Mylan's combined strength of cutting-edge science, clinical development and manufacturing capabilities.

Putting India on the Global Biosimilars Map

We had started a global study in 2013 to evaluate the comparative efficacy and safety of our biosimilar Trastuzumab versus the reference product. This HERITAGE study was the last major step of a multi-phased program to demonstrate that our biosimilar Trastuzumab met the criteria for equivalence in comparison to the reference product. Results of the landmark study allowed our partner Mylan to submit a robust data package to the U.S. FDA as part of its Biologics License Application for biosimilar Trastuzumab in November 2016.

In mid-2017, the U.S. FDA's Oncologic Drugs Advisory Committee (ODAC), which provides independent expert advice to the agency on issues including product approvals, unanimously concluded that no clinically meaningful differences existed between our biosimilar and the innovator product in terms of safety, purity and potency.

The 16-0 recommendation by ODAC culminated in the final approval for Ogivri® in December 2017, making us the first globally to win U.S. approval for biosimilar Trastuzumab indicated for certain HER2-positive early stage and metastatic breast cancers, as well as, metastatic gastric cancer. It was a historic achievement, as we were the first company from India to get U.S. FDA approval for a biosimilar.

We followed up with regulatory approvals for Ogivri® in the developed markets of EU and Australia in 2018. Breast and gastric cancer patients in several countries in Europe are now benefiting from our biosimilar Trastuzumab after Mylan commercialized it in early 2019.

We have also made this key cancer therapy affordable and thus accessible for cancer patients in several emerging markets in the Latin America, AFMET and APAC regions.

1st to Launch Key Biosimilar Cancer Therapy in U.S.

Biocon and Mylan achieved another first in the form of U.S. FDA approval for the jointly developed biosimilar Pegfilgrastim, Fulphila®, in June 2018, crossing the finishing line ahead of a pack of strong competitors.

The approval for Fulphila® was based on a comprehensive package of analytical, non-clinical and clinical data, which confirmed that the product is highly similar to the innovator brand. The drug reduces the duration of febrile neutropenia (fever or other signs of infection with a low count of neutrophils, a type of white blood cells) in patients treated with chemotherapy in certain types of cancer.

Fulphila® became the first biosimilar from our joint portfolio and the first biosimilar Pegfilgrastim commercialized in the U.S. Since its introduction in July 2018, Fulphila® has captured a 21% share of Pegfilgrastim syringes market volume in the U.S. *(Bloomberg Symphony data in Goldman Sachs report May 2019)*.

60+

Our biosimilar Insulin Glargine has been approved in over 60 countries and has been commercialized in several countries globally.

Fulphila® has also won approvals in the developed markets of EU, Australia and Canada. These approvals have expanded our oncology portfolio for the benefit of cancer patients and supported our global mission to improve access to high quality, affordable biologic therapies to treat cancer.

Expanding our Oncology Portfolio In India

We launched KRABEVA®, our biosimilar Bevacizumab, in India in November 2017. Our second oncology biosimilar in India after Trastuzumab, KRABEVA® is prescribed for metastatic colorectal cancer (mCRC) and several other types of lung, kidney, cervical, ovarian and brain cancers. We obtained approval to market this biosimilar in India on the basis of a Phase III clinical study conducted on mCRC patients.

To take the drug to a global patient pool we are conducting global Phase III clinical trials for biosimilar Bevacizumab, which are making good progress.

Working on Next-Gen Biosimilars

In 2018, we signed another global partnership for biosimilars with Sandoz, a Novartis division to co-develop a set of immunology and oncology biosimilars.

The collaboration with Sandoz will give us the opportunity to participate in end-to-end development and manufacturing of partnered products, as well as obtaining regulatory approvals and commercializing them in chosen geographies.

Work on the biosimilars partnered with Sandoz, though at an early stage, prepares us for the next wave of biosimilar opportunities scheduled to emerge by the middle of next decade.

Promising Opportunities Ahead

Given their potential to deliver enhanced patient care, the medical and pharmaceutical world is very optimistic about the biosimilars opportunity. More than 400 million patient days of clinical experience worldwide have been generated between and 2006 and 2016, providing enough evidence to suggest that biosimilars can be used as safely and effectively as their reference medicines.

At the same time, biosimilars have increased patient access to latest treatments. The availability of biosimilar Filgrastim ensured 44% more patients in the five largest EU markets gained earlier access to gold standard medicines between 2006 and 2014 *(Medicines for Europe report)*.

Thus, biosimilars are an exciting space to be in, promising long-term growth for early movers like Biocon.

Over a span of a decade, we have developed a rich pipeline of approved and in-development biosimilars that have concurrently built high end R&D and regulatory expertise. Along with Mylan, we have successfully commercialized three biosimilars in the developed markets, viz. Pegfilgrastim in U.S., Trastuzumab and Insulin Glargine in Europe. Biocon-supplied products also hold dominant shares for Trastuzumab, rh-Insulin and Insulin Glargine biosimilars in several key emerging markets.

Our biosimilars addressed the needs of nearly 2 million* patients in FY19, and we aim to touch 2.6 million patient lives in FY20 in line with our commitment to make a difference to patients globally in managing diseases that are chronic, and where medical needs are largely unmet and therapy costs are high.

**Note: The estimated patient reach numbers have been calculated indirectly based on volume supplied and certain assumptions related to dosage per patient, duration of treatment, units sold, internal data and market research reports.*

Status of Biocon's Global Biosimilars Portfolio

	Therapeutic Area	Molecule	Status
MYLAN & LOCAL PARTNERS	Oncology	TRASTUZUMAB	Launched in EU & Emerging Markets. Approved in U.S., Canada & Australia.
	Oncology	PEGFILGRASTIM	Launched in the U.S. Approved in EU, Australia & Canada.
	Oncology	BEVACIZUMAB	Launched in India. Global Phase III.
	Oncology	FILGRASTIM	Preclinical
	Oncology	PERTUZUMAB	Early development
	Diabetes	INSULIN GLARGINE 100 IU/ML	Launched in the EU, Japan# & Emerging Markets. Approved in Australia & New Zealand. Under review in U.S.
	Diabetes	INSULIN GLARGINE 300 IU/ML	Early development
	Diabetes	INSULIN ASPART	Global Phase III
	Diabetes	INSULIN LISPRO	Preclinical
	Diabetes	RECOMBINANT HUMAN INSULIN	Launched in Emerging Markets. In active development for U.S. (partnered with Lab PiSA)
	Autoimmune	ADALIMUMAB	Partner Mylan has launched in-licensed product Hulio® in EU. Biocon benefits from economic interest
	Autoimmune	ETANERCEPT	Partner Mylan's in-licensed product filed for approval in EU. Biocon retains economic interest
SANDOZ	Oncology & Immunology	VARIOUS ASSETS	Early stage development

#Japan launch is outside of the Mylan partnership

As on May 2019

BIOLOGICS: FY19 at a Glance

Revenue

15,169

₹ Million

Growth 97%

FY19 has been a landmark year for the Biosimilars business, with revenues of the Biologics segment doubling over last year, to cross the USD 200 million milestone. Our biosimilars strategy has begun to deliver results with the launch of our key biosimilars in the U.S. and Europe and other global markets. The launch of biosimilar Pegfilgrastim in the U.S. and increasing sales of biosimilar Trastuzumab in the emerging markets were the main contributors to this growth.

Other notable highlights include launch of biosimilar Insulin Glargine, biosimilar Trastuzumab and in-licensed biosimilar Adalimumab, by our partner Mylan in Europe.

Higher revenues, including impact of profit share in both developed and emerging markets, offset higher R&D and fixed costs, leading to significant improvement in margins not only in the Biologics segment, but also at the consolidated level. Segment PBIT improved from negative 2% last year to 26% in FY19, reflecting a very strong performance over last year.

+ Read more on Biologics Business : Page 136

Sources:
1. *Biosimilars: An emerging market opportunities in India (P Rushvi, K Charmy, C Nirav, C Narendra - Pharmaceut. Reg. Affairs, 2016)*
2. *U.S. FDA website*
3. *Cell factories for insulin production (Baeshen NA, Baeshen MN, Sheikh A, et al. - Microb Cell Fact, 2014)*
4. *Pichia Power: India's biotech industry puts unconventional yeast to work (Chandra Shekhar - Chemistry & Biology, 2008)*

Reliving Yesteryears **Co-creators**

Brand Ambassadors

Murali Krishnan

1981-2014

Chief Accountant -> President, Group Finance -> Advisor

Former CFO, Biocon

It has been a wonderful journey of four decades from a start-up to a leading global biopharmaceuticals company. From being a part of a four member team to an over 11,000 people strong organization today, it has been a journey of immense pride. Kiran's leadership style of giving responsibility with complete authority to take decisions encouraged all of us to go beyond the call of duty. As the CFO of Biocon my mission was to enable growth of Biocon through prudent financial management.

Suresh Talwar

2003-2014

Former Board Member

Biocon

It was a great pleasure for me to serve on the Board of Biocon for over 10 years. After I retired from Biocon, I joined the Board of Syngene on Kiran's request. I am proud of my association with Biocon and Syngene, which was a direct consequence of my relationship with the late Neville Bains and John Shaw who were keen to have me on the Board of Biocon. I am grateful to Kiran for personally inviting me to join Biocon and serve as a member of the Board. My law firm handled the legal aspects of Biocon's IPO in 2004 and witnessed the landmark success of India's first publicly listed Biotech Company.

Dr. Vijay Chandru

1990 onwards

INAE Distinguished Technologist, Indian Institute of Science; Co-Founder Director, Strand Life Sciences

Key Stakeholder in Biocon's 40-year Journey

My deepest felicitations to the Biocon family and Kiran in particular on this wonderful occasion of the 40th anniversary of its extraordinary journey. My reflections on this journey have personal and professional dimensions. Kiran and I were born the same year in families that were socially connected. When I was a young academic in the U.S., I would meet Kiran on visits to Bengaluru and learn about her early entrepreneurial adventures. I joined the faculty of the Indian Institute of Science in the 1990s and a group of us began to work at the interface of computation and biology which led to the creation of Strand Genomics, India's first example of academic entrepreneurship.

It was Kiran and the Biocon leadership that advised and mentored us when we set up Strand. For the last two decades, we have been colleagues in the development of the bioeconomy of India as entrepreneurs, industry advocates and policy advisors to the state. It has been amazing to witness the dramatic scale-up of Biocon from its garage beginnings to its breakthroughs in innovation and the manufacture of recombinant human Insulin, Trastuzumab and the enormous impact in diabetes and cancer management that Biocon now has a global footprint in. We are all so proud of Biocon's achievements and what it has done to make Bengaluru, the 'Boston of the Orient'.
Happy 40th Biocon.

Current Marshals

Dr. Anuj Goel

1996- Present

Management Trainee - > Vice President

R&D, Biocon

I joined R&D in the early days to set up the process development group. I have built teams, infrastructure and processes in R&D over the last 20 years. Starting with fermentation processes for statins and immunosuppressants in the initial years, the team enabled Biocon's entry into recombinant human insulin, insulin analogs and other biosimilar microbial products.

Our team's foray in cell culture allowed us to bring technologies for Nimotuzumab and Itolizumab into India. The development of state-of-the-art platform cell culture processes have enabled Biocon to manufacture best quality and cost-effective processes for monoclonal antibody biosimilars. Working with a vibrant and high performing R&D team has been the most rewarding moments of my career at Biocon.

When I started my career with Biocon, it was evolving from an enzymes to a biopharmaceuticals company. I was fortunate to have been a part of Biocon's evolution from developing and manufacturing fermentation-based APIs and complex molecules to generic formulations and biologicals. The environment, the open culture of the company, the freedom to operate, and the passion to achieve the impossible were the driving forces behind my long stint.

A large part of my life was filled with work and the only way to be truly satisfied is to do what I believe is great work.

It is not easy to sustain a long career. It involves hard work, perseverance, learning, sacrifices and most of all a passion to pursue your dreams. More than 17 years later I am still with this great organization and have no regrets.

Along the way, I have received immense support from team members, leads, heads of departments and the management. During my time at Biocon I have learnt that it's not what you achieve, it's what you overcome that defines your career.

Girija Kelath

2002 – Present

Deputy Manager - > Associate Vice President

Regulatory Sciences, Biocon

A Journey of **Differentiation**

BRANDED FORMULATIONS

India and UAE

~400,000

Our flagship brands, Insugen® and Basalog®, have cumulatively made a difference to nearly 400,000 diabetes patients in India since launch.

The launch of India's first indigenously developed and produced recombinant human Insulin, branded as Insugen®, marked the Company's successful foray into the branded formulations space in 2004. Today, we offer a wide portfolio of branded biosimilars, novel biologics and small molecule formulations to patients in India and UAE.

The growing burden of non-communicable diseases (NCDs) in the developing world has led to a widening of healthcare inequities. Patients with NCDs face several barriers to access that are related to affordability and availability as most of them pay out of pocket for essential medicines, which are often unavailable when needed. Each year, 15 million people between the ages of 30 and 69 years, die from one of the NCDs, and over 85% of these 'premature' deaths occur in low- and middle-income countries, according to the WHO.

For countries like India the NCDs burden is further magnified due to the lack of adequate public healthcare system and low per capita income which makes access to chronic therapies unaffordable for many. Having identified this challenge early on, Biocon chose to make a difference to patients in the Chronic therapy areas by developing high quality, advanced bio-pharmaceuticals leveraging its affordable innovation model and dovetailing it with its world class manufacturing capabilities.

A portfolio approach, focused on chronic disease segments such as diabetes, cancer, end-stage renal illnesses, immune disorders and other life-threatening conditions, enabled us to offer patients in India and UAE a wide portfolio of branded small molecule generics, biosimilars and novel biologics.

Beyond therapy, we support patients through disease awareness, prevention and management initiatives. We also assisted healthcare professionals and patients with the treatment of complex medical conditions. In the process, we built considerable brand equity and market leadership in the chosen therapeutic areas.

Making a Difference in Diabetes Management

When we started our pharma journey, India was home to the largest population of people with diabetes in the world. It was solely dependent on expensive imported insulins till the early 2000s resulting in poor access to this essential diabetes management therapy. In 2004, we successfully addressed this challenge by leveraging our expertise in fermentation technology to launch India's first indigenously developed and produced recombinant human Insulin (rh-Insulin), branded as Insugen®.

The availability of our affordable insulin in the market triggered a series of developments. Innovator insulins companies lowered the price of their products for India, the government gained the confidence to bring rh-Insulin under price control since it finally had a domestic solution. We thus made a significant difference to diabetes management in the country, impacting a large patient pool, both directly as well as indirectly.

As the insulins market developed, doctors began graduating patients to modern insulin analogs. We introduced Basalog®, a long-acting insulin analog, in 2009 that allowed better metabolic control thereby resulting in an improved quality of life and treatment satisfaction for people with diabetes in India.

Introducing Patient-Friendly Devices

Continuing to spearhead the transformation of diabetes management in India, we decided to supplement our portfolio of insulin vials and refills with both reusable and disposable insulin delivery devices to maximize patient convenience.

Biocon launched INSUPen®, an affordable reusable insulin pen, in 2011 and Basalog

90,000+

Through our oncology portfolio we have served the needs of over 90,000 patients in India since launch.

One®, a pre-filled, disposable insulin pen, in 2015.

Improving the Diabetes Management Ecosystem in India

Today, we are one of the leading companies in the diabetology space in India with a wide basket of products across oral anti-diabetic drugs, rh-Insulin and Insulin Glargine. Our flagship brands, Basalog® and Insugen®, have cumulatively made a difference to the lives of ~400,000 patients in India since 2004. *(Lancet report, IMS/IQVIA &CMARC data).*

Basalog® is ranked as the No.2 Insulin Glargine brand in India, while Insugen® is positioned among the Top 3 brands of rh-Insulin. Insugen® and Basalog® reported combined sales of over ₹2 billion in FY19. *(IMS/IQVIA).*

Besides addressing the large need for affordable insulin therapy, we took the initiative to empower the medical ecosystem to efficiently address the needs of diabetes patients in the country. Our flagship patient outreach program, designed to sensitize and educate people with diabetes on self- monitoring of blood glucose, exercise and dietary routines to maintain a healthy lifestyle, has proven to be highly effective. Our award-winning diabetes education initiative for medical practitioners is enhancing the understanding of the disease and its diagnosis and treatment to improve clinical outcomes.

Healing Heart Diseases

The strong correlation between diabetes and an increased risk of heart disease led Biocon to launch a dedicated Cardiology division in 2008 to leverage in-house R&D strengths for delivering cutting-edge products to treat cardiovascular diseases.

From cholesterol reducing agents such as BESTOR® and STATIX®, obesity management drugs like OLISAT® to ACTIBLOK™IPR for patients with hypertension and heart failure, our products widened the treatment scope for cardiologists, diabetologists and general physicians.

The Diabetology and Cardiology divisions were later merged to form the Metabolics division, which offers a complementary portfolio for holistic treatment of co-morbid diabetes, hypertension and dyslipidemia.

Crusading Against Cancer

Biocon entered the therapy space for cancer when the disease burden was posing a debilitating challenge for India, both socially and economically. At that time, the incidence of the deadly disease was alarmingly high.

In the early 2000s, the treatment paradigm for cancer was moving from small molecule cytotoxic chemotherapies to targeted therapies based on monoclonal antibodies and combinations thereof. Whilst India's generic industry had significantly brought down the cost of cytotoxic drugs, targeted drugs or

25,000+

Our biologic cancer therapies, BIOMAb EGFR®, CANMAb™ & KRABEVA® have benefited over 25,000 patient lives in India, so far.

biologics remained beyond the reach of most Indian cancer patients.

Biocon chose to invest in cutting-edge R&D to deliver affordable biologics that provide greater access to patients and thereby make a difference. The Oncotherapeutics division, set up in 2006, offered a comprehensive range of chemotherapy and supportive drugs.

We launched India's first novel monoclonal antibody Nimotuzumab in 2006 as BIOMAb EGFR® for the treatment of head & neck cancer. In 2010, we introduced Evertor™ as the first generic brand of Everolimus in India for the treatment of patients with advanced renal cell carcinoma. We also successfully developed and launched the world's first biosimilar Trastuzumab for patients of HER2-positive metastatic breast cancer in India as CANMAb™ in 2014. We expanded our portfolio in 2017 with KRABEVA®, a pan-cancer biosimilar Bevacizumab for patients suffering from metastatic colorectal cancer and other types of lung, kidney, cervical, ovarian and brain cancers.

As one of India's leading oncology companies, Biocon has made noteworthy impact in cancer care through an affordable yet high quality mix of innovator, biosimilar and generic products. Our biologic cancer therapies have benefited over 25,000 patient lives since 2006 *(IPSOS, Internal data)*, and the division has cumulatively touched over 90,000* lives till date.

Offering Differentiated Products to Patients

The Branded Formulations business in India did not stop at bringing a niche portfolio of high-end therapeutics to patients, we also looked at innovative ways to ensure better patient compliance and convenience.

When we introduced two of our life-saving products, NUFIL Sf™ pre-filled syringes for Filgrastim and ERYPRO safe™ pre-filled syringes for Erythropoietin, in 2008 we incorporated them with an Ultrasafe Passive® Delivery System that enabled protection from needle stick injuries and offered enhanced patient comfort.

In 2014, we introduced CANMAb™ in a unique 150 mg multi-use vial whose availability allowed cancer patients to save money by buying smaller quantities as per their precise requirements, and storing the unused quantity for their next dose rather than wasting it. When used in conjunction with the standard 440 mg vial, the 150 mg presentation helped eliminate drug wastage and enabled additional savings for patients.

Patients using TBIS®, our brand of Tacrolimus ointment, benefited from a 36-month shelf life as compared to 24 months offered by competing products.

In 2017, we introduced KRABEVA® with an innovative temperature-sensitive packaging. The thermo-chromic stickers in the 'Qual Check' mechanism would change colour irreversibly if the cold chain temperature was not maintained within the prescribed range, thus ensuring the safety, purity and potency of the drug at the point of administration to the patient.

Improving Treatment of Immunological Disorders

In 2013, we launched the world's first novel anti-CD6 monoclonal antibody, ALZUMAb™, which offered dermatologists in India the option of prescribing a 'first-in-class' biologic drug to treat acute psoriasis. A new treatment paradigm for patients, ALZUMAb™ offered a less aggressive dosing regimen and a longer treatment free period. It complemented our niche portfolio of oral and topical immunosuppressants to treat dermatological disorders such as psoriasis, atopic dermatitis and vitiligo.

Patients with skin disorders often have to face social ostracism in India. Through our key Immunotherapy brands such as TBIS®, PSORID® and CALPSOR® C we are today offering a better quality of life to these patients.

2,000+

CytoSorb®, a novel extracorporeal cytokine filter, has benefited over 2,000 patients in India so far.

Caring for Patients of Kidney Disease

At a time when the incidence of chronic kidney disease (CKD) was rising in India, Biocon's Nephrology division offered patients one of the most comprehensive and cost-effective portfolio of therapies. At that time, less than 10% of all CKD patients in India received any kind of renal replacement therapy as these treatments were a low priority for the cash-strapped public hospitals. Also, the number of renal transplantations were woefully low at 3.25 per million population. *(Clinical Kidney Journal; Evolution of Kidney Transplantation in India).*

As one of the largest manufacturers of immunosuppressants in the world, we had the widest range of products for patients undergoing organ transplantation, coupled with affordable yet world class products for renal anemia management.

We introduced a range of specialty products in Nephrology, including Tacrograf™ (Tacrolimus), Renodapt® (Mycophenolate Mofetil) for transplant patients and ERYPRO safe™ (Erythropoietin) and BIONESP™ (Darbepoetin) for anaemia management.

In 2013, we launched an in-licensed 'first in class' sepsis management therapy to enable physicians to treat critically ill patients. CytoSorb®, a novel extracorporeal cytokine filter for sepsis management helps remove excess cytokines that cause multi organ failure, has benefited over 2,000 patients since its launch.

These differentiated products have enabled Biocon to emerge among the leading players in the nephrology market and transplant segment in India.

Boosting Critical Care in India

Launched in 2010, Biocon's Critical Care division is playing a crucial role in the critical illness segment with a strong anti-infective portfolio, such as IVNEX™, PENMER™ and KOOLISTIN®. At a time when the infectious disease burden in India is rising, with life-threatening bacteria mutating into 'multi drug,' 'poly drug' resistant strains posing a major threat to overall disease management, our wide range of injectable antibiotics and plasma products are ensuring affordable access to life-saving therapies.

Strong Value Builder

The Branded Formulations business has been a strong value builder for Biocon. We have built considerable brand equity with doctors and patients over the years through our affordable and differentiated portfolio in challenging disease spaces. A combination of products, patients and physician support programs have enabled us to be a strong player in the therapeutic areas of diabetology, cardiology, oncology, immunology, nephrology and critical care.

**Note: The estimated patient reach numbers have been calculated indirectly based on volume supplied and certain assumptions related to dosage per patient, duration of treatment, units sold, internal data and market research reports.*

Branded Formulations UAE

In 2007, Biocon and Neopharma established NeoBiocon, a joint venture company headquartered in Dubai to provide affordable life-saving drugs to the people of UAE. A pioneering initiative, the joint venture aimed to provide niche, life-saving biopharmaceutical products in key therapeutic areas.

One of the fastest growing players in the region, today, NeoBiocon ranks amongst the Top 15 pharmaceutical companies in UAE. It is the No. 1 generic company in UAE in the cardiovascular and diabetes markets, and is also ranked among the Top 3 generic companies in the country. *(IMS/IQVIA).*

Supported by more than 40 brands across cardiovascular, diabetes, respiratory, acute, oncology and gastrointestinal therapy segments, its sales are well diversified across branded generics, biosimilars and in-licensed novel products. The Top 10 brands contribute over 65% of sales. *(Internal Data).*

Most of NeoBiocon's branded generic products are ranked among the Top 5 in their respective segments. Brand Statix (Atorvastatin) is at No. 2 in the UAE lipid management market and is among the Top 50 brands in the overall UAE pharma market. *(IMS/IQVIA).*

Biocon launched CANHERA, the first biosimilar Trastuzumab in UAE aimed at providing affordable access to patients suffering from breast cancer, in FY19. The launch of CANHERA represents Biocon's second biosimilar launch in the UAE market, having launched biosimilar Insulin Glargine under the brand name Glaricon® earlier.

BRANDED FORMULATIONS: FY19 at a Glance

Revenue

6,564

₹ Million

Growth 7%

In FY19, the Branded Formulations segment grew 7% to ₹6,564 million from ₹6,115 million, led by good growth in the India business, both in sales as well as profitability. The good performance in India was offset by a subdued performance of the business in UAE which was impacted by delays in product registrations with the local health authorities and repricing of branded generic products by the Ministry of Health.

The Metabolics, Nephrology, Critical Care and Market Access divisions were the key growth drivers for the Branded Formulations - India (BFI) business. Key brands like Insugen®, Basalog®, ERYPRO™, TACROGRAF™ and PSORID™ reported strong double-digit growth. The Top 10 brands in our BFI portfolio grew 15% and accounted for ~78% of total sales in FY19. As a specialty products company, 70% of our overall India business is now accounted for by biologics / biosimilars products.

In UAE, while newly launched branded generics, biosimilars and in-licensed products grew during the year, overall performance was impacted by certain external factors.

+ Read more on Branded Formulations Business : Page 139

Sources:

1. *Chronic Kidney Disease in India: Challenges and Solutions (S.K. Agarwal & R.K. Srivastava - Nephron Clin Pract, 2009)*
2. *Clinical Kidney Journal*

A Journey **of Reliability**

RESEARCH SERVICES

CRO, CMO

330+

A global base of over 330 clients across diverse industries.

Biocon established Syngene, India's first CRO, in 1993 as its subsidiary to spearhead a new concept of providing scientific research services to the global pharmaceutical industry. Syngene took on the challenge to position India as a 'destination of choice' for outsourcing scientific research activities and thus became India's first contract research organization. Today, Syngene is a global scale integrated research services organization offering 'end to end' discovery and development services to life sciences companies across the world.

In the 1980s, the Indian pharma industry had begun to make an impact by manufacturing generic pharmaceuticals for the global markets; however, the concept of Contract Research Organizations (CROs) had not yet emerged in India. It was only at the turn of the century that the global pharma industry started to explore India as a destination to set up their offshore research operations since India offered a large scientific talent pool with a significant cost arbitrage in terms of infrastructure and people.

Biocon established Syngene, India's first CRO, in 1993 as its subsidiary to spearhead a new concept of providing scientific research services to the global pharmaceutical industry. Syngene took on the challenge to position India as a 'destination of choice' for outsourcing scientific research activities. Today, Syngene is a global scale integrated research services organization offering 'end to end' discovery and development services to life sciences companies across the world.

As global pharma companies grappled with dwindling R&D budgets and growing pressure to introduce new drugs rapidly and at lower development costs, there was an increasing opportunity for outsourcing more R&D activities.

Syngene made the best of this opportunity by continuously expanding its service offerings across the drug discovery and development value chain and eventually becoming a 'one-stop' integrated scientific research service provider.

Embarking on a New Growth Phase

In 2009, Syngene initiated operations in safety assessment and formulation development, while also expanding process development and manufacturing services by setting up a new cGMP-compliant plant.

In 2007, Syngene set up its first dedicated R&D center, Biocon BMS Research Center (BBRC), for Bristol-Myers Squibb (BMS) to advance the multinational drug maker's discovery and early drug development programs. This heralded a new phase in Syngene's advancing capabilities in providing high-end services in drug discovery research.

BBRC was tasked with accelerating new candidate discovery for the partner. Over time, this dedicated center became BMS' largest R&D facility outside U.S. with a team of nearly 500 dedicated Syngene scientists working closely with the global R&D teams of BMS. BBRC has contributed to the discovery and pre-clinical development of numerous drug candidates for further study and helped BMS reduce time and costs associated with advancing new compounds to first-in-human studies. The collaboration for BBRC has been renewed till 2026 and Syngene has set up additional infrastructure and expanded its team of scientists working at the centers.

Over the years, Syngene set up dedicated R&D centers for other Big Pharma companies viz., Abbott in 2012, Baxter International in 2013, Amgen in 2016 and Herbalife Nutrition in 2017.

Its dedicated research center for Baxter houses a multi-disciplinary team of about 150 scientists to work on product and analytical development, preclinical evaluation in parenteral nutrition and renal therapy. In 2018, the Company expanded the scope of its R&D collaboration with Baxter and extended it to 2024.

4,000

At Syngene, over 4,000 qualified scientists offer integrated research services to customers globally.

The dedicated research center for Amgen, called the Syngene Amgen Research & Development Center (SARC), has a multi-disciplinary team of about 185 Syngene scientists supporting variety of discovery and development projects for biotechnology and small molecule medicines. SARC focuses on medicinal and process chemistry, biologics, bioprocess, drug metabolism, pharmacokinetics, bioanalytical research and pharmaceutical development.

Adding New Capabilities

As a one-stop shop, Syngene helps advance its clients' molecules through the discovery and development process, providing services encompassing various multi-disciplinary activities such as drug substance and drug process development and cGMP-compliant manufacturing (from gram scale to multi-kg scale), formulation and analytical development and stability studies.

To remain ahead of the curve, Syngene steadily enhanced its investments in building new capabilities to align with the changing requirements of the global R&D focussed industries. For example, in 2009 it invested in biologics development capabilities in line with the increasing focus on large molecules by global organizations.

The Company also invested in new capabilities such as the discovery and development of antibody-drug conjugates and oligonucleotides. A bio-analytical center was set up to undertake high-end analysis to supplement the clinical services business. In 2016, Syngene added new capabilities in bioinformatics by acquiring the assets related to systems biology, Heptox and pharma bioinformatics services of Bengaluru-based Strand Life Sciences.

At the same time, the Company has built significant credibility and regulatory track record across a range of domains. This helped in expanding client base across diverse industries going beyond biopharma. Today, Syngene has over 330 global clients across industries ranging from pharma, biotech, nutrition, agrochemicals, animal health, specialty chemicals, consumer goods, academic and non-profit organizations.

Moreover, Syngene built state-of-the-art infrastructure, which has been audited successfully by the U.S. Food and Drug Administration, European Medicines Agency, Association for Assessment and Accreditation of Laboratory Animal Care International, Japan's Pharmaceuticals and Medical Devices Agency and major life sciences partners.

The expansion of its service offerings and client additions helped Syngene almost double annual revenue from ₹5.50 billion in FY13 to ₹10 billion in FY16.

Going Public

Syngene reinforced its pre-eminent position as the leading end-to-end research services company in India, when it successfully unlocked immense value through a listing on the Indian stock exchanges in August 2015. It crossed a market cap of USD 1 billion within a week of listing. Today, Syngene is the only publicly listed 'pure play' research services company in India.

Transforming into a CRAMS Player

Syngene has plans to evolve from a CRO into a Contract Research and Manufacturing Services (CRAMS) organization with commercial-scale manufacturing capabilities. It is establishing a facility in Mangalore to manufacture novel small molecules for innovator companies. Statutory approvals have been received and the construction activities, which began in December 2017, are on schedule and expected to be complete by end of FY20.

Prepared for the Next Phase of Growth

The global CRO market value for drug discovery and development is expected to reach USD 45 billon by 2022 from USD 32 billion in 2017, according to a report by Grandview Research.

Syngene is well positioned to benefit from this opportunity as it has built a strong reputation of being the 'innovation partner' for many of its clients through a track record of successful delivery of complex projects, process efficiencies, consistent innovation, turnaround times and enhanced productivity.

With nearly 4,000 qualified scientists and 1.4 million square feet of world-class R&D and manufacturing infrastructure, Syngene today offers high-end, fully integrated scientific research services that drive innovation, deliver greater efficiency and ensure value creation for its clients.

RESEARCH SERVICES: FY19 at a Glance

Revenue

18,256

₹ Million

Growth 28%

FY19 was a good year for Syngene, with revenue rising 28% on the back of broad-based growth across three verticals: Discovery Services, Dedicated R&D centers and Development and Manufacturing Services. During the year, Dedicated R&D Centers made good progress with the extension and expansion of key collaborations such as the one with Baxter Inc. Discovery Services and Development Services delivered solid performances with widened capabilities and increased capacity. Syngene's active client roster grew to over 330 active clients during the year. The company also continued to expand the scope of engagement with many existing clients. Revenue contribution from the Top 10 clients stood at 66% in FY19 down from 71% in FY15, reflecting the progress in diversifying its client base to reduce dependence on any single group of clients.

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Reliving Yesteryears **Co-creators**

Current Marshals

Ankur Bhatnagar

2001 – Present

Scientist -> General Manager

R&D, Biocon

Soon after joining Biocon I realized that I was surrounded by highly passionate and bright minds ready to challenge and push the boundaries of science to develop therapies impacting global health. What drives us every day at our work is the mission of delivering "affordable medicines" with the potential to benefit a billion patients globally. A clear sense of purpose, along with our core values, help the teams transform goals into realities. Biocon provides opportunities to work on latest and differentiated technologies at world class facilities and acquire new skillsets. It also has a strong culture of empowering employees to take ownership, which drives them to go the extra mile and make a difference.

Ritesh Kumar Sharma

2004 – Present

Executive -> General Manager

Corporate Strategy, Biocon

My journey with Biocon started in 2004, when I joined as an Executive. There has been no looking back since then apart from a short break for further studies in 2010. When I look back at my journey over the last 15 years, I see how Biocon has grown significantly leading to changes in the way we function as an organization. But one thing that hasn't changed is the entrepreneurial spirit which differentiates us from others and this is one of the key reasons for our success.

Sudha Victor

2001 – Present

Management Executive -> Associate Manager

HR, Biocon

I joined Biocon in the year 2001 as a Management Trainee and since then there has been no turning back. This is my first job in a pharma company and it has indeed been a pleasure for me to be a part of this journey.

Although the journey initially was tough, I am thankful to my colleagues and the people around who made the work environment smooth and comfortable. The bonding with the team and the cross-functional teams has also played a vital role in my tenure here. The experience and exposure at Biocon helped me grow tremendously, both professionally and personally. I have witnessed immense changes in these 18 years and today I am proud to say, "I am a Bioconite!"

Sheethal Kumar

2005 – Present

Executive -> Associate Director

Central Engineering, Biocon

It is my proud privilege to be a part of Biocon since 2005, when I joined as an Executive and assigned to manage the Biocon Park project. Although everything was new and unknown to me, I was fortunate to work with a great team who nurtured and trained me. Subsequently, I worked on various projects under the able guidance of my seniors which helped me grow both personally and professionally. The management at Biocon gives adequate freedom to all its employees. I received technical support on all projects assigned to me. These endeavors helped me to transform myself and lead a team which is involved in infrastructure projects.

Dr. Ramakrishnan MS

1999 - Present

Senior Scientific Associate -> Vice President

R&D, Biocon

My journey in Biocon has involved extensive learning in drug development, specifically for novel biologics and biosimilars. I have had the privilege to drive the novel biologic R&D efforts that led to the approval of Itolizumab in India in 2013. I was also a part of the team that worked towards the approval of biosimilar Trastuzumab in U.S. and Europe. I am proud to have been a part of Biocon's pioneering journey in biologics.

I joined Biocon as an Executive in 2008 and it has been an eventful journey of over a decade. Being part of the Corporate Communications team, I have had the privilege to witness and document several milestones that Biocon has successfully crossed. It has been an exciting and enriching experience for me to participate, connect, learn and share the Biocon story and translate my design learning for the benefit of Brand Biocon. I look forward to contributing more towards enhancing Biocon's reputation as an innovation-led, world class biopharmaceuticals organization.

Nagaraj Bhadraiah

2008- Present

Executive -> Deputy Manager

Corporate Communications, Biocon