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.

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Four Decades of Pioneering Excellence

40
YEARS OF
BIOCON

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Follow us on twitter: @bioconlimited

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.*

FY19 at a Glance

Revenue
56,588
₹ Million

Profit for the Year*
9,053
₹ Million

EBITDA Margin
27
%

R&D Spend (Gross)
4,796
₹ Million

Employees
11,000+

EPS
15.2
₹

* includes exceptional income

Vision

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

Mission

To be an integrated biotechnology enterprise of global distinction.

Essential to this mission is excellence in:

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

Business Revenue Mix#

Small Molecules
17,728
₹ Million

Biologics
15,169
₹ Million

Branded Formulations
6,564
₹ Million

Research Services
18,256
₹ Million

Other Income
1,444
₹ Million

Geographic Distribution

Includes inter-segment revenue

Values

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

FORTITUDE
Four Decades of Pioneering Excellence

CHAIRPERSON'S REVIEW

Kiran Mazumdar-Shaw
Chairperson & Managing Director

Dear Shareholders,

Forty years ago, I started Biocon with the vision of creating a business that would leverage science for the benefit of society.

With just two employees, Biocon started making industrial enzymes in a 3,000 square feet shed in Bengaluru. Our beginning was small, but our aspirations were big.

In the next 40 years, we balanced scientific risks, capability risks, regulatory risks, financial risks and business risks to emerge as India's premier biopharmaceutical enterprise. Today, we are known for our world-class products, our talented human capital, our marquee partners and our pioneering role in building a biotechnology-led business in India.

Our fortitude led us to brave the odds in building a business model around the then nascent field of biotechnology. We were driven by a business purpose to replace polluting chemical technologies with eco-friendly enzyme based technologies, an idea ahead of its times. It was a big challenge to convince industry leaders to invest in clean, eco-friendly biotechnology-based solutions at a time when environmental sustainability was not a global priority. We persisted and finally succeeded in getting many companies across different industries to make the switch to environmentally responsible enzyme based technologies as early as 1980.

4FORTITUDE Journey of

Our revenue stood at over ₹5 billion in 2004 at the time of our IPO, growing from ₹318 million in 1999.

We were an enzymes-led biotechnology enterprise until 2007 when we divested this founding business to fuel our ambition of making a difference to patients through our biopharmaceuticals business. That said, over nearly three decades, Biocon had emerged as India's largest enzymes company which led to a rich value being ascribed for the acquisition.

The new focus on biopharmaceuticals drew its mission from the huge unmet need that patients in India and the developing world suffered on account of lack of access and affordability. Moreover, we truly believed that we could drive exponential growth through this new strategic intent. Thus Biocon moved from revenues of ₹318 million in 1999 to over ₹5 billion in 2004, a milestone that provided us the confidence to go for an Intial Public Offering (IPO).

Statins: Risk-Taking Pays Off

Our foray into biopharmaceuticals started with statins, a class of small molecules that lower cholesterol levels in the blood by reducing its production in the liver. We had to negotiate a host of scientific capability and regulatory risks to go from manufacturing enzymes to making fermentation-derived statins for global markets. Our ability to take this kind of a risk paid off when in 2001 Biocon became the first Indian company to be approved by the U.S. FDA to manufacture Lovastatin using solid state fermentation technology.

We subsequently became one of the biggest statins producers worldwide. Today, our Active Pharmaceutical Ingredients (APIs) or drug substances are used to produce billions of statin pills globally.

Insulins: Making a Difference by Being Different

We took another calculated risk when we chose to expand our strategic options from small molecules like statins to recombinant proteins like insulins to address the growing healthcare challenges associated with diabetes. We did not hesitate to exploit differentiated technologies, such as a proprietary yeast platform based on Pichia pastoris to make recombinant human Insulin (rh-Insulin) at a time when other insulin makers were using the 'tried and tested' Escherichia coli bacterial expression system. We continue to be the only company in the world that is producing rh-Insulin and insulin analogs on a Pichia platform. Taking this risk has enabled Biocon to emerge as a leading insulins player globally. Biocon today has the science, scale, scope, technology and over 15 years of experience in addressing the needs of patients with diabetes, having provided over 2 billion doses worldwide.

In India, we built on the impact we created through our branded insulin, Insugen®, to develop a Branded Formulations portfolio aimed at patients suffering from life-threatening conditions such as cancer and renal illnesses.

Novel Biologics: Upping the Ante

We did not limit ourselves to generic insulins but decided to push scientific boundaries and create new knowledge that was breakthrough in its impact to human existence through novel biologics and novel targets in the area of large molecules. At a time when the prevailing business ethos of the Indian pharma industry centred on manufacturing generic medicines, we decided to embark on an IP-driven strategy of differentiation to build credibility while enabling a first mover advantage in many cases.

4FORTITUDE Journey of

We took another calculated risk when we chose to expand our strategic options from small molecules like statins to recombinant proteins like insulins to address the growing healthcare challenges associated with diabetes.

It was a huge scientific risk because we decided to start our novel molecules journey with a complex entity: a monoclonal antibody. It paid off and Biocon earned the distinction of launching India's first indigenously produced novel monoclonal antibody for head & neck cancer, Nimotuzumab, in 2006. The effectiveness of our molecule was endorsed last year as an outcome of an investigator-initiated study on head & neck cancer patients at the prestigious Tata Memorial Hospital, Mumbai, which demonstrated that Biocon's Nimotuzumab in combination with chemo-radiation showed statistically significant improvement in progression-free survival over the standard of care, which is chemo-radiation alone.

Our work on first-in-class drugs, including oral insulin (Insulin Tregopil) and anti-CD6 antibody (Itolizumab), allowed us to push the boundaries of science to invest in developing affordable therapies that can impact global health.

Through Itolizumab we were able to offer an affordable biologic therapy, which involved a less aggressive dosing regimen and a longer treatment free period, to psoriasis patients in India when we launched it as ALZUMAb™ in 2013.

While Itolizumab was indicated for chronic plaque psoriasis in India, this unique molecule is potentially a 'pipeline in a product'. In FY19, a Phase I b / II trial in acute graft-versus-host disease (aGVHD) using Itolizumab was initiated by our partner Equillium, who has licensed the molecule for development in U.S. and Canada. Equillium has been awarded 'fast track' and 'orphan drug' designations for the molecule in both prevention and treatment of aGVHD by the U.S. FDA.

Taking Our Novels Play to the Next Stage

Translating great laboratory discoveries into clinical success is a major challenge for the global biopharma industry. To lower the risk of failure and translate our new molecule discoveries to the clinic more effectively, we have strengthened our already existing translational sciences capabilities by

building a dedicated and experienced scientific team within R&D and entered into key collaborations.

In FY19, we incorporated Bicara Therapeutics based in Boston, U.S., as a wholly owned subsidiary of Biocon to focus on developing a pipeline of bifunctional antibodies that exploit the recent advances in immuno-oncology. We believe bi-specific antibodies are the next big opportunity as they offer an advanced therapy option against cancer.

In doing so, Biocon has today emerged as a strong innovation-driven biopharma company operating out of Asia, which has put India on the global innovation map.

Riding the Biosimilars Opportunity

Biocon was among the early movers in industry to pursue a high risk strategy of developing biosimilars for global markets. This was a key strategic decision taken by the management to further advance our commitment for providing affordable access to life-saving biologics. In hindsight, it was an enormous financial and business risk with a number of unknown regulatory risks. It was sheer fortitude that has enabled us to take a lead in this very coveted new business segment.

Through our 'Made in India' biosimilars business, we seek to pursue a humanitarian path that will provide affordable access to high quality generic biologics to make a difference to diabetes, cancer and autoimmune diseases.

Our long-standing global biosimilars strategy of 'emerging markets first' and 'developed markets later' is paying off well. We have succeeded in bringing the benefit of high quality biosimilars to patients in India, other emerging market countries in Latin America, Africa, Middle East & Turkey, Asia-Pacific regions and also now in developed markets of U.S., EU and Japan.

As our biosimilars business has reached a new inflection point, we are consolidating the development, manufacturing and commercialization operations under an independent entity, Biocon Biologics with its own dedicated management. We have recently appointed Dr Christiane Hamacher as the CEO of Biocon Biologics. I am confident that with her depth of knowledge and experience of global markets, she will successfully lead the company to its next milepost of benefiting millions of patients across world markets.

End-to-end Integrated Discovery & Development Services

Our tryst with innovation started with Syngene in 1993, which was set up to spearhead a new concept of providing scientific research services to global innovator companies. We took on the challenge to position India as a 'destination of choice' for outsourcing scientific research activities. Today, Syngene offers 'end-to-end' integrated discovery and development services to leading life sciences companies like Bristol-Myers Squibb, Amgen and Baxter.

Sustainability Programs and Corporate Social Responsibility

Our underlying ethos of access and affordability goes beyond our business. We had set up Biocon Foundation in 2004 as part of our Corporate Social Responsibility (CSR) to address gaps in essential healthcare services, basic education, sanitation and hygiene in underserved urban and rural areas of India. We undertook various CSR initiatives with the aim of promoting socio-economic inclusion through innovation and sustainable models that deliver scalable solutions.

4FORTITUDE Journey of

Biocon was among the early movers from India to pursue a high-risk strategy of developing biosimilars for the global markets. Through this business, we seek to pursue a humanitarian path to provide access to high quality affordable biologics.

4FORTITUDE Journey of

We brought effective primary healthcare services to the doorsteps of the less privileged in rural and urban India through our unique technology enabled eLAJ Smart Clinics operational at the PHCs in collaboration with the government.

As a pharmaceutical company working in the space of chronic diseases, we were painfully aware of the struggle that the poor and marginalized in India face in accessing even basic healthcare services. To address this situation, we brought effective primary healthcare services to the doorsteps of the less privileged in rural and urban India by establishing Primary Healthcare Centers (PHCs), actively creating awareness about disease prevention, public health and nutrition. We took this a step forward through our unique, technology-enabled eLAJ Smart Clinics, which are providing prevention, early diagnosis and better treatment outcomes, as well as, reducing out-of-pocket expenditure for communities with poor healthcare access. eLAJ Smart Clinics were operational at 18 PHCs which recorded nearly 167,000 patient visits in FY19.

Given that a third of oral cancer cases in the world are reported in India, Biocon Foundation initiated formation of an Oral Cancer Task Force comprising seven eminent oncologists from all over India. This Task Force has developed guidelines for the management of head & neck cancer in India During the year, nearly 11,000 people were screened for oral, breast and cervical cancers by the Foundation which helped in early diagnosis and treatment.

As a company that has worked on cleaner and greener biotechnologies based on enzymes, we have taken a novel approach to revive some of Bengaluru's polluted lakes. We have implemented a three-step bioremediation process using technology which is unique and cost effective in comparison to conventional draining and cleaning processes and have succeeded in restoring the ecosystem of the dying 35-acre Hebbagodi Lake, located in the outskirts of Bengaluru. This project has won several awards including a place in the Limca Book of Records for introducing the largest artificial floating wetlands in India. The 'proof of concept' established at Hebbagodi Lake has opened the path for Biocon Foundation to initiate other lake rejuvenation projects.

The evolving science in the biotech sector is leading to a demand for high-skilled jobs in India. We realized that a wide gap exists between the quality of human capital available in India and the growing needs of the industry. In order to address this huge talent deficit we established the Biocon Academy in partnership with Keck Graduate Institute, U.S., in 2013. The Academy currently runs four specialized programs in collaboration with leading institutes from India including its flagship Biocon KGI Certificate Program in Biosciences. Over 500 students who have graduated from the Academy, have been placed across 50 leading biotech and pharma companies in India.

Financial Highlights: FY19

Biocon has scaled up its size manifold in terms of revenue and profits during its 40-year journey. In FY19, we reported a robust growth of 31% with a Consolidated Revenue of ₹56,588 million. Our Net Profit for the year soared 143% to ₹9,053 million. Adjusted for exceptional items and associated tax, our Net Profit almost doubled in FY19 to ₹7,291 million.

During the year, three of our strategic business segments, Small Molecules, Biologics and Research Services, crossed the ₹15 billion revenue milestone. FY19 was a landmark year for the Biologics business, which reported a growth of 97% to ₹15,169 million, thus emerging as a key driver for Biocon's incremental growth. Our annual revenue performance was also supported by a 28% growth in the Research Services segment to ₹18,256 million and 18% growth in Small Molecules to ₹17,728 million. Branded Formulations revenue grew a modest 7% to ₹6,564 million.

A higher share of Biologics revenue in FY19, boosted profitability as reflected in the consolidated EBITDA margin of 27% for the full year despite a 34% increase in Net R&D expenses on account of higher spends on biosimilars as well as the Generic Formulations programs. We continue to invest heavily in R&D as we believe it is the fuel that will spur our future growth. At a gross level, we spent ₹4,796 million on R&D this year, corresponding to 13% of revenues excluding Syngene.

Looking Ahead

In the next few years, we aim to make our R&D engine extremely efficient. Having successfully delivered several biosimilars to patients in U.S., EU and Japan, we have gained rich experience in managing the risks entailed in taking advanced therapies from 'bench to bedside' even in the most stringently regulated markets.

We aim to develop the next wave of biosimilars through a faster and far more predictable process supported by high-end computing and data analytics. Biocon, with Mylan, Sandoz and its other partners, will certainly focus on maximizing the efficiencies that we enjoy as a fully integrated biosimilars company.

Currently, some of our partners have taken the onus of commercializing Biocon-manufactured biosimilars in global markets. Going forward, Biocon aspires to front-end the commercialization of some of its biosimilar assets in global markets. We believe that to succeed in an increasingly competitive market place we will need to be disruptive in the way we serve patients, prescribers and payers. We are investing in digital technologies that can help us differentiate our products in global markets to deliver sustained success.

FY20 promises to be an exciting year for Biocon as all our growth verticals including Biologics, Small Molecules, Branded Formulations and Research Services, build on their performances of FY19, opening up immense growth opportunities for the Company.

In conclusion, I would like to state that our strategy of being a differentiated biopharmaceuticals company, leveraging innovation for affordable access has been fraught with risks and challenges. We have succeeded in making a difference to millions of patients, enduring the complexity of the ecosystem through our courage of conviction and commitment to address global health challenges.

I would like to thank our shareholders for traversing this arduous journey along with us and reposing their trust in the Company's management. We look forward to their encouragement and contribution, as we pursue the next phase of our journey.

Thank You.
Yours sincerely,

Kiran Mazumdar-Shaw
Chairperson & Managing Director
May 29, 2019

4FO Journey of FORTITUDE

Going forward, we aim to develop the next wave of biosimilars through a faster and far more predictable process supported by high-end computing and data analytics.

Memories
of Yesteryears

40
YEARS OF
BIOCON

1978 1980 1983 1990 1990

2004 2005 2006 2006 2006

2012 2012 2013 2014 2014

2019

FORTIFYING
Our Position

Q&A
WITH THE CEO

Dr. Arun Chandavarkar,
CEO & Joint Managing Director

2018

Fulphila®, the first biosimilar Pegfilgrastim to be approved and commercialized by our partner Mylan in the U.S. in mid 2018, has garnered over 20% market share in the pre-filled syringes market.

Q. Biocon is among the front-runners in commercializing the first wave of biosimilars. How will it sustain this momentum?

A. **FY19 has been a landmark year for the biosimilars business. Commercialization of biosimilar Pegfilgrastim in the U.S. by our partner Mylan and the continued strong growth in biosimilars in emerging markets contributed significantly to a near doubling of our Biologics revenue in FY19, which crossed the USD 200 million revenue milestone.**

Our biosimilars strategy has begun to deliver with our key products gaining acceptance with prescribers and patients. Fulphila®, the first biosimilar Pegfilgrastim to be approved and commercialized in the U.S. in July 2018 by our partner Mylan, has garnered over 20% market share# in the pre-filled syringes market. Biocon- supplied products also hold dominant market shares for biosimilar Trastuzumab, rh-Insulin and Insulin Glargine in many key emerging markets.

This growth momentum can be sustained in the near term through a combination of key launches and new approvals for these first-wave products from our Mylan collaboration. A key milestone will be the launch of biosimilar Trastuzumab in the U.S. in 2019, which is already commercialized in EU and emerging markets. We also have approvals for biosimilar Pegfilgrastim in EU, Canada and Australia and have launched it in the U.S. We have commercialized Insulin Glargine in Japan, EU and some emerging markets. We have approvals in Austrialia and the next major near term milestone for this molecule will be its approval and launch in the U.S.

The growth will be augmented in the mid-term by our advanced pipeline of biosimilars comprising Bevacizumab, Insulin Aspart and rh-Insulin which are currently progressing as planned through their clinical development phase. In fact, rh-Insulin provides us the opportunity to establish a direct commercial presence in the U.S. and select markets elsewhere.

In the long term, our global partnership with Sandoz for a set of oncology and immunology biosimilars is progressing well and is preparing us for the next wave of biosimilar opportunities that open up towards the middle of the next decade. This will be bolstered by new opportunities to expand our biosimilar portfolio which is already amongst the largest and broadest, straddling monoclonal antibodies and insulin analogs. And these opportunities could leverage our direct commercial presence in many markets.

We will continue to support this broad portfolio through prudent investments in R&D and high quality manufacturing infrastructure to deliver on our commitment of providing affordable access to safe and effective biosimilars to patients around the world.

Q. Biocon has unlocked value several times in the course of its evolution. What do you see as the next value unlocking opportunity?

A. Biocon has successfully incubated new businesses within its fold and unlocked value in many of them. This is demonstrated by Biocon's own IPO in 2004 on the back of our successful statins business, followed by the divestment of our enzymes business in 2007 and then the listing of our Research Services business (Syngene) in 2015.

Our Biosimilars business has demonstrated success and established global credibility with three of our molecules being approved and launched in developed markets. This business is at an important inflection point as we gain commercial success with our first wave of products and invest in long term sustainability through broadening of our pipeline and commercial presence and further expanding our manufacturing scale. We have therefore begun acting on our intent to unlock value in the Biosimilars business by housing it under a separate subsidiary, Biocon Biologics. This, we believe, will enable this business to focus, invest, compete and win in the large and growing opportunity for biosimilars.

2019

Bicara Therapeutics has been set up in Boston to anchor the development of novel immuno-oncology assets.

Q. What will be the focus of Bicara Therapeutics in the U.S.?

A. There is considerable excitement around immuno-oncology therapies that activate an individual's immune system, enabling it to recognize cancer cells and destroy them. Rapid technological advancements are helping the growth of the global immuno-oncology market which is expected to exceed USD 100 billion by 2022, according to a report published by Research and Markets. Biocon has been pursuing the development of novel bi-functional fusion antibodies which work on the concept of preferentially targeting the tumor micro-environment.

We have recently set up a subsidiary, Bicara Therapeutics, based in Boston, to anchor the development of these novel immuno-oncology assets. This allows us to access the thriving innovation ecosystem in the U.S. and accelerate development of cutting edge therapies to improve outcomes for cancer patients. We will leverage synergies between our Boston and Bengaluru based talent pool and infrastructure to progress breakthrough innovation rapidly and in a cost effective way.

2019

Insugen® and Basalog®, our flagship insulin brands, reported combined sales of over ₹2 billion in FY19, in India.

Q. How does Biocon plan to accelerate the momentum gained by the Small Molecules segment in FY19?

A. The Small Molecules segment reported an increase of 18% in revenue in FY19, driven by a strong growth in APIs as well as Generic Formulations. The successful launch of formulations in the U.S., better product mix in APIs and an improved pricing environment contributed to the robust performance of this segment.

Biocon has always focused on leveraging its historical strengths in fermentation by creating a distinctive portfolio of fermentation based APIs. We will continue to expand our API portfolio where we can enjoy a competitive advantage in terms of manufacturing complexity. We intend to forward integrate into formulations for all our key APIs whereby our direct commercial presence will enable us to capture a bigger share of the value. We will also focus selectively on formulation technologies that ensure durability of commercial success through limited competition. We intend to replicate our early success in the complex area of biosimilars by investing appropriately in R&D and infrastructure for complex small molecules. This strategy of vertical integration encompassing APIs and Formulations will be backed by continued investments in Quality systems to sustain our exemplary track record in global regulatory audits.

Q. How is your strategy of returning the Branded Formulations business to a higher growth trajectory playing out?

A. Our focus on increasing market share for our specialty brands in critical therapy areas is working well. Our Top 10 brands in India grew 15% over last year, accounting for ~78% of sales, up from 76% in FY18. 70% of our overall India business is now accounted for by biologics / biosimilar products.

Basalog® is ranked as the No. 2* Insulin Glargine brand, while Insugen® is positioned among the Top 3* brands of rh-Insulin in India. During FY19, Basalog® sales grew 34% while Insugen® sales grew 21%, outpacing the covered market growth of 17% and 13% respectively*. Insugen® and Basalog® reported combined sales of over ₹2 billion in FY19.

We are also making a significant difference to cancer care in India. CANMAb™, the No. 1 brand of Trastuzumab in the country, garnered a value market share of 27%*. Our novel BIOMAb EGFR® has helped treat over 11,000 patients since launch in 2006.

Whilst we have witnessed an improvement in margins through a combination of portfolio rationalization and cost control, we do recognize that India is a price sensitive and fiercely competitive market. We intend to leverage our globally endorsed product portfolio to bring high quality biosimilars and other critical products to patients in India.

In the UAE, we continue to enjoy a dominant position in all our key brands. We are bolstering our current portfolio of branded generics and in-licensed products with biosimilars. During FY19, we launched the first biosimilar Trastuzumab in UAE under the brand name CANHERA, our second biosimilar introduction in the market after Glaricon® (Insulin Glargine) in FY18. However, in the near term our UAE business is impacted by certain adverse pricing decisions taken by the local health authorities and inventory adjustments.

Q. The high price of insulins has generated a lot of heat in the U.S. with lawmakers there calling for higher biosimilars competition to help rationalize the cost of therapy. How is Biocon positioned to benefit from this potential opportunity?

2018

We launched CANHERA, the first biosimilar Trastuzumab in UAE and our second biosimilar introduction in the market after Glaricon® (Insulin Glargine) in FY18.

A. Biocon is amongst the few global biosimilar players to have a strong presence in monoclonal antibodies as well as insulins. Our rh-Insulin and Glargine products are already benefiting people with diabetes in many emerging and developed markets through improved access and affordability. Our rapid acting insulin analog, Aspart, is progressing well in clinical development. We have invested, and continue to invest, in creating large scale high quality insulin manufacturing facilities. This gives us the full spectrum of insulins (regular, basal and rapid) and the global scale necessary to make a difference to diabetes patients in the U.S. We expect our partner Mylan to launch our first insulin analog in U.S. in 2020. We are greatly encouraged by the positive actions taken by the U.S. FDA in clarifying the path to approval for biosimilar insulins through transition from the 505(b)(2) to the 351(k) legislations and in terms of specifying requirements for an interchangeable designation.

Q. How do you see your Research Services subsidiary, Syngene, contributing to Biocon's growth in future?

A. Syngene has been a strategic growth driver for Biocon and in FY19 has delivered a revenue growth of 28% at ₹18,256 million driven by a robust performance across its divisions. Over the years its contribution to Biocon revenue has increased as reflected in FY19 performance where Research Services contribution to Biocon's revenue stands at 32%.

Strengthening its long term relationships with its prime clients, Syngene has further expanded its multi-year agreements with key clients like

Baxter till 2024 and Bristol-Myers Squibb till 2026. Syngene continues to acquire more clients and is currently servicing over 330 clients across the globe. Deeper engagement with various strategic clients along with a healthy demand in both discovery services and biologics augurs well for the future. Furthermore, the company's focus on investing in future-ready capability build up will provide a strong growth momentum for this business.

Syngene has expanded its expertise to include yeast display platforms for antibody discovery, sophisticated immuno-oncology assays, CAR-T design and micro sampling PK studies. These investments will support the company in addressing emerging client needs in both large and small molecule discovery programs, from target identification and validation all the way through IND.

We expect our Research Services business vertical to sustain a robust growth going forward.

Q. How is Biocon preparing to meet capacity requirements as product commercialization in global markets picks up pace?

A. We always dovetail capacity to our market plans and ensure that capacities come online to cater to increased market share or to anticipated regulatory approvals in various jurisdictions. Whilst we have adequate capacity to cater to our near term needs, we have triggered expansions of existing facilities and new greenfield constructions to support our future needs in Biosimilars and Small Molecule APIs and Formulations. These facilities are in various stages of construction or qualification with some expected to come online in FY20. We have also selectively partnered for local fill-finish manufacturing to benefit from any preference for locally manufactured drug product.

2020

Some of the facility expansions and new greenfield constructions we had triggered to support our future needs in Biosimilars and Small Molecule APIs and Formulations are expected to come online in FY20.

** IMS/IQVIA # Bloomberg Symphony data, Goldman Sachs report May 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)

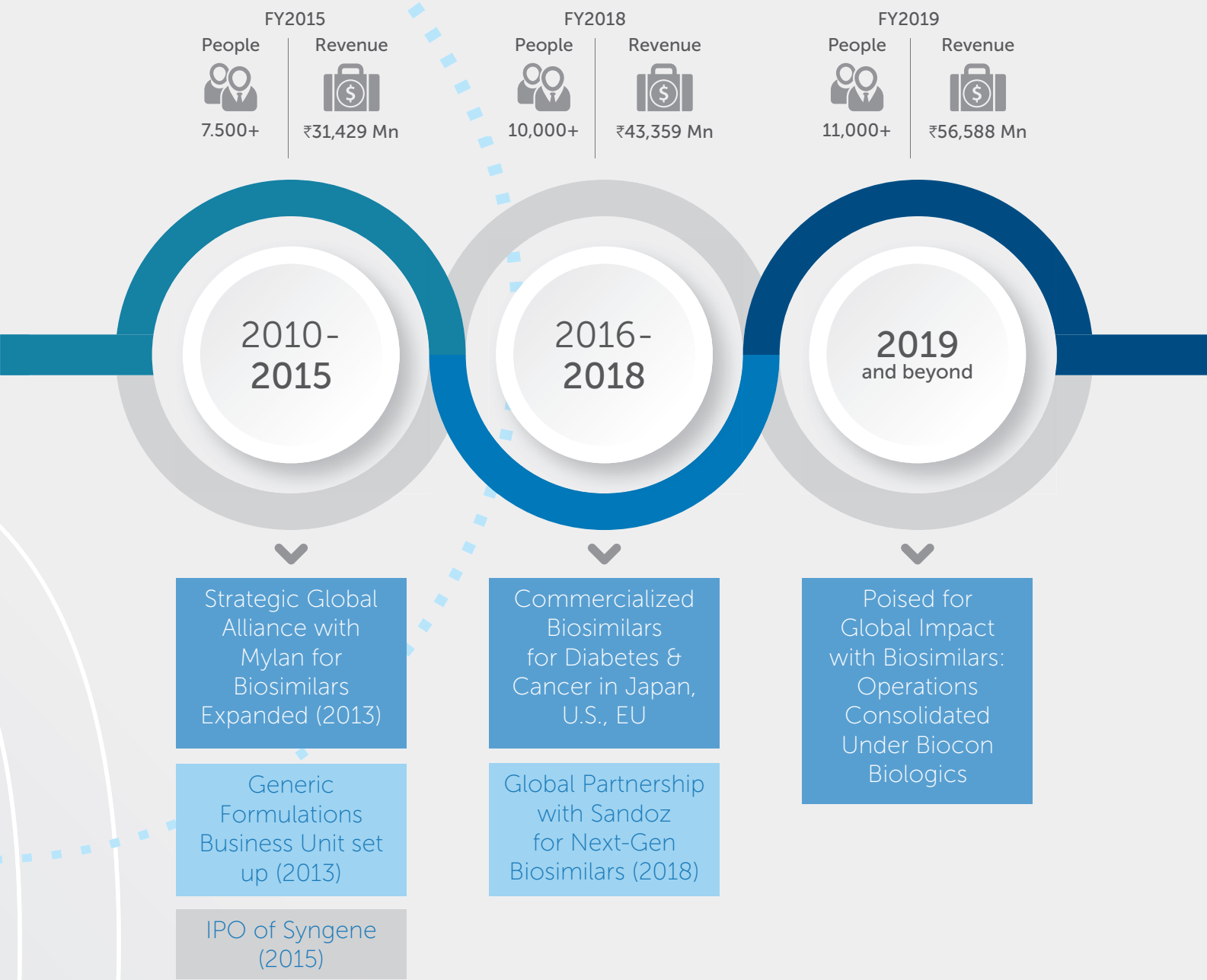
2005-2009

Building the Base Business and Expertise in Biologics

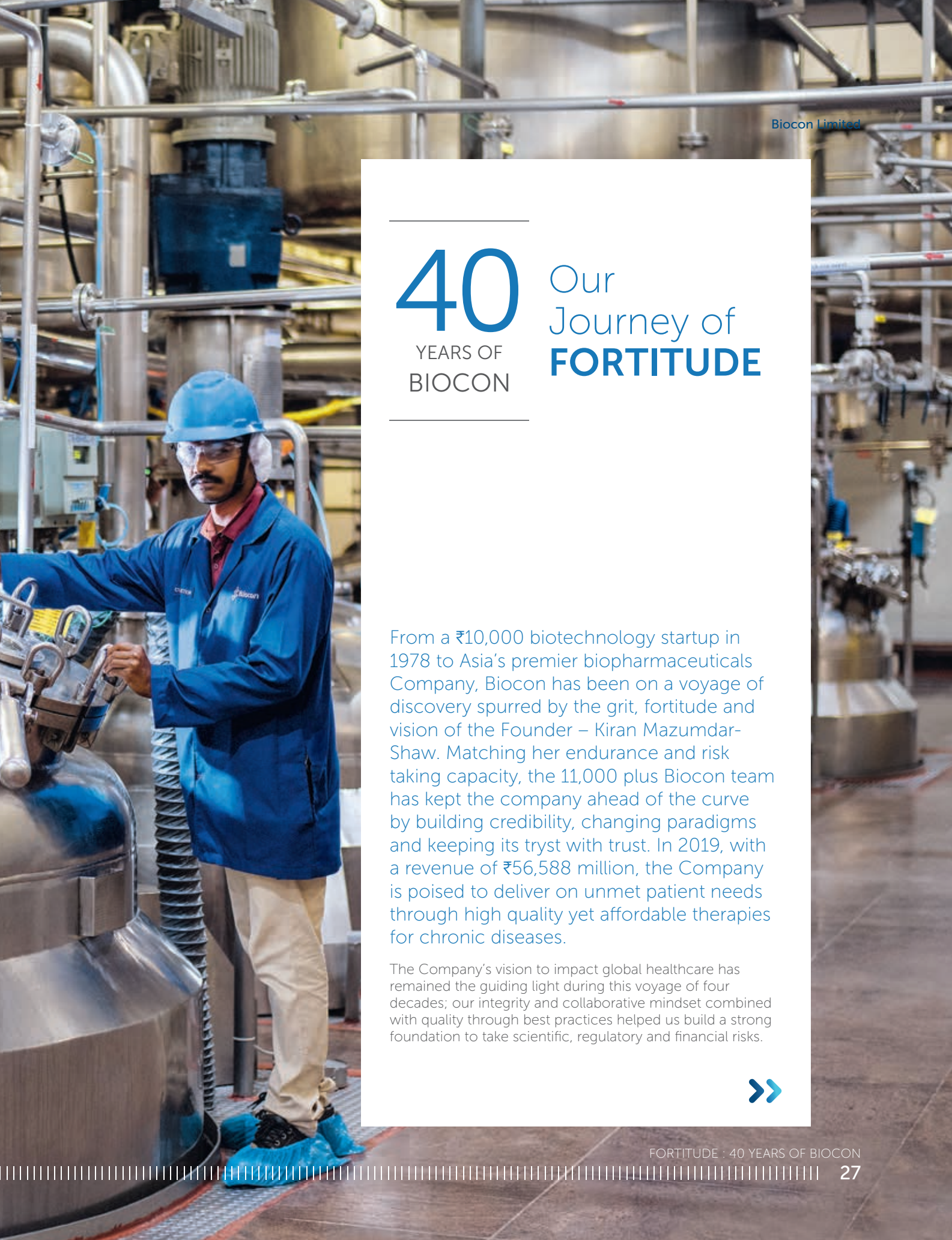
Enzymes Business Divested (2007)

Global Development of Biosimilars in Partnership with Mylan (2009)

40
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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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.

3

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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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.

Board of **Directors**

L-R sitting : Dr. Arun Chandavarkar • Kiran Mazumdar-Shaw • Mary Harney
standing : Prof. Ravi Mazumdar • M. Damodaran • Russell Walls • Bobby K Parikh • John Shaw • Dr. Jeremy Levin
Daniel M. Bradbury • Dr. Vijay Kuchroo

The composition of Biocon's board of directors reflects our commitment to uphold the highest standards of corporate governance through competence, integrity and constructive involvement of individual directors. This diverse and multidisciplinary group of erudite and experienced professionals provide the necessary expertise, capacity and guidance to the management to pursue the Company's stated mission of enhancing global healthcare whilst upholding our firm commitment to ethics and values. Our board's diversity, in terms of gender, age, experience, ethnicity, geography, and industry expertise, contributes significantly to enriching the quality of the Company's decision-making process.

Our directors have vast insights and experience in various fields such as Research & Innovation, Corporate & Financial Management, Regulatory & Compliance, Global Healthcare and International Marketing. Our international board members are based in U.S., Europe and Canada and bring diverse perspectives to address the demands of global healthcare. The board of seven independent and four non-independent directors provides the oversight, insight and foresight necessary for ethical and responsible corporate leadership that ensures that the interests of the board, management and stakeholders are aligned.

Kiran Mazumdar-Shaw

Chairperson & Managing Director

First generation entrepreneur with nearly 44 years' experience in biotechnology + Global business leader + Board member, Infosys, Narayana Hrudayalaya, United Breweries + Recipient of Indian civilian honors Padma Shri & Padma Bhushan + Highest French civilian honor Chevalier de l'Ordre National de la Légion d'Honneur + Full-term Member of the Board of Trustees of Massachusetts Institute of Technology, Cambridge U.S. + Member of the U.S. based National Academy of Engineering + AWSM Award for Excellence by Feinstein Institute for Medical Research U.S. in 2017 + Othmer Gold Medal by Chemical Heritage Foundation, U.S.+ Forbes 'World's Most Powerful Women' + Forbes 'World's Self-Made Women Billionaires' + No. 1 Business Captain in global Medicine Maker 2018 Power List + TIME Magazine's '100 Most Influential People in the World' + Signatory to 'The Giving Pledge,' the global philanthropy initiative.

John Shaw

Vice Chairman and Non-Executive Director

With Biocon since 1999 + Foreign promoter + Former Finance and Managing Director of Coats Viyella Group + Former Chairman, Madura Coats Ltd + Honorary Doctorate from University of Glasgow, UK + M.A. (Economics Hons.) in History and Political Economy from University of Glasgow, UK.

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

OCI = Overseas Citizen of India

Dr. Arun Chandavarkar

Chief Executive Officer & Joint Managing Director

Joined Biocon in 1990 + Core member of Biocon's leadership team + Ph.D. in Biochemical Engineering from the Massachusetts Institute of Technology (MIT), Cambridge, U.S. + B. Tech in Chemical Engineering from the Indian Institute of Technology (IIT), Mumbai + Past Chairman, Confederation of Indian Industry's (CII) National Committee on Biotechnology.

Prof. Ravi Mazumdar

Non-Executive Director

With Biocon since 2000 + University Research Chair Professor, Department of Electrical and Computer Engineering, University of Waterloo, Canada + Professor in several prestigious universities including Purdue University, U.S., Columbia University, U.S., University of Essex, UK, McGill University, Canada and the Indian Institute of Science, Bengaluru +J.D. Gandhi Distinguished Visiting Professor at IIT, Mumbai + Adjunct Professor at TIFR, Mumbai + Member of several advisory committees and working groups + Member of U.S. Congress Sub-Committee on Science and Technology + Fellow of the Royal Statistical Society + Fellow of the Institute of Electrical and Electronics Engineers + Has over 150 refereed publications to his credit + Ph. D. from the University of California, Los Angeles (UCLA) + M.Sc. from Imperial College, London + B. Tech in Electrical Engineering from IIT, Mumbai.

Russell Walls

Independent Director

With Biocon since 2011 + Experience of more than 49 years in the field of finance + Fellow member of the Association of Chartered Certified Accountants, UK + Ex-Treasurer and Trustee of the British Red Cross and currently the Chairman of Aviva Italia Holdings. + Experience as Director across pharmaceuticals, textiles, transport and leisure industries + BSc. from University of Glasgow, UK.

Mary Harney

Independent Director

Deputy Prime Minister of the Republic of Ireland (1997 – 2006) + Held different ministerial positions in the Irish Government for 19 years + Retired from politics in 2011 and

now acts as a consultant + Longest serving woman ever in the Irish Parliament, for over 31 years + Chancellor, University of Limerick + Chairperson, Pharmed Group and VideoDoc + Board member, Diona Technology and Leaseplan Insurances + Involved in several charitable organizations + Board Member, Irish Hospice Foundation and Vital Voices Europe.

Daniel M. Bradbury

Independent Director

With Biocon since 2013 + Life sciences executive with over 36 years of experience in creating and implementing strategies, transforming businesses + CEO, Chairman and Co-Founder of Equillium Inc. + Managing Member, BioBrit LLC + Former CEO, Amylin Pharmaceuticals, a leading metabolics company, acquired by BMS in 2012 + Member, Board of Trustees of the Keck Graduate Institute, California, U.S. + Member, Advisory Council of Rady School of Management, San Diego +'Director of the Year Award' by Corporate Directors Forum + Completed International Executive Program from INSEAD, France + Diploma in Management Studies from Harrow and Ealing Colleges of Higher Education, UK + Bachelor of Pharmacy from Nottingham University, UK.

Dr. Jeremy Levin

Independent Director

With Biocon since January 2015 + CEO & Chairman of Ovid Therapeutics since 2015 + Member since 2016 and current Chairman of Board of Biotechnology Innovation Organization + Board member of Lundbeck since 2016 + Former President & CEO of Teva Pharmaceuticals + Former Executive Committee Member of Bristol-Myers Squibb+ Served as Global Head of Strategic Alliances at Novartis + Recognized among 'Top 25 Most Influential People in the Biopharmaceutical Industry' + Recipient of Kermode Prize and Albert Einstein Award for Leadership in Life Sciences + Bachelor's Degree in Zoology, Master of Arts (MA) and a Doctorate (D. Phil) from the University of Oxford + Degrees of Bachelor of Medicine, Bachelor of Surgery from the University of Cambridge, UK.

Dr. Vijay Kuchroo

Independent Director

With Biocon since 2015 + Samuel L. Wasserstrom Professor of Neurology & Director of Evergrande Center for Immunologic Diseases at Harvard Medical School + Senior Scientist at Brigham and Women's Hospital, and Co-Director of the Center for Infection and Immunity, at the Brigham Research Institutes, Boston + Associate member, Broad Institute + Participant in a Klarman Cell Observatory project that focuses on T cell differentiation + Research focus includes autoimmune diseases and cancer immunotherapy + Holds 25 patents + Serves on scientific advisory boards and works in advisory capacity to several companies, including Pfizer, Novartis and GlaxoSmithKline + Founded 5 different biotech companies including CoStim Pharmaceuticals and Tempero Pharmaceuticals + Published over 325 original research papers in immunology + A paper he authored on development of Th17 is one of the highest cited papers in immunology + Ph.D. from University of Queensland, Brisbane, Australia + Fred Z. Eager Research Prize and medal for his Ph.D. + Fogarty International Fellow at The National Institutes of Health, Bethesda + Javits Neuroscience Award by the National Institutes of Health in 2002 + Named as Distinguished Eberly Lecturer in 2014 + Recipient of Peter Doherty Award for Excellence in STEM in 2014.

M. Damodaran

Independent Director

With Biocon since 2016 + 30 years of experience in financial services and public sector enterprises + Founder Chairman, Indian Institute of Management, Tiruchirappalli + Chaired Government of India Task Force to set up the Resolution Corporation of India + Former Chairman, Securities Exchange Board of India (SEBI), Unit Trust of India (UTI) and Industrial Development Bank of India (IDBI) + Former Chief Secretary, Government of Tripura + On the Boards of leading Indian Corporates as well as on the Advisory Boards of a few foreign entities + Founder Chairperson of Excellence Enablers Private Limited, a niche Corporate Governance advisory firm.

Bobby Kanubhai Parikh

Independent Director

With Biocon since 2018 + Founder of Bobby Parikh Associates + Co-founder of BMR Advisors + Former CEO EY in India + Country Managing Partner of Former Accounting Firm Arthur Andersen + Works closely with regulators and policy formulators + Over 30 Years of experience in advising a number of private equity investors, banking groups, investment banks, brokerage houses, fund managers and other financial services intermediaries + Member of a number of trade and business associations + Member of the advisory or executive boards of non-governmental, not-for-profit organizations and private as well as listed Indian companies + Graduate in Commerce from the University of Mumbai + Qualified Chartered Accountant from the Institute of Chartered Accountants of India in 1987.

Scientific **Advisory Board**

Alan D. Cherrington, PhD

Professor, Molecular Physiology and Biophysics + Associate Director of the Vanderbilt Diabetes Research and Training Center & Charles H. Best Professor of Diabetes Research + Holds Jacquelyn A. Turner and Dr. Dorothy J. Turner Chair in Diabetes Research + Past Chairman, Molecular Physiology & Biophysics Department, Vanderbilt University + Past President of the American Diabetes Association (ADA) + Member ADA since 1972 + Member of editorial boards for scientific journals + Published 287 peer-review papers and 84 review articles over past four decades + Honoured with the Frederick Banting Award in 1997 & Josiah Kirby Lilly Sr. Distinguished Service Award in 2002

G. Alexander Fleming, MD

Founder and Executive Chairman of Kinexum LLC + President and Chief Executive Officer of Tolerion + Member of the expert working groups on Good Clinical Practices and General Considerations for Clinical Trials of the International Conference on Harmonization (ICH) + Frequently published scientific articles and book chapters

Harold E. Lebovitz, MD FACE

Professor of Medicine at National Institutes of Health (NIH) + Ex-Professor of Medicine/ Chief of Endocrinology & Diabetes of NIH-sponsored Clinical Research Center at the State University of New York, Health Science Center, Brooklyn + Ex Director of NIH-sponsored Clinical Research Center + Serves on the Board of Directors of the American Association of Clinical Endocrinologists (AACE) + Served on numerous review committees for ADA, NIH and the Veterans Administration + Has authored more than 200 peer-reviewed publications and more than 100 book chapters + Recipient of several awards including the 1994 Albert E. Renold Medal of the ADA

Satish K. Garg MD, DM

Professor of Medicine and Pediatrics; Garg Endowed Chairs & Director Adult Program, Barbara Davis Center for Diabetes, University of Colorado, Denver + Editor in chief of Diabetes Technology and Therapeutics journal since 2006 + Chair of the planning committee for Clinical Therapeutics and New Technology area for 2007 & 2008 Annual ADA meetings + Member of several Endocrine and Diabetes Societies + On the editorial boards for many diabetes journals globally + Published more than 285 original manuscripts in peer-review journals and several book chapters

John Petrie, PhD

Professor of Diabetic Medicine, Institute of Cardiovascular & Medical Sciences, University of Glasgow + President, European Group for the Study of Insulin Resistance + Lead author of a statement on the risks and benefits of Insulin Pumps in 2015 + Member of the joint ADA and European Association for the Study of Diabetes (EASD) Technology Committee + Associate Editor of the journal of EASD, Diabetologia and joined its Advisory Board in 2014 + Currently, Senior Associate Editor of the journal Cardiovascular Endocrinology + Served in the grant-awarding panels of multiple reputed organizations like NIH, JDRF etc. + Authored more than 100 publications in peer-reviewed journals.

Brian Kotzin, MD

Senior VP of Clinical Development at Nektar Therapeutics since April 2018 & Head of Clinical Development for Immunology Program since May 2017 + Over 30 years of expertise in inflammation and immunology + Member of Scientific & Clinical Advisory Board at Equillium, Inc + Previously, served as VP Global Clinical Development and Head of the Inflammation Therapeutic Area of Amgen Inc. + Industry Representative, Arthritis Advisory Committee, Center for Drug Evaluation and Research, FDA + Chairman of the NIH Autoimmunity Centers of Excellence + Advisory Council of the National Institute of Arthritis and Musculoskeletal and Skin Diseases at the NIH + Published extensively and served on the editorial boards of Arthritis and Rheumatism, The Journal of Immunology and the Journal of Clinical Investigation + Elected Master of the American College of Rheumatology + Kirkland Scholar Award for Lupus Research + Henry Claman Chair in Clinical Immunology + Gretchen Kramer Award for Outstanding Contributions to Medicine

Lawrence Steinman, MD

George A. Zimmermann Professor and Professor of Pediatrics, Genetics & Neurology & Neurological Sciences, Standford University + Served as the Chair of the Stanford University Interdepartmental Program in Immunology from 2003-2011 + Key Research Interests – Remission & Relapse in MS, Vaccine against MS, Brain Inflammation + Co-inventor of leading MS drug Natalizumab and several new therapies for autoimmune diseases + Senior author on the seminal 1992 Nature article that reported the key role of a particular integrin in brain inflammation + John M. Dystel Prize from the American Academy of Neurology & National MS Society + Charcot Prize for Lifetime Achievement in MS research + Awarded twice the Senator Jacob Javits Neuroscience Investigator Award by the National Institute of Neurological Diseases and Stroke + Member of the National Academy of Sciences and the National Academy of Medicine

Brian Daniels, MD

MS & BS from MIT + Venture Partner at 5AM Venture Management LLC + Former Senior VP, Bristol-Myers Squibb Co. + Directed and Conducted clinical research at Merck Research Laboratories and Genentech + Extensive experience in clinical development, medical affairs and corporate strategy across therapeutic areas + Volunteer at The Gladstone Institutes at the University of California in San Francisco as a Translational Partner

Vijay Kuchroo DVM, PhD

Samuel L. Wasserstrom Professor of Neurology & Founding Director of Evergrande Center for Immunologic Diseases at Harvard Medical School, USA + Senior Scientist at Brigham and Women's Hospital & Co-Director of the Center for Infection and Immunity at the Brigham Research Institutes, Boston + Associate member of the Broad Institute + Participant in a Klarman Cell Observatory project that focuses on T cell differentiation + Named 'Distinguished Eberly Lecturer' in 2014 + Obtained Nobel Laureate Peter Doherty Lecture / Prize in 2014 + Holds 25 patents and numerous publications + Founded 5 different biotech companies including, CoStim Pharmaceuticals and Tempero Pharmaceuticals + Serves on scientific advisory boards and works in advisory capacity to several internationally recognized pharmaceutical companies + Javits Neuroscience Award by NIH

Reliving Yesteryears **Co-creators**

Brand Ambassadors

Dr. Tara Jayaram

1987 – 2014

Chemist -> Associate Vice President

Led Quality & Regulatory Systems

Biocon + Syngene

It was an amazing 26-year journey at Biocon, during which I led a 250-member team that helped set up world class quality systems (GMP, GLP, GCP, ISO 9001, ISO 14001 and OHSAS 18001) at Biocon and Syngene.

I had the privilege of leading Biocon during its first ISO 9001 certification process in 1993 from RWTUV of Germany, first USFDA inspection in 2001 and first GLP Inspection in 2009 by BfArM of Germany.

We became the first life sciences company in India to get the ISO 9001 Certification and the first Indian company to receive the Integrated Certification for ISO 14001 and OHSAS 18001 from TUV NORD of Germany. We received numerous approvals from the U.S. FDA and other global regulatory agencies including EU GMP on a regular basis over the two-decade period.

Dr. Nirupa Bareja

1989 – 2005

Chemist -> Group Head, HR

Led Quality, Manufacturing & HR

Biocon

Biocon was my first corporate job after completing a Ph.D. in Biosciences, and it has been a joyous, empowering and fulfilling experience. My oft-quoted line during this 16-year journey was "either I work with Biocon or not at all." A scientist at heart, I cherished the fact that the Company gave me the freedom to experiment and innovate with a sense of responsibility and accountability. As a woman, I never felt discriminated, on the contrary, I was fully empowered and was elevated to various positions of responsibility and leadership very early in my career. The trust and confidence instilled in me by Kiran enabled me to achieve the distinction of becoming India's first woman Production Manager, heading Biocon's entire manufacturing functions in 1994. Every role I played, whether heading Quality or Manufacturing or Human Resources, gave me a great sense of accomplishment. I will cherish the experience forever!

Dr. Manoj Nerurkar

2009 – 2018

Head, Formulation Development -> COO

Strategic and operational leadership

Syngene

When I decided to return to India from the U.S. over a decade ago, I was looking for a professional opportunity that would allow me to build the right set of skills, help me grow in my career and give me the freedom to be myself. Today, I can say that joining the Biocon family was the best career decision I made in my professional life. Innovation, quality excellence, professionalism and the desire to be world class are attributes that are embedded in the Group's DNA and have contributed to its success. I am extremely grateful to my colleagues, the management and the entire Biocon family for making this one of the most memorable experiences of my life. I wish the Group continued success in the years to come.

Key **Management Team**

Biocon Limited

Kiran Mazumdar-Shaw
Chairperson & Managing Director

Dr. Arun Chandavarkar
CEO & Joint Managing Director

Dr. Christiane Hamacher
CEO, Biocon Biologics

Siddharth Mittal
Chief Financial Officer

Shreehas Tambe
Chief Operating Officer, Biocon Biologics

Prasad BSV
Chief Operating Officer, Biocon Generics & APIs

Dr. Gopala Krishna Dasika
Head, R&D, Biocon Biologics

Paul V Thomas
Chief Commercial Officer, Biocon Biologics

Abhijit Zutshi
Commercial Head, Biocon Global Generics

Nehal Vora
Commercial Head, Biocon Global APIs

Suresh Subramanian
Head, Branded Formulations India

Sriram A.V.
Head, Quality, Biocon Biologics

Sridhar Balasubramanian
Head, Quality, Small Molecules

Amitava Saha
Head, Human Resources

Seema Shah Ahuja
Global Head, Corporate Communications

FOSTERING
Growth

Q&A
WITH THE CFO

Siddharth Mittal,
President, Finance & CFO

31%

Consolidated Revenue grew 31% to ₹56,588 million in FY19 from ₹43,359 million in FY18.

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

A. **In FY19, our consolidated revenue grew 31% from ₹43,359 million to ₹56,588 million. Our three strategic business segments Small Molecules, Biologics and Research Services have reported a top-line of over ₹15,000 million each this fiscal.**

We witnessed revenue growth across all segments with Biologics leading the way with 97% growth (₹15,169 million vs. ₹7,702 million in FY18). This was well supported by 28% growth in Research Services (₹18,256 million vs. ₹14,231 million in FY18), 18% in Small Molecules (₹17,728 million vs. ₹15,077 million in FY18) and 7% in Branded Formulations (₹6,564 million vs. ₹6,115 million in FY18).

Earnings before Interest, Depreciation and Amortization (EBITDA) increased 49% (₹15,381 million vs. ₹10,353 million in FY18) A higher share of Biologics revenue boosted profitability as reflected in the consolidated EBITDA margin of 27% for the full year up 3% from FY18.

Reported Net Profit increased 143% to ₹9,053 million (vs. ₹3,724 million in FY18). When adjusted for exceptional items and associated tax, Net Profit for FY19 was ₹7,291 million, a growth of 96% vs. FY18.

Q. Biocon's Biologics segment posted robust YoY revenue growth in FY19, but sequentially between Q3 and Q4 of FY19, the revenue traction was more or less steady, despite new launches in EU. What kind of revenue growth should we expect in FY20 and beyond?

A. We expect the revenue growth momentum in Biologics segment to continue in FY20 driven by new launches and increased penetration of products already launched by our partners in various markets. While the segment revenues will reflect strong growth on a full year basis, a significant part of this growth will be towards the second half of FY20.

Q. What led to the steady increase in R&D expenses in FY19? How much do you expect to spend on R&D in FY20?

A. R&D is an integral part of our business and in order to drive future business growth, we will continue to invest in R&D across all our business segments.

In FY19, gross R&D expenses were ₹4,796 million, corresponding to 13% of revenues ex-Syngene. The increase was on account of higher spends on ANDA programs and biosimilars, driven by the Sandoz collaboration pipeline.

In FY20, we expect R&D expenses to increase compared to FY19 on account of both addition and advancements in our biosimilars, novels and ANDA pipeline. Gross R&D spends are expected to be ~15% of revenues ex-Syngene.

96%

Net Profit (before exceptional items) grew 96% to ₹7,291 million in FY19 from ₹3,724 million in FY18.

Q. You have guided for higher manpower costs in FY20. How do you expect this increase to impact operating margins in FY20?

A. The staff costs will primarily increase on account of annual salary increments and hiring additional manpower for new manufacturing and research capacities. Additionally we will also be hiring employees at various levels to support independent functioning of biosimilars business under Biocon Biologics India Limited (Biocon Biologics) and novel immuno-oncology programs under Bicara Therapeutics, Inc. (Bicara Therapeutics).

We expect that margins from revenue growth will offset increase in operating expenses including higher manpower costs resulting in core EBITDA margin percentage (i.e. EBITDA margins net of licensing, impact of forex and net R&D expenses) to be at similar levels of FY19.

Q. Your Branded Formulations business reported a muted performance in FY19 because of the impact from UAE? When do you expect headwinds in the UAE to recede?

A. The UAE performance for the year was impacted by uncertainty in the local market, including delays in drug registration with the local health authorities and re-pricing of branded generic products mandated by the Ministry of Health. We expect some challenges to continue in the first half of FY20.

On a positive note, we launched our first biosimilar Trastuzumab under the brand name CANHERA, which is aimed at providing an affordable treatment option and increasing access to this medicine for patients suffering from breast cancer. The launch of CANHERA represents our second biosimilar launch in the UAE market, initially having launched Biosimilar Insulin Glargine under the brand name Glaricon®.

Q. What is the capacity utilization of current antibody manufacturing facility? Do you have sufficient capacity to service the developed markets? When will the new antibody manufacturing facility be commissioned?

A. In line with our expectations of biosimilars penetration to be gradual in developed markets, we do have sufficient capacity to support launches of biosimilar antibody products in the developed markets. To address volume growth on account of increased penetration in developed and emerging markets and also to support new biosimilar antibody product development and launches, in FY18 we had initiated construction of a greenfield antibody manufacturing facility in Bengaluru. The construction of this facility is on track and the facility is expected to be commissioned in FY20 followed by qualification and validation activities in FY21. We expect regulatory approvals and subsequent commercialization from this facility to commence in FY22.

We have also started work on expansion of the current R&D facility and additional infrastructure and equipment to support greater R&D capacity requirements for our future pipeline.

49%

EBITDA increased 49% to ₹15,381 million in FY19 vs. ₹10,353 million in FY18.

A higher share of Biologics revenue boosted profitability as reflected in the consolidated EBITDA margin of 27% for the full year up 3% from FY18.

Q. What is your capex guidance for FY20? How do you plan to fund it?

A. The greenfield antibody facility in Bengaluru entails an investment of ~USD 200 million with cash outflow over four years starting FY18. In FY19 we also initiated upgradation of our insulins drug substance facility in Bengaluru. In FY19, we incurred ~USD 100 million largely attributable towards these projects along with recurring maintenance capex across all our verticals.

In FY20, we plan to add incremental drug substance and drug product capacities across biosimilars (antibodies, insulins and proteins) as well as Small Molecules businesses. We will also commence construction work to build a greenfield facility in Visakhapatnam, Andhra Pradesh to support growing demand of immunosuppressant products in Small Molecule business. We are also evaluating construction of the second phase of our Malaysia Insulin facility which will require investment of ~USD 200 million. Excluding Syngene's capex and capitalized R&D/ intangible assets, we expect capex spend in FY20 to be in the range of USD 150-200 million.

We plan to fund the capex through a combination of internal accruals, additional debt, contribution from our co-development partner and a potential equity infusion into our biosimilars business.

Q. Have you achieved breakeven in Malaysia? What has been the progress of your Malaysia facility?

A. In FY19, at an operational level, the Malaysian entity had losses of USD 4 million on account of fixed operating expenses which were partially offset by sales in emerging markets, recovery from co-development partner and R&D activities.

While we expect growth from insulin sales in the emerging markets, primary growth driver will be the launch of Insulin Glargine in the US. Further our partner, Mylan launched Insulin Glargine in the EU in the second half of FY19 and sales are expected to ramp up over the next two years.

Q. What is your outlook for Biocon in FY20?

A. FY19 witnessed a robust growth in revenues led by our biosimilars business which also contributed to the significant margin expansion over FY18. We expect the growth momentum across our business segments to continue in FY20 especially driven by biosimilar launches in the U.S. in the latter part of the year. We expect to sustain the healthy core EBITDA margins witnessed in FY19. We will continue ramping up our R&D investments to support our growing pipeline of biosimilars, novel assets and generics to secure our future growth. We intend to complete the organizational restructuring and strengthening of the human resource required to fully operationalize Biocon Biologics and Bicara Therapeutics as distinct entities with the intent to unlock value in biosimilars and novel immuno-oncology assets respectively in future. Despite a short term impact on costs, we believe that these investments along with the expansion of our manufacturing and R&D infrastructure will position us to be a leading player in providing affordable access to patients globally.

₹4,796 Mn

In FY19, gross R&D expenses were ₹4,796 million, corresponding to 13% of revenues ex-Syngene.

In FY20, we expect R&D expenses to increase compared to FY19 on account of both addition and advancements in our biosimilars, novels and ANDA pipeline.

Financial **Highlights**

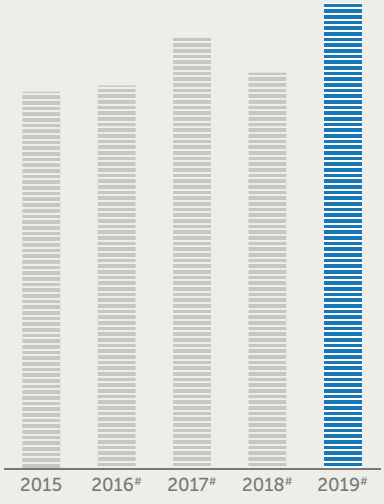
Segment-wise Revenue*

Small Molecules

₹ Million

Growth 18%

2015	2016#	2017#	2018#	2019#
14,432	14,583	16,405	15,077	**17,728**

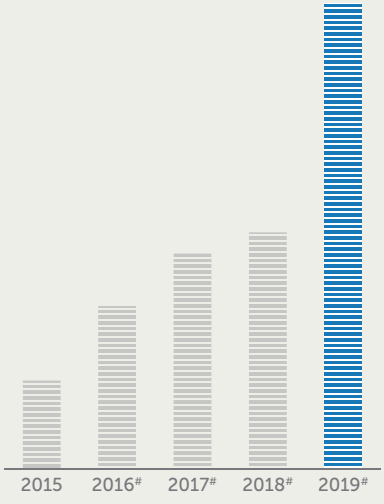


Biologics

₹ Million

Growth 97%

2015	2016#	2017#	2018#	2019#
2,857	5,296	7,018	7,702	**15,169**

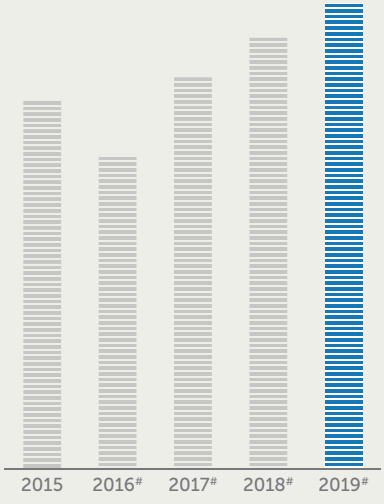


Branded Formulations

₹ Million

Growth 7%

2015	2016#	2017#	2018#	2019#
5,212	4,409	5,489	6,115	**6,564**

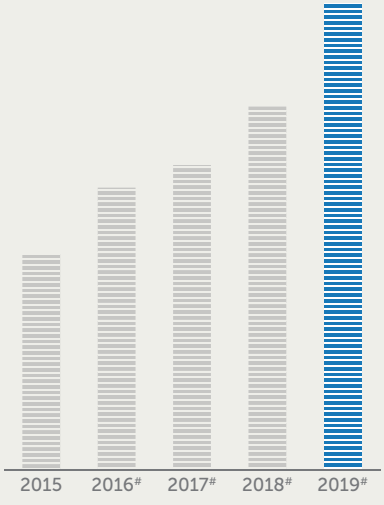


Research Services

₹ Million

Growth 28%

2015	2016#	2017#	2018#	2019#
8,514	11,070	11,925	14,231	**18,256**

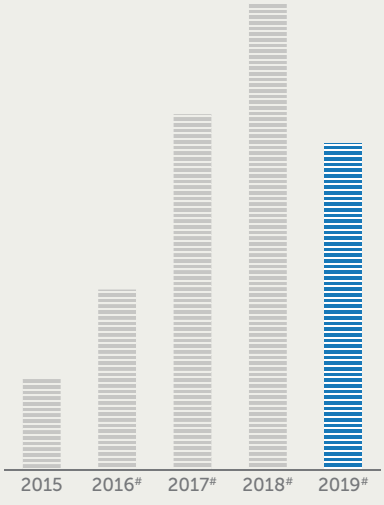


Other Income

₹ Million

Growth -30%

2015	2016#	2017#	2018#	2019#
414	792	1,571	2,062	**1,444**

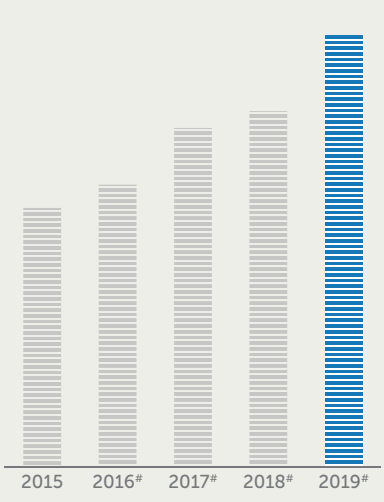


Total Revenue

₹ Million

Growth 31%

2015	2016#	2017#	2018#	2019#
31,429	34,602	40,787	43,359	**56,588**

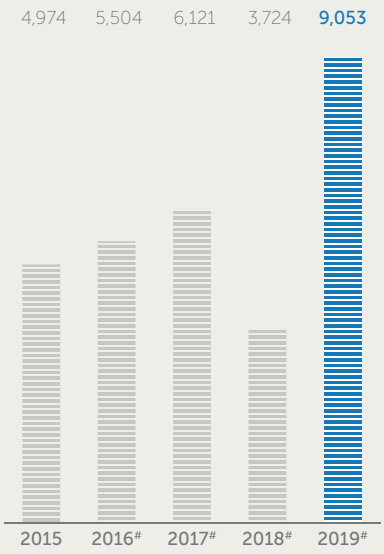


* Includes inter-segment revenue
# 2016-2019 figures are as per Ind AS

Profit*

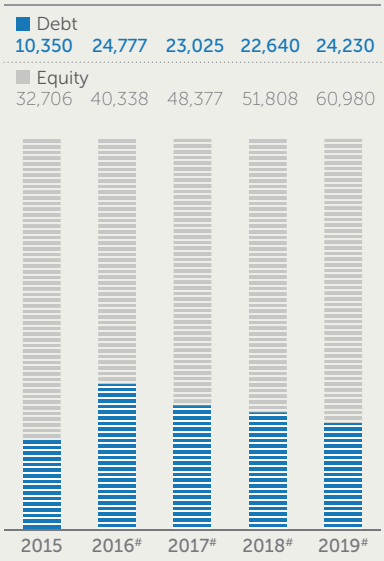
₹ Million

Growth 143%



Debt : Equity

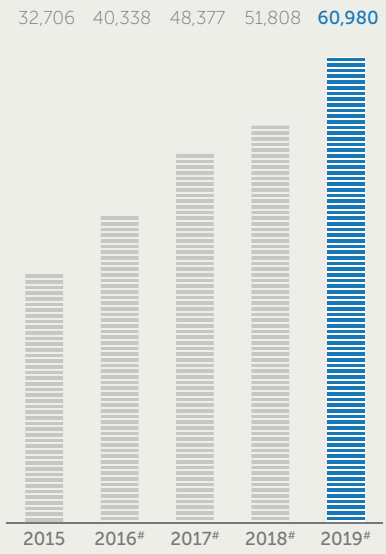
₹ Million



Net Worth

₹ Million

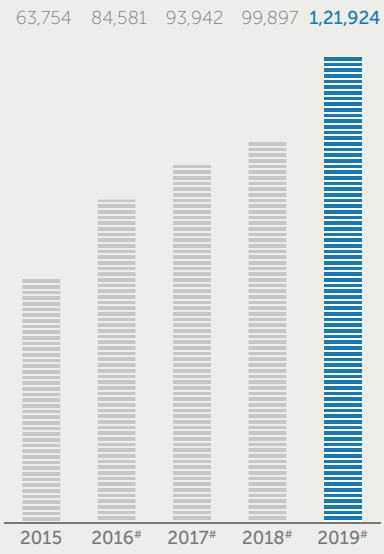
Growth 18%



Total Assets

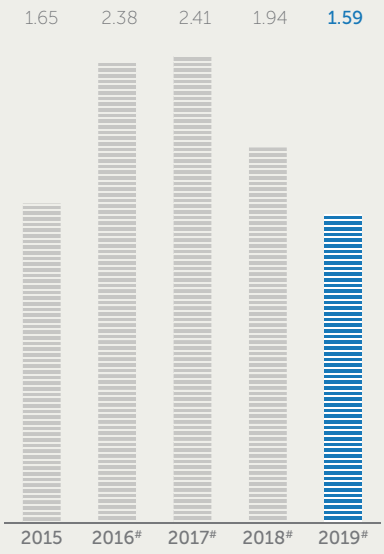
₹ Million

Growth 22%



Current Ratio

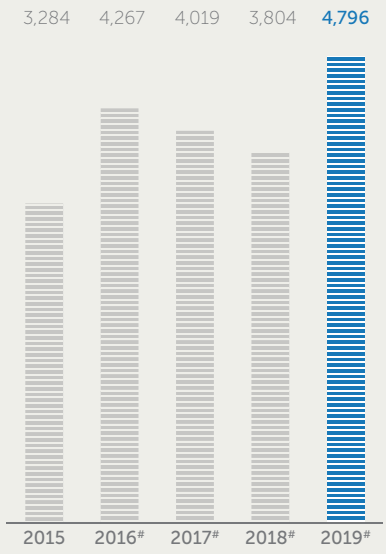
₹ Million



Gross R&D Spend

₹ Million

Growth 26%



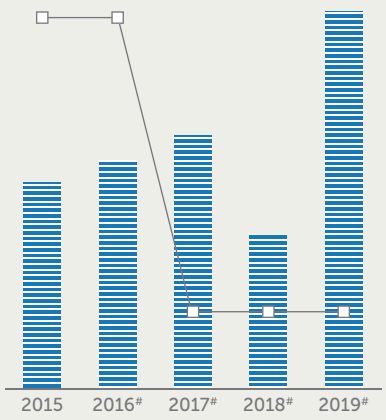
* includes exceptional income for the years 2015, 2016 and 2019
# 2016-2019 figures are as per IndAS

Financial **Highlights**

EPS & Dividend per Share*@

₹

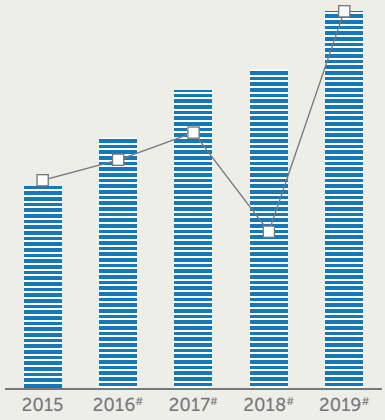
	2015	2016#	2017#	2018#	2019#
EPS	8	9	10	6	15
Dividend per share	2	2	1	1	1



EPS & Book Value Per Share*@

₹

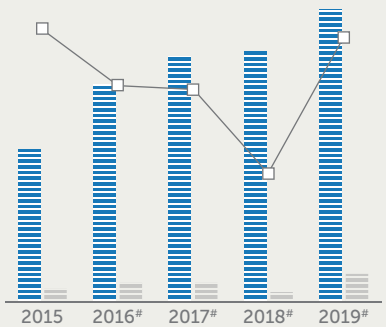
	2015	2016#	2017#	2018#	2019#
Book value per share	55	67	81	86	102
EPS	8	9	10	6	15



Return on Net Assets*^

₹ Million

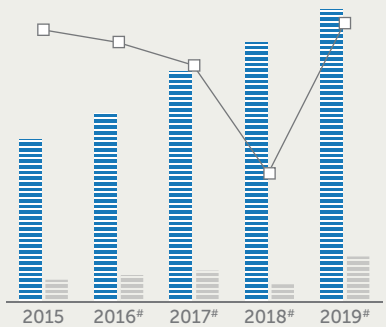
	2015	2016#	2017#	2018#	2019#
Net Assets	48,207	67,924	77,159	78,484	91,548
Profit	4,974	5,504	6,121	3,724	9,053
Return on Net Assets	10%	8%	8%	5%	10%



Return on Net Equity*

₹ Million

	2015	2016#	2017#	2018#	2019#
Average Equity	31,487	36,480	44,358	50,093	56,394
Profit	4,974	5,504	6,121	3,724	9,053
Return on Net Equity	16%	15%	14%	7%	16%



* Includes exceptional income for the years 2015, 2016 and 2019

\# 2016-2019 figures are as per IndAS

@ 2015 - 2017 are adjusted for bonus issue in 2018

^ Net assets = Total assets - Current Liabilities

Biocon Limited

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.

+ Read more on Research Services Business : Page 140

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

Sustainability

103,200

We achieved a reduction of 103,200 tons of CO_2 emission in FY19.

Sustainability has been part of our core at Biocon, driving us forward in our journey of fortitude over four decades. With innovative programs that seek to resolve several primary issues, we aim at delivering sustainable solutions to our people, patients and partners. Our flagship initiatives are based on the principle of making an enduring impact through programs that encompass primary healthcare, education, community development and environmental sustainability. Our integrated outreach strategy, designed to support this principle, has manifested in the application of 'sustainable thinking' in everyday life.

ENVIRONMENT

We are committed to enabling the planet's transition to a circular economy even as we pursue breakthroughs in biotechnology and drive business growth. Blending our scientific expertise with our passion for sustainable development, we are engaging the society for a lasting impact.

With a philosophy of "achieving more with less" we have woven Environment, Health and Safety (EHS) into our corporate ethos. As we push our limits, with a zeal to make a significant contribution to society, environment and the national economy, we surpass basic EHS standards. While our safety and sustainability initiatives are driven by stringent targets, we promote sustainable practices at all our manufacturing plants, research facilities and offices.

EHS Management Systems

Our EHS Management System and the Occupational Health and Safety Management Systems are established in compliance with ISO 14001:2015 and OHSAS 18001:2007, respectively. The comprehensive EHS Management System encompasses all operations in manufacturing, research & development, supply chain network, as well as, administration.

In our constant endeavor to raise the bar, we are transitioning to the new ISO 45001:2018 standard, the first global standard and a single benchmark for management of Occupational Health and Safety. Continuous self-evaluation, correction and improvement of operations and processes based on findings of annual internal and external audits continue to lead us to the next orbit in EHS.

Health and Safety at Workplace

Safety and health of employees is of paramount importance for any organization, therefore, we have built a strong culture of occupational health and safety at Biocon over the years.

Several safety-related initiatives, awareness campaigns and drives were conducted to promote a "zero incidents" mindset among employees. These efforts resulted in behavioural change, making FY19 a zero-reportable-incidents year.

By applying scientific risk assessment technologies at work on chemicals and biologicals, we ensured that highest workplace safety standards were implemented across R&D and the manufacturing value chain. We accorded additional focus on road safety by initiating a comprehensive logistics and road safety assessment of our facilities and designed a traffic management blueprint for enhanced man-material segregation in Biocon facilities.

~22,000

Nearly 22,000 man-hours of EHS training were imparted in FY19 to enhance employee awareness on safety-related issues.

Emergency Preparedness & Response

Risk engineering and emergency response planning are critical components of our EHS management system. We have a well-trained emergency response team (ERT) and advanced fire protection systems to respond quickly to emergencies. During the year, several EHS training workshops were held to augment the ERT's efficiency to ensure swift response during any emergency.

We further strengthened our fire protection system and emergency preparedness by introducing an advanced firefighting vehicle with a 42-meter aerial ladder platform and hydraulic rescue tools.

Periodic Mutual Aid meetings were organised with representatives from nearby industrial units for enabling collaboration and swift response during any emergency.

EHS Training and Employee Engagement

We organized close to 22,000 man hours of training for our employees across 346 sessions covering chemical safety, lab safety, fire safety, emergency preparedness, first aid and advanced process safety.

As a part of our commitment to enhance employee awareness on EHS-related matters, several awareness campaigns were held around World Environment Day, National Safety Week, Fire Services Week, World Water Day, and World Ozone Day.

Environmental Conservation

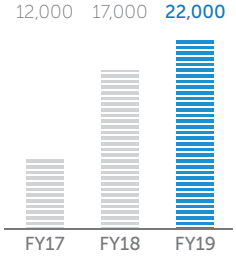
Water conservation forms an important part of our environmental agenda and responsible water usage is a key constituent of our commitment to resource conservation. In addition to being a zero-liquid discharge facility, we undertook several measures to reduce Biocon's overall water footprint. From rainwater harvesting to recycling and reducing water usage, several initiatives contributed to water conservation at our facilities.

We have adopted best-in-class practices to reduce solid waste during the conversion of raw materials to finished goods Solid waste generated during production is disposed/ recycled in compliance with applicable environmental laws.

Energy & Climate Change

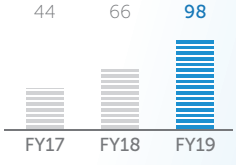
Biocon is committed to responsible energy and greenhouse gas (GHG) emissions management through strategic energy sourcing and continual improvements of our energy management systems. We strive to

EHS Training Man-Hours

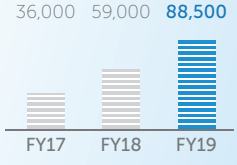


Carbon Footprint Reduction

Green Power (Million Units)



CO_2 Emission Reduction (In tons)



FY19

88,500 tons
CO_2 emission reduction from green power

54%
Green Power used.

14,700 tons
CO_2 emission reduction due to switchover from furnace oil to natural gas for steam generation

1,03,200 tons
Total CO_2 emission reduction achieved

improve the efficiency of our production processes and lower GHG emissions by incorporating renewable energy technologies to supplement our power needs.

Consistent efforts to optimize energy consumption in production processes and utilities were undertaken in FY19.

The continuous adoption of renewable energy as a preferred source has enabled us to increase its share in our total power consumption to more than half for the first time this fiscal year.

With the procurement of over 98 million units of wind power, we successfully reduced our carbon footprint in FY19 by about 88,500 tons. Our switch to natural gas from furnace oil for steam generation further reduced our carbon footprint by 14,700 tons, thus bringing the total CO2 emissions reduction to 1,03,200 tons in FY19.

We also participated in the Carbon Disclosure Project (CDP) this year.

Our engagement with CDP reflects our commitment to good environmental management and our desire for continuous performance improvement.

Lake Rejuvenation

Our efforts at resuscitating Bengaluru's shrinking water bodies, specifically the Hebbagodi lake, in partnership with the government and community groups achieved significant milestones. Bioremediation techniques, such as application of enzymes and specially selected eco-friendly microorganisms and energy-efficient mechanical aerators, gave the dying 35-acre Hebbagodi lake a new lease of life. The floating wetlands deployed for continuous natural cleaning, secured us a place in the Limca Book of World Records for the 'Largest Area of Artificial Floating Wetlands Created in a Lake in India'.

Encouraged by these recognitions, the Foundation has submitted to the Karnataka government a Detailed Project Report (DPR) for the revival of Yarandahalli lake in Bengaluru. On World Environment Day, a community green belt plantation drive was conducted around this Lake. A draft DPR is being prepared for a third lake in Kammasandra based on a preliminary survey.

Taking the Hebbagodi project beyond water restoration, a children's park and walkways were developed in the lake's vicinity. Creating a public open space around the lake for physical activity and recreation has helped generate a sense of ownership among local residents. A safe drinking water unit using reverse osmosis water filtration system has also been set up at the lake for visitors and the neighbouring community.

Namma Biocommunity

Through Namma Biocommunity, a Biocon neighbourhood community connect initiative, we have been making a positive impact on people's lives in urban and rural areas by ensuring a clean, green and safe environment. During the year, several drives involving local community members were organized to commemorate World Environment Day, National Road Safety Week and Swachh Bharat Abhiyan.

Awards

- 18th Annual Greentech Environment Award for excellent performance and outstanding achievement in Environment Management in 'Gold Category'
- 'Best Fuel Efficient Industrial Boiler' Award from Karnataka State Safety Institute, Department of Factories and Boilers
- 17th Annual Greentech Safety Award for Excellence in Occupational Health and Safety Management Practices in the Pharmaceutical Sector in 'Gold Category'

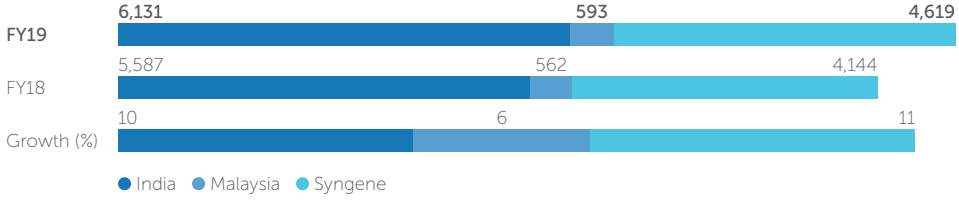
PEOPLE

79,500

The HR function clocked 79,500 learning hours in FY19, a 76% increase over the previous year.

Biocon's globally recognized people-centric practices make us India's most preferred biotech employer. We believe that the fortitude, determination and endurance of our talent have helped us build an innovation-driven company and stay ahead of the curve. Biocon's efforts at building a globally respected organization have been validated by the U.S.-based Science magazine for six consecutive years. Standing 7th on the prestigious list of Global Biotech Employers in 2018, we proudly remained the only Asian company to feature among the Top 20 in the annual Science Careers Top Employers Survey.

Global Employee Base

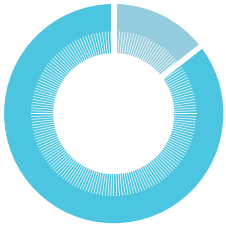


Attracting Talent

Recognized as an employer of choice, Biocon has attracted the best global talent over the last 40 years. In FY19, expanding our sourcing mix, we doubled the international hires, a reflection of the growing interest of foreign talent in Biocon. For young Indians actively using social media, Biocon runs regular talent acquisition campaigns on platforms such as Facebook, LinkedIn & Twitter. In FY19, nearly 30% of new talent were hired through social media. We also hired from top institutes such as the Indian School of Business, Narsee Monjee Institute of Management Studies, The Institute of Chemical Technology, and National Institute of Pharmaceutical Education and Research. Among the leaders in the biotech industry, Biocon offered internships to nearly 600 students, including international interns, in FY19.

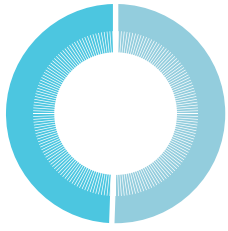
Talent Profile*

Employer of Choice



- Freshers 14%
- Experienced 86%

Talent Profile of Employees



- Graduates 51%
- Post-Graduates+ PhDs 49%

Learning & Development

In FY19, digitization of learning methods received a significant push with the mobile phone-enabled Learning Management System hosting SOP training and assessments and SocioLogues propagating social learning. An in-house online mentoring and coaching platform and an e-Library to host scientific content are under development.

During the year, we clocked in 79,500 learning hours, a 76% increase over the previous year. Biocon Malaysia also reported an additional 10,000 learning hours. Four high potential employees were nominated to the Global Executive MBA in Pharma Management and another 63 high performing junior executives were upskilled through MPower, a nine-month technical certification program. Close to 800 production and quality employees underwent assessments for pharma-related National Occupational Standards certification under the Pradhan Mantri Kaushal Vikas Yojana and National Skill Development Council.

The 87 employees who began their i-LEAP journey in 2018, were joined by another 96 during the year. Designed under Biocon's Leadership Competency Framework, the learning in the program was strengthened through assessment centers, feedback and individual development plans. Twenty senior women employees also embarked on a leadership journey with a five-day program at the Indian Institute of Management, Bengaluru, followed by in-house mentorship.

At Malaysia, 18 high performing employees underwent training under the myCEKAP program, which has been designed to develop leadership skills among the local talent. The HR team in Malaysia also organized industrial visits to Biocon's facility to expose students there to biotechnology manufacturing systems.

Diversity and Inclusivity

Biocon strongly advocates diversity and inclusion as a key business imperative and inculcates it as a core value. Diversity for us is not just about promoting gender balance, it is about appreciation of different cultures, backgrounds and generations and ideas. The company is committed to promote diversity in the workplace and provide equal opportunity for all employees

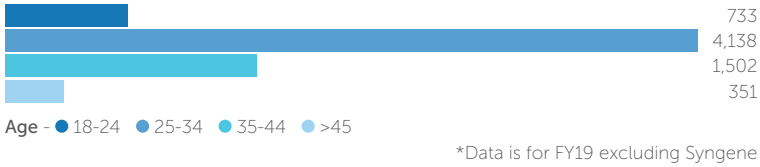
Gender Diversity*

6,724
Total Employees

5,673
Male Employees

1,051
Female Employees

Employee Age Profile*



*Data is for FY19 excluding Syngene

regardless of race, colour, religion, age, gender, sexual orientation, national origin, disability and other factors. We believe that a diverse workplace promotes a culture of innovation and collaboration.

We maintained a healthy gender balance in our workforce and provided both men and women equal opportunities to excel in their careers.

We strengthened our women friendly policies, which included extending maternity leave by an additional 52 weeks and offering part-time opportunities to women returning to work after a career break. We also exclusively offered our women employees programs for maintaining and improving their physical fitness and emotional and mental wellness.

Biocon joined the Indian Women Network, a forum started by the Confederation of Indian Industry (CII), Southern Region, to encourage more women to participate actively in business and society.

Employee Engagement

We believe that an engaging and encouraging environment not only aligns the team to organizational goals and values, but their enhanced sense of own well-being motivates them to deliver their best. In FY19, we rolled out a slew of initiatives to create a welcoming, engaging and conducive work environment.

We supported our crèche with an online management system, which allowed for easier registration of grievances and faster redressal leading to increased use of the facility.

The Biocon Adventure and Sports Club, a platform for our employees to pursue their interests beyond work, witnessed a jump in memberships after it introduced an online platform for event updates and registrations.

A series of health-related initiatives such as the annual employee health check-up, preventive health awareness sessions conducted through the BioPulse wellness initiative and a wellness mobile app encouraged employees to adopt a healthy lifestyle.

Employees showcased their talent through a series of events that culminated in Invivo 2018 marking Biocon's 40th Anniversary. Over 300 people were recognized for their valuable contribution to business through long service awards.

Our g2G (good to GREAT) program, launched in FY18 to transform our work culture and enable us to embark collectively on our next phase of growth, has since become a truly employee-driven initiative.

Performance Management

We are constantly working on improving our performance management program to ensure that merit is recognized and rewarded. This year, we introduced revised focus areas for the top management with shared goal of 'Driving Financial Performance'. To enable effective functioning of individuals and departments in a complex environment, we introduced a matrix structure with dual reporting in Malaysia. We introduced competency-based assessments for first time managers.

Awards

- Gold Award at CLO Summit for Best Corporate University
- Gold Award at CLO Summit for Best Quality Improvement Program
- Anand Kumar M., Senior Director, Biocon received The Great Manager Award in the category 'Drives for Results', presented by People Business Consulting and The Economic Times

SOCIAL

~400,000

Our eLAJ Smart Clinics have recorded nearly 400,000 patient visits since launch.

BIOCON FOUNDATION

Globally, the Corporate Social Responsibility (CSR) concept is evolving from philanthropy to maximizing societal benefits alongside achieving business goals. At Biocon, however, CSR has always gone beyond philanthropy to civic engagement with a special emphasis on socio-economic development of the most disadvantaged sections of society. Our CSR efforts, driven through Biocon Foundation, have often traversed uncharted territory to deliver scalable solutions through innovative and sustainable models.

Biocon Foundation, the Corporate Social Responsibility arm of Biocon, has been working to empower marginalized communities since 2005. We believe our corporate social responsibility lies in creating comprehensive programs that address the myriad developmental challenges facing India through projects in four key thematic areas: healthcare, education, environmental sustainability and rural development.

Healthcare Programs

One of the biggest developmental challenges facing India is to make affordable and quality healthcare available to every citizen. In addition, while the country's burden of non-communicable diseases (NCDs) such as hypertension, diabetes and cancer is escalating, the public health system is struggling to tackle the issues of maternal mortality, premature births, low birth weight babies and stillbirths.

Biocon's healthcare programs are designed to deliver sustainable solutions in the area of basic health, as well as, ensuring early screening, diagnosis and treatment of common cancers and other NCDs.

eLAJ Smart Clinics

Given India's limited healthcare infrastructure, especially in rural areas, Biocon Foundation designed the 'eLAJ Smart Clinic' model. Integrating preventive and outpatient primary healthcare services, these clinics address the issue of healthcare delivery in remote areas of the country, bridge the rural-urban healthcare divide and reduce patient movement to the overburdened secondary and tertiary centres.

At the close of the year, the Foundation was operating 15 eLAJ Smart Clinics at Karnataka's government-run primary health centers (PHCs), apart from the three clinics run exclusively by the Foundation in Bengaluru and its outskirts. We also supported three Rajasthan government-run PHCs to transition from the eLAJ platform to the government's integrated health management system platform this year.

The eLAJ clinics witnessed over 167,000 patient visits and nearly 65,000 registrations during FY19. They have recorded ~400,000 visits since launch.

NCD Clinics

In response to the increasing cases of non-communicable diseases (NCDs) in the communities in which we serve, we have added impetus to the NCD programs across our clinics.

According to National Family Health Survey 4 (2015-16), consumption of tobacco in Nagaland is 69%, which is way above the national average of 44%. The elevated risk of oral cancer because of high tobacco usage in the state led the Foundation to launch a NCD clinic in association with a local health institute and the Government of Nagaland at Medziphema sub-division in Dimapur district.

We also carried out NCD screenings for Bruhat Bengaluru Mahanagara Palike (BBMP) pourakarmikas, or Bengaluru's municipal sanitary workers, who often operate in hazardous working conditions and usually cannot afford a visit to a health center.

The Foundation organizes breast and cervical cancer screening programs to create a responsible health seeking behaviour at the primary level and reduce pressure at the secondary and tertiary centres. We screened ~450 women for breast and cervical cancers this year.

Oral Cancer Screening

The Foundation has developed and executed a mobile phone-based health technology platform to capture data and intra-oral images of patients for recognizing symptoms and signs of oral cancer in high risk groups. In FY19, we conducted oral cancer screenings in collaboration with hospitals run by the South Western Railway in the states of Karnataka, Tamil Nadu and Andhra Pradesh. We conducted over 10,000 oral cancer screenings during the year.

Cancer Task Force

Given that oral cancer ranks among the top three types of cancer in India *(Lancet)*, Biocon Foundation has initiated the formation of an Oral Cancer Task Force comprising seven eminent oncologists from all over India and it has developed guidelines for the management of head & neck cancer in India.

Training Initiatives

On the premise that gynaecologists are the best placed to detect breast and cervical cancer in the early stages, the Government of India is training them to screen such cancers through the primary healthcare system. To support this initiative, Biocon Foundation trained BBMP's gynaecologists on breast and cervical cancer screening in line with the National Institute of Cancer Prevention and Research (NICPR) guidelines.

A new mobile application, which allows two-way communication on oral cancer screening and treatment between frontline health workers and remote specialists, was rolled out during the year.

Cumulatively, we trained ~650 specialists and frontline health workers on screening of common cancers through training sessions and workshops organized in six states and Union territories.

Tackling Malnutrition

To aid the Government of India's efforts at addressing malnutrition, a major cause of child mortality in India, we provide financial aid to the Akshaya Patra Foundation in support of the mid-day meal scheme.

We provided nutritious meals daily to 550 children at government schools in Jigani in the outskirts of Bengaluru and to 1,775 children below five years as well as pregnant women at anganwadis (rural child care centers) in Sangareddy, Telangana.

WASH Initiatives

India faces key challenges of providing its citizens access to clean water, sanitation facilities and eliminating open defaecation. The Government of India has thus pledged to make the country Open Defecation Free (ODF) through the Water and Sanitation Hygiene (WASH) program. In line with the above, the Foundation is setting up multiple community and school sanitary complexes in rural areas.

We installed RO units in 15 Karnataka government schools to provide access to safe drinking water to over 750 students. A community RO water plant in Srirampura village in the outskirts of Bengaluru is benefiting over 2,000 residents.

Education Programs

The Biocon Foundation has developed curriculum, pedagogy and self-directed learning material in Mathematics, English and Kannada for students of Grades 4 to 9 to help enhance their learning. During FY19, workbooks were delivered to over 2.5 million students, under a partnership with the Department of State Educational Research and Training (DSERT), Government of Karnataka. Continuing the DSERT engagement, the Foundation is also facilitating inclusion of adolescent health into the High School Biology curriculum. A Community Radio Program in partnership with Narayana Health, helped bring focus on education and environment.

The Foundation has provided computers to various government institutions for delivering digital literacy programs that benefit over 1,000 students annually.

This year, our employees volunteered to provide career counselling to almost 500 students of Class 9 across four government schools under the Vocational Training and Career Counselling program.

The Foundation also provided a grant to the Institute of Bioinformatics and Applied Biotechnology (IBAB) towards the 'Biocon Chair' to encourage research & training in biotech, bioinformatics and related areas.

Awards

CSR Project of the Year Award under the 'Environment Sustainability' category for the Hebbagodi Lake Rejuvenation Project at the India International CSR Conclave & Awards 2018.

SKILL DEVELOPMENT

500+

More than 500 graduates from Biocon Academy have built careers at leading pharma, biotech companies.

India's biotechnology sector has evolved steadily over the last two decades, placing the country among the top 12 biotechnology destinations in the world. Biotechnology is not just applicable to healthcare solutions, but to finding innovative solutions for improving agricultural yields and food security, as well as, addressing the challenges related to environmental sustainability. To harness the possibilities, the biotechnology industry requires a pool of well-trained scientists and life sciences professionals.

BIOCON ACADEMY

Since 2014, the Biocon Academy has been addressing the wide gap between the quality of human capital available in India and the growing needs of the biotech industry. The Academy, a premier Center of Excellence for Advanced Learning in Applied Biosciences, is developing a high quality talent pool that is industry-ready to enable the biotechnology sector in India remain globally competitive.

Backed by decades of industry experience, Biocon has taken the collaborative route to design unique industry-oriented programs. It has tied up with leading academic institutions

such as the Keck Graduate Institute (KGI), California, BITS, Pilani, and M.S. Ramaiah College, as well as, life sciences companies like Thermo Fisher Scientific and BiOZEEN. Taking forward our commitment to affordability and access, Biocon offers merit scholarships of 60%-75% to all students selected for the Academy's programs.

Over 500 students have graduated from the Academy and have been placed across 50 leading biotech and pharma companies. In FY19, the Academy trained 119 students, including 81 students of the Biocon-KGI Certificate Program in Biosciences and 38 students of the BITS Biocon Certificate Program in Applied Industrial Microbiology. We maintained our record of 100% placement and ensured all the graduating students were placed successfully across 22 companies including Biocon, Syngene and other leading Indian companies. Twenty-eight faculty members from more than 20 universities and colleges across India received training at the Academy under the Biocon Academy Certificate Program in Faculty Development.

Promoting Knowledge Sharing

The Academy sponsored a number of high profile conferences during the year, including an international conference on Chemical and Structural Biology at Chennai; Helix-2018, a students' technical summit, at Bengaluru; and the 4th edition of the Medicinal Chemistry, Drug Discovery & Development India 2019.

Reaching Out to Stakeholders

Our passion to excite life sciences graduates find meaningful career opportunities in biotechnology culminated in the launch of the 'Each One Bring One' campaign, which resulted in our students nominating 15 youngsters to attend classes at the Academy for a day.

We organized student-faculty interactions at over 35 colleges and universities, as well as, launched a monthly e-newsletter, BioZesta, to build awareness about various initiatives of the Academy.

Outlook

The Academy, which currently runs four specialized programs, is continuously looking at ways to align with the growing needs of the global biotech industry through new programs. In FY20, we plan to introduce the Management Program in Biosciences in association with our long-standing partner KGI. We also plan to roll out the Certificate Program in Quality Control Analytical in association with M.S. Ramaiah College and Thermo Fisher Scientific to provide the industry with quality professionals.