Biocon

THE impact MANIFESTO

ANNUAL REPORT 2020

Touching a billion lives through affordable innovation

The **Biocon** Manifesto

We seek to leverage differentiated technologies to transform healthcare by ensuring access to affordable, quality assured, complex therapies that significantly improve patient outcomes and are available to all. Our roadmap for the future is to enable a healthier world.

As a committed stakeholder of the global health agenda under the UN Sustainable Development Goals (SDGs), Biocon has drawn up a manifesto to deliver on its commitment to universal healthcare.

accessibility

- Use our science, scale and expertise to enhance access to essential drugs for patients on the lowest rung of the economic ladder
- Uncover new medical insights aimed at expanding the scope of therapy to address unmet needs

affordability

- Focus on the kind of innovation that adds the condition of affordability to accessibility
- Bring competition for expensive innovator medicines through our generics and biosimilars

availability

- Build strategic global and regional partnerships to make high-quality biopharmaceuticals available to the maximum number of people
- Create a robust portfolio of 'blockbuster' drugs with the potential to benefit a billion patients

assurance

- Demonstrate the highest levels of ethics, compliance and governance
- Assure continuous supply of high-quality products conforming to international regulatory standards

Business Highlights

At Biocon, we have concluded yet another meaningful year, breaking new ground, crossing new milestones and delivering high-quality biopharmaceuticals to millions worldwide.

We made significant headway in the commercialization of multiple products in key markets. We also made strategic investments, brought new partners on board, entered new markets, received regulatory approvals, expanded production capacity, added to our expertise and unlocked value for our stakeholders.

generics

- Crossed an annual revenue milestone of ₹ 20,000 million for the first time
- Extended footprint to China through a licensing deal for 3 Generic Formulations
- Filed new Drug Master Files and equivalents for multiple APIs
- Started construction of a greenfield, fermentation-based manufacturing facility in Andhra Pradesh, India to cater to anticipated growth in APIs business

novel molecules

- Started global clinical trials for our first-in-class oral insulin molecule, Insulin Tregopil, in Type 1 diabetes
- Clinical trials initiated by partner Equillium to study our novel anti-CD6 molecule, Itolizumab, in Lupus Nephritis and severe Asthma
- Started a clinical trial in India to study Itolizumab in treating moderate to severe patients with COVID-19 complications

biologics

- Touched the lives of 2.1 million patients through access to our biosimilars
- Initiated value unlocking of Biocon Biologics through private equity investment for a minority stake, indicating an equity valuation of USD 3 billion
- Committed to enable universal access to rh-Insulin at less than 10 U.S. cents / day in low- and middle-income countries in the run-up to the insulin centenary
- Expanded commercial footprint of key biosimilars: Pegfilgrastim (Australia, Canada), Trastuzumab (U.S., Australia, Canada) and Insulin Glargine (Australia) through our partner Mylan
- Received regulatory clearances from both U.S. and EU regulators for our Insulin Glargine manufacturing facility in Malaysia
- Expanded R&D footprint through the acquisition of R&D capital assets to set up a 60,000 sq. ft. world-class integrated R&D facility in Chennai
- Enhanced production capacity for Drug Substance and Drug Product for key biosimilars through brownfield and greenfield projects

research services

- Commissioned new research facilities in Bengaluru and Hyderabad
- Commenced qualification of API manufacturing facility in Mangaluru
- Extended biologics discovery and preclinical research capabilities in CAR-T therapy, an innovative cell-based approach to treating cancer
- Received Good Laboratory Practice (GLP) certification for viral testing facility from the NGCMA, making it India's first and only GLP-certified viral clearance study service provider
- Repurposed a high-end laboratory to conduct RT-PCR tests for COVID-19
- Partnered with Pune-based Mylab to supply reagents for use in its indigenously developed COVID-19 testing kits

FY20 at a Glance

Revenue
65,286
₹ Million

Profit for the year*
7,482
₹ Million

EBITDA Margin
27
%

R&D Spend (Gross)
5,271
₹ Million

Employees (Total)
12,000+

EPS
6.3
₹

**includes exceptional items*

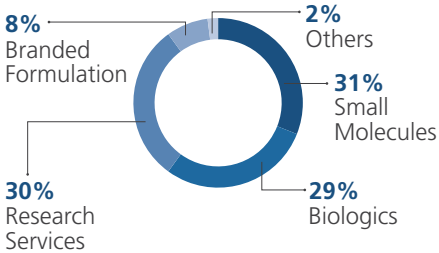
Business revenue mix#

Small Molecules
20,937
₹ Million

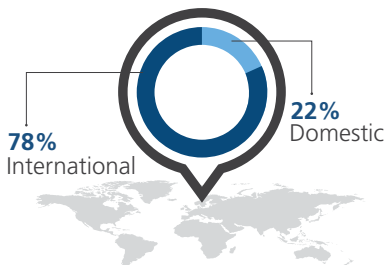
Biologics
19,513
₹ Million

Research Services
20,119
₹ Million

Branded Formulations
5,362
₹ Million



Business Revenue Contribution



Geographic Distribution

#includes inter-segment revenue

Chairperson's Review

Kiran Mazumdar-Shaw
Executive Chairperson

On a mission to **impact a billion lives**

Dear Shareholders,

Biocon's philosophy of affordable innovation to make life-saving medicines accessible to everyone, anywhere on the planet, has never been more relevant than it is today. We are in the throes of a global pandemic and the world is looking up to the healthcare industry to develop vaccines, treatments, diagnostics and products that will see it through the COVID-19 crisis.

The novel coronavirus outbreak has demonstrated that if humanity is to survive as a species, it is imperative that there is equitable access to all essential health products and technologies without distinction of race, religion, political belief and economic or social condition. Universal access to quality healthcare for all is non-negotiable.

In the fight against COVID-19, low- and middle-income countries (LMICs) seem to be faring better than wealthier, better-resourced, developed nations. With this change in dynamics, we are likely to witness greater reciprocity and sharing of best practices between LMICs and high-income countries (HICs) leading to genuine bi-directional partnerships.

As well established business models are dismantled and long-held assumptions dispelled, we could see healthcare being reshaped and democratized around the planet.

The novel coronavirus outbreak has demonstrated that universal access to quality healthcare for all is non-negotiable.

The future will call for a new approach to prevention, screening, diagnosis, therapy, monitoring and management of disease. Demand for therapies that are patient-focused, data-driven and digitally enabled will increase. Patient care will move to non-clinical settings driven by technology and connectivity, even as accelerated adoption of digital therapeutics empowers patients with point-of-care management.

Greater application of Artificial Intelligence (AI) and Machine Learning will make drug discovery and development more innovative, cheaper and faster. Efficient capacity creation and productivity optimization will be critical in the next normal. This will expand the application of medical technology at a pace and scale not witnessed before.

The novel coronavirus has exposed significant shortcomings in public healthcare systems worldwide. In the aftermath of the crisis, citizens will demand better and

more resilient national health systems. This will force governments to explore innovative partnerships with the private sector to address essential healthcare infrastructure, create viable healthcare contingency plans and build strategic reserves of key supplies.

There will be a reprogramming of national economic priorities towards universal healthcare and providing social safety nets for the most vulnerable sections of society.

COVID-19: A potential opportunity for the Indian pharmaceutical industry

The COVID-19 emergency has spurred a re-discovery of India's capabilities in both high-end scientific research and mass production. The Indian healthcare industry swiftly responded to the crisis with innovative and indigenous solutions. Indian companies have also tied up with international vaccine developers to offer their global-scale infrastructure to produce potential COVID-19 vaccines in bulk.

Our Impact Manifesto reinforces our commitment to ensure that everyone, anywhere on the planet, can realize the right to a healthy life.

India is currently the world's third-largest producer of pharmaceuticals in volume terms, supplying to over 200 countries. India also caters to 60% of the world's vaccine demand. The country exported USD 19 billion worth of pharmaceuticals in FY19. With the right kind of policies and incentives, India can reinforce its global standing as a pharmaceutical powerhouse.

As a company led by innovation and global scale manufacturing capacity to take complex generics and biosimilars to the maximum number of people, Biocon is well-positioned for the future.

Having completed a successful 40-year journey, we are now looking ahead to the next four decades. We will use our science, scale and expertise to reduce disparities in **access** to essential drugs, develop innovative solutions to resolve issues of **affordability,** ensure **availability** of our biopharmaceuticals to the maximum number of people and **assure** continuous supplies of quality products while demonstrating the highest levels of ethics, compliance and governance.

Our Impact Manifesto reinforces our commitment to ensure that everyone, anywhere on the planet, can realize the right to a healthy life.

Unlocking universal access to affordable insulin

In the run-up to the 100th anniversary of the discovery of insulin as a treatment for diabetes, we have embarked on a mission to unlock universal access to high-quality insulin guided by the conviction that such an essential therapy needs to be accessible to patients globally.

Our 'Mission 10 cents' coincides with WHO's first-ever insulin pre-qualification program.

More than a 100 million people require insulin therapy for the management of their diabetes — the 'silent pandemic' that currently affects 475 million *(Source: IDF)* people worldwide.

At a time when the world is seeking viable, long-term solutions to improve insulin access and affordability, our 'Mission 10 cents' is offering recombinant human Insulin (rh-Insulin) at less than 10 U.S. cents / day for direct procurement by governments in LMICs, where millions of people cannot access insulin as it is unaffordable. This initiative coincides with WHO's first-ever insulin pre-qualification program. Biocon Biologics is talking to several governments for ways to disintermediate the supply of insulin.

The recent approval of our Insulin Glargine by the U.S. Food and Drug Administration will enable us to serve the needs of patients in the U.S.

Delivering on our commitment in FY20

We reported a robust 15% growth in consolidated revenue at ₹ 65,286 million in FY20. The Small Molecules and Research Services businesses crossed annual revenue milestones of ₹ 20,000 million each, growing by 18% and 10% respectively. On the other hand, the Biologics segment reported annual growth of 29% with revenues at ₹ 19,513 million despite a weak fourth quarter. We ended the year with a Net Profit (before exceptional items) of ₹ 7,600 million, an EBITDA margin of 27% and Net Profit margin of 11%.

Supply chain disruptions, impaired mobility and industry-wide dislocation as a fallout of the COVID-19 pandemic affected parts of our business, with the Biologics business bearing the brunt in the concluding quarter.

Still, Biocon reinforced its reputation of resilience and reliability by continuing to supply life-saving therapies worldwide despite lockdowns and other production and supply chain disruptions due to COVID-19.

Biocon reinforced its reputation of resilience and reliability by continuing to supply life-saving therapies worldwide despite COVID-19-related lockdowns.

An effective business continuity plan allowed us to run essential and critical manufacturing and quality operations with reduced staffing, thus minimizing the impact on patients and partners. At the same time, we prioritized the health and safety of our employees and implemented additional safety measures at our facilities.

United against COVID-19

Meeting our business commitments amid unprecedented challenges did not deter us from contributing to global efforts to tackle COVID-19 through innovative science.

Biocon is repurposing its psoriasis biologic drug ALZUMAb™ (Itolizumab), an anti-CD-6 IgG1 monoclonal antibody, to treat COVID-19. Earlier during the year,

we received the Drugs Controller General of India's approval to conduct a clinical trial in moderate to severe patients with COVID-19 complications. This trial is underway at multiple hospitals in Mumbai and Delhi and we are seeing an encouraging response from patients being treated with Itolizumab.

Our research services subsidiary Syngene has repurposed one of its high-end laboratories to conduct RT-PCR tests for COVID-19, helping scale up the testing capacity in Bengaluru by offering their services for free to government hospitals. Syngene is also working to supply reagents (primers and probes) for COVID-19 diagnostic testing to clients. At the same time, it is collaborating on research projects related to vaccine development, which could represent a longer-term solution for fighting the coronavirus pandemic.

Caring corporate citizen

Going beyond business, we are addressing the needs of the disadvantaged and underserved populations through our Corporate Social Responsibility (CSR) initiatives.

Biocon Foundation touched nearly 230,000 lives in FY20 through various healthcare delivery programs.

Biocon Foundation continues to make consistent long-term impact in improving the public healthcare system through its various programs. **The Foundation touched nearly 230,000 lives in FY20 through its various healthcare programs such as eLAJ smart clinics, NCD clinics and oral cancer screening camps.**

The sustainability ethos at Biocon Foundation drives our efforts to resuscitate Bengaluru's dying lakes. After reviving the Hebbagodi lake, the Foundation has started work on rejuvenating the polluted Yarandahalli lake in the vicinity. Embankment strengthening, fencing and lake de-weeding have been completed. Artificial floating wetlands have also been deployed for continuous natural cleaning of the water and a green belt has been developed around the lake.

The Foundation also responded to the plight of daily wage earners and migrant laborers affected by the economic fallout of the COVID-19 crisis and provided dry ration food kits to thousands of migrants in Bengaluru, Hyderabad and Visakhapatnam. Biocon and its employees also contributed to the PM CARES Fund. The Foundation also contributed additional funds to the Chief Minister's Fund for relief and rehabilitation work in the areas of Karnataka that were worst hit by devastating floods in 2019.

Through Biocon Academy, we are helping upskill life sciences graduate and post-graduate students with world-class training. **In FY20, 120 students successfully graduated from the Academy and found jobs with leading biotech and biopharma companies in India.** Over 20 faculty members from more than 10 universities and colleges across India and Malaysia also received training under the Biocon Academy Certificate Program in Faculty Development.

Management and Board changes

Dr Arun Chandavarkar retired as Chief Executive Officer (CEO) and Joint Managing Director of Biocon in November 2019, after 29 years of outstanding contribution to the evolution and success of the Company. Siddharth Mittal, who was President, Finance and a core member of the leadership team since May 2013, succeeded him. I am confident that as CEO and Managing Director of Biocon Ltd, he will build immense value for Biocon and its stakeholders. Starting April 1, 2020, I have taken on the responsibility of steering the Company as Executive Chairperson for a period of five years.

During the financial year under review, Dr Jeremy Levin resigned as an Independent Director from the Board owing to his expanding commitments in the U.S. and Russell Walls stepped down as an Independent Director on attaining the age of 75 years. We thank both of them for their valuable contribution to the Company.

As the situation improves and spending returns, there will be tremendous opportunity for a ramp-up in generics and biosimilars sales.

Dividend declaration postponed

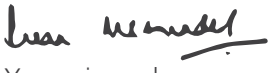
Owing to the uncertainty created by the unprecedented circumstances of the COVID-19 pandemic, the Board of Directors has deemed it prudent not to declare a dividend for FY20 in order to prioritize cash and maintain liquidity. As the business environment evolves over the coming months, the Board will review the proposal for dividend as appropriate for FY21.

Looking ahead

Spending on medicines across the globe for non-COVID diseases has been reprioritized with healthcare systems strained due to the pandemic. As the situation improves and spending returns, there will be a tremendous opportunity for a ramp-up in generics and biosimilars sales. **Our differentiated offerings across segments position us well to make a significant impact in a post-COVID world.**

Finally, I would like to thank our esteemed shareholders, partners and other stakeholders for putting their faith in us. We are confident of emerging stronger together from this global crisis.

Thank You.



Yours sincerely,
Kiran Mazumdar-Shaw
Executive Chairperson
June 15, 2020

Biocon Biologics
Transforming Healthcare. Transforming Lives.

Our Biosimilars **Business**

Our Vision

Most inspiring global leader in Biologics delivering affordable access to innovative and inclusive healthcare solutions, transforming patient lives.

Biocon Biologics
Impact Manifesto

As a fully integrated, pure-play biosimilars organization, we hold a unique position globally. It is time to transform patient lives by delivering affordable access to innovative and inclusive healthcare solutions.

inspire

- Pursue the mission of delivering world-class quality products to millions of patients globally
- Be recognized as a 'partner with a purpose' for global healthcare systems by significantly reducing their healthcare spends
- Create universal access to high-quality insulin nearly 100 years post its development by providing rh-Insulin at less than 10 U.S. cents per day in low- and middle-income countries
- Leverage a technology-enabled operating model to address unmet patient needs going beyond the product in various healthcare archetypes

innovate

- Create a culture of constant innovation where our people are willing and able to contribute their slice of genius, inspired by a clear sense of purpose
- Leverage cutting-edge science, innovative tech platforms and our research & development capabilities to lower treatment costs while improving healthcare outcomes
- Lead the transformation of patient ecosystems in collaboration with partners and disruptive operating models
- Unleash the power of technology to improve the quality of performance, increase efficiency and enable highest levels of quality compliance

invest

- Platform of 28 biosimilar molecules across diabetes, oncology, immunology, dermatology, ophthalmology, neurology, rheumatology and inflammatory diseases
- Capacity enhancement to support product pipeline and meet expanding global demand
- Pairing of our products with technologies that address the healthcare needs across archetypes of healthcare systems

include

- Widen access to high-quality biosimilars, reduce healthcare disparities and achieve 'access for all'
- Build on our scale and cost of production advantages and take a leadership position in most of the world (MoW) markets
- Aspire to reach 'one in five' insulin-dependent people with diabetes worldwide through our 'Mission 10 cents' aimed at LMICs

impact

- Touch 5 million patient lives by FY22
- Aim to reach a revenue milestone of USD 1 billion in FY22
- Be a global leader in delivering high-quality and low-cost biosimilars across the world

Our Biosimilars Business

Executive Leadership Team

Healthcare systems across the world are skewed towards serving the affluent, denying access to many. **We are challenging the status quo by putting 'patients first' 'followed by profits' to make a long-term social impact. Biocon Biologics is co-creating a future that allows access to complex therapies for all.** We believe meaningful change cannot limit itself to the one, or to the few. It must impact the many. The bedrock of this change is a culture of 'collective genius', where each one of us is 'willing' and 'able' to innovate, holding ourselves to the highest standards of ethics and compliance. Our relentless desire to make a real difference pushes us to redefine innovation and build a disruptive business model that lowers treatment costs and improves healthcare outcomes, whilst delivering on shareholder value and our business objectives.

It's TIME

To **bring affordable innovation to many**

To **deliver USD 1 billion in FY 22**

Dr Christiane Hamacher
CEO and Managing Director

To **challenge the status quo**

Dr Gaurav Laroia
Chief Strategy Officer & Head of Business Development

To **redefine innovation**

Dr Gopala Krishna Dasika
Head of R&D

To go **beyond delivering financial results**

Chinappa M.B.
Chief Financial Officer

To **redefine healthcare delivery**

Dr Sandeep Nilkanth Athalye
Head of Clinical Development & Medical Affairs

To **serve millions of patients**

Fionnuala Doyle
Head of Regions

To **partner** for **disruptive solutions**

Paul Vazhayil Thomas
Chief Commercial Officer, U.S.

To create a **sustainable operating model**

Shreehas P Tambe
Chief Operating Officer

To create a **culture** of **continuous innovation**

Seema Ahuja
Global Head of Communications and Corporate Brand

To **give back** and make a **long-term social impact**

Sigrid Martina Koeth
Chief of Staff

To leverage the **collective genius** of all our people

Preeti Kalra
Head of People & Organization Effectiveness

To instill **uncompromising ethics and compliance**

Akhilesh Nand
General Counsel & Chief of Governance, Risk & Compliance

To **lead with a purpose**

Dr Sundar Ramanan
Global Head of Regulatory Affairs

To ensure **world class product quality**

Thibaud Du Merle
Head of Quality

To provide **access for all**

Dr Alexander Zach
Head of Market Access & Policy

To be a **partner 'with a purpose'** across stakeholders

Peter Meeus
Head of Commercial Product & Portfolio Strategy

Dr Christiane Hamacher
CEO and Managing Director
Biocon Biologics

Biocon Biologics aspires to co-create with its stakeholders a patient ecosystem that goes beyond the product to transform the lives of millions of patients globally. It's time to leverage new operating models that facilitate access to life-saving therapies for all. As a global company focused exclusively on biosimilars with full vertical integration, we are uniquely positioned to achieve this ambition. Our 40-year legacy of being on the cutting edge of science has enabled us to simultaneously build global scale with a competitive cost structure.

We have one of the broadest and deepest biosimilars platforms in the industry and many firsts to our credit, including the first U.S. FDA approval for a biosimilar Trastuzumab. The latest U.S. FDA approval of our Insulin Glargine* paves the way for its launch in the U.S. later this year.*

Our culture of continuous innovation supports our agility as we evolve to meet the changing market needs over the next decade. We will continue to innovate and shape the biosimilars market to serve the unmet needs of healthcare systems globally.

*Partnered with Mylan

Our Biosimilar Business

Expanding access through innovative, **inclusive healthcare solutions**

During FY20, we worked towards building Biocon Biologics into the most inspiring global leader in biologics. Our strong foundation, which rests on 40 years of experience in innovative science, clinical development, global-scale biopharma manufacturing, as well as, our experience of navigating an evolving biosimilars regulatory landscape, gives us the confidence to build our business further on the four pillars of Patients, People, Partners and Business.

Our exceptional scientific talent pool and world class R&D infrastructure for developing and manufacturing complex biosimilars together with the commercialization strengths of our partners, position us well to be a global leader in the biosimilars space over the long term. As we move ahead, we are confident of capitalizing on the new global opportunities. We have set ourselves a target of impacting 5 million patient lives and attaining a revenue milestone of USD 1 billion in FY22.

Patients

Patients are at the center of everything we do at Biocon Biologics. During the year, we moved forward on our journey towards delivering affordable access, innovative and inclusive healthcare solutions, and transforming patient lives.

At a time when the world is seeking viable, long-term solutions to improve insulin access and affordability, Biocon Biologics came forward with its **'Mission 10 cents'.** We offered our recombinant human Insulin (rh-Insulin) at less than 10 U.S. cents / day for direct procurement by governments in low- and middle-income countries (LMICs), where high prices keep it out of the reach of millions of patients with diabetes.

The announcement, made in September 2019 at a UNAIDS Health Innovation Exchange event held on the sidelines of the 74th session of the UN General Assembly in New York, was welcomed by UNAIDS.

Biocon Biologics is now engaging with several governments to explore ways to disintermediate the supply of insulin and ensure that insulin pricing is not a constraint to the well-being of individuals and of communities.

We are collaborating with several international organizations, including International Diabetes Foundation, PATH, NCD Coalition and MedAccess to establish Biocon Biologics as a responsible global leader in diabetes management.

At the same time, we are also working closely with the Union for International Cancer Control (UICC) to support cancer societies with the value of affordable biosimilars.

Simultaneously, we are engaging with therapeutic area experts, physicians, scientists, educators, healthcare professionals, government representatives and policymakers, to take forward our 'Mission 10 cents'.

Our efforts to unlock affordable access to insulin received a boost when WHO launched its first-ever insulin prequalification program to increase treatment for diabetes in LMICs.

As a committed global biologics player, we are leveraging our science, scale and expertise to shift the access paradigm for patients in need of biosimilars across the globe.

Policy shaping

We advocated globally to shape policies such that they ultimately benefit patients.

In May 2019, Biocon Biologics presented at the U.S. Food and Drug Administration's (FDA) public hearing to facilitate the development of insulin biosimilars and other interchangeable insulin products to address the soaring cost of these life-saving medications for people with diabetes in the U.S. We advocated for a patient-first, science-based regulatory pathway to approve biosimilar insulins. As insulins are simple proteins, we argued that regulatory requirements should be proportional to the complexity of the molecules.

Subsequently, the U.S. FDA released a draft guidance on Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products. The FDA has updated their thinking, in that for some insulin products (when a sponsor demonstrates high similarity with state-of-the-art technology, demonstrating little or no residual uncertainty), there will be no need to conduct a comparative clinical immunogenicity study for interchangeability, which we interpret to mean that there is no need for Phase III clinical trials.

The new policy could help accelerate insulin development programs, ultimately bringing biosimilar insulin products to the market more quickly and benefiting patients.

People

Biocon Biologics recognizes that when we bring together the strengths of our people we can deliver extraordinary outcomes. In pursuit of our mission of global leadership in biosimilars, we are creating an organization-wide, performance-driven culture wherein every individual and each team will understand the long-term vision and align their efforts to it. The human-centered nature of our approach led us to launch Mission 11.5.1, emphasizing on the organization's journey towards touching 5 million patient lives globally, powered by 11 key strategic initiatives enabling us to clock revenues of USD 1 billion by FY22.

Combining the unique strengths of each individual employee has led to the creation of high-performing innovation teams, which are driving the initiatives needed to achieve the vision of 'Transforming Healthcare, Transforming Lives'.

Partners

Biocon Biologics has built strategic global and regional partnerships of a symbiotic nature that have allowed us to share risks, lower costs, maximize efficiencies, expedite development and commercialize products in various global markets. Through our strong network of partners, we continue to expand affordable access to biopharmaceuticals and make an enduring impact on global health.

During the year, Biocon Biologics in-licensed an early-stage preclinical biosimilar asset from Just - Evotec Biologics, a subsidiary of Evotec SE, and will develop, manufacture and commercialize the biosimilar under the Biocon Biologics label in global markets. Just - Evotec received an undisclosed license fee and will receive milestone payments.

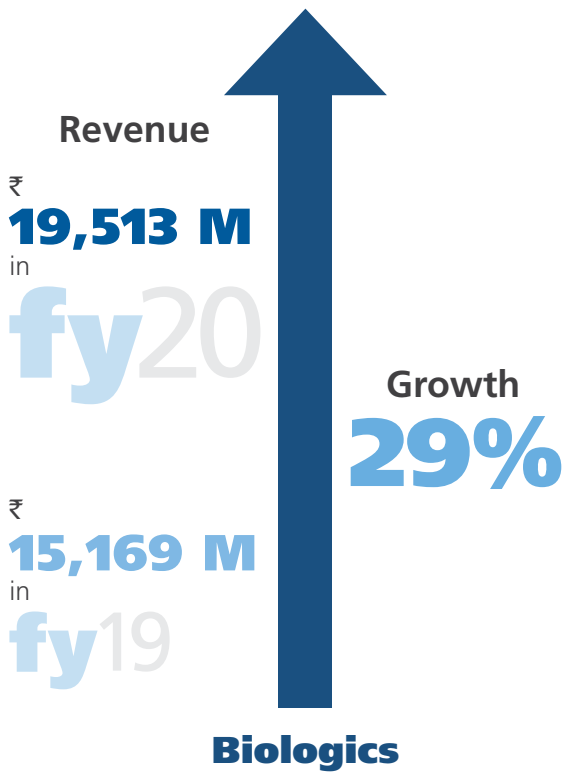
During FY20, our partner Mylan has extended the commercialization rights for in-licensed Hulio™ (biosimilar Adalimumab) from Europe to global markets. Under the terms of our global partnership with Mylan for monoclonal antibodies, we retain an economic interest in this expanded in-licensing arrangement and will gain a share of profits from global markets.

Business

The Biologics business ended FY20 on a strong note, reporting a 29% growth in revenue at ₹ 19,513 million. During the year, we extended our global footprint with the commercialization of some of our key biosimilars coupled with regulatory approvals in developed and most of the world (MoW) markets.

We also enhanced R&D capabilities, expanded manufacturing capacity for our key biosimilars and broadened collaborations to enlarge our biosimilars portfolio.

Strong financial performance



Mission 11.5.1

11 strategic initiatives

5 Million patients

1 Billion USD $ revenue

by FY 2022

Strategic initiatives

Biocon Biologics' vision of transforming healthcare and transforming patient lives is fuelled by 11 key strategic initiatives which will drive the organization to bring Mission 11.5.1 to fruition.

1. Creating a patient ecosystem
2. Broaden access and accelerate funding
3. Living patient centricity
4. Integrating core values into the business
5. Culture of continuous innovation - 'collective genius'
6. Strength-based people development
7. a. Evolving the commercialization model - MoW
   b. Evolving the commercialization model - U.S.
8. Development of product portfolio, capacity, and capability enhancement
   a. COGS reduction and capacity optimization
   b. Accelerate portfolio
   c. Build and enhance pipeline
9. a. Business assurance
   b. Increase in efficiency
10. A strong Biocon Biologics global brand
11. Digitization evolving to digital innovation

1. Creating a patient ecosystem
Reimagining the patient ecosystem by developing a technology-dependent operating model that enables personalization of care, thus going beyond the product to reduce both the cost of the drug as well as the cost of administering the drug.

2. Broaden access & accelerate funding
Disintermediating the value chain, policy shaping through engagement with key stakeholders and finding alternative financing models to broaden access to our high-quality biosimilars in most of the world countries as well as in the developed world.

3. Living patient centricity
Keeping patients at the core of our business by gathering insights from them through digitally enabled platforms and then leveraging data science to integrate these insights into our development programs enabling us to design a service or solution around the patient.

4. Integrating core values into the business
Defining and embedding core values that support, sustain and promote our culture of continuous innovation throughout the organization through constant communication and role modeling.

5. Culture of continuous innovation – 'Collective Genius'
Creating extraordinary outcomes by encouraging a culture of collective genius where everyone's slice of genius is respected and valued, making them both willing and able to innovate.

6. Strength-based people development
Adopting a strengths-based approach that fosters inclusion and diversity of thought that are critical for innovation to occur.

7. Evolving commercialization model : U.S. & MoW
Driving profitable revenue expansion from new geographies and new assets, while optimizing existing market presence by increasing market share profitably and reaching more patients in the process.

8. Development of product portfolio, capacity & capability enhancement
Focus on innovation in manufacturing and supply chain to optimize manufacturing capacity and improve productivity by reducing cost of goods sold (COGS). Accelerate product launches to secure a 'first mover advantage' via shorter clinical studies and accelerated regulatory approvals. Improve our price competitiveness and reach many more patients by effectively managing our production costs.

9. Business assurance and increase in efficiency
Identify, develop & operationalize processes at par with global best practices ensuring business continuity, while retaining risk taking agility. We are in the process of establishing a world class ethics, compliance and corporate audit program. We are also identifying & remedying process inefficiencies across the three functional areas of R&D, manufacturing and warehousing & logistics.

10. A strong Biocon Biologics global brand
Building Brand Biocon Biologics as an innovative, and most importantly, trustworthy global brand that resonates with our vision to transform healthcare and impact millions of patients' lives globally. Also, position it as a preferred employer that provides a sense of purpose to its employees.

11. Digitization evolving to digital innovation
Focus on enhancing patient experience, employee engagement, compliance and operational excellence by leveraging best-in-class digitalization. Use digital innovation in manufacturing and supply chain to gain real-time control all the way from procurement to patient. Going ahead, we plan to build a AI-powered technology-dependent operating model.

Product launches

Biocon Biologics became the first company from India to have two biosimilars in the U.S. through its partner Mylan, with **Ogivri™** (biosimilar Trastuzumab) being commercialized in the market in end 2019 and **Fulphila®** (biosimilar Pegfilgrastim) in 2018. Patients suffering from HER2-positive breast cancer in Australia, Canada and a few European countries also received access to this critical biologic therapy after Mylan's launch of Ogivri in those markets in FY20.

In the U.S., Ogivri's share of the biosimilar Trastuzumab market is showing a gradual uptake. Ogivri has reported a significant market share improvement in several European countries, as well as, meaningful traction in Australia and Canada.

In Latin America, we hold registrations for our biosimilar Trastuzumab in over 10 countries and during FY20 we commercialized it in many of these markets.

Fulphila, our high-quality, affordable biosimilar Pegfilgrastim co-developed with Mylan, was commercialized in Australia and Canada this year. In these two countries, the potential market Fulphila can address is estimated to be USD 74 million *(Source: IQVIA).*

In the U.S., Fulphila's market share has been stable as the underlying market demand from hospitals and clinics has been consistent.

We commercialized **Semglee®**, our biosimilar Insulin Glargine co-developed with Mylan, for the benefit of insulin-dependent diabetes patients in Australia and a couple of European countries in FY20.

We are seeing encouraging market penetration for Semglee in certain parts of Europe, and our partner Mylan will build on this experience to spread to other countries.

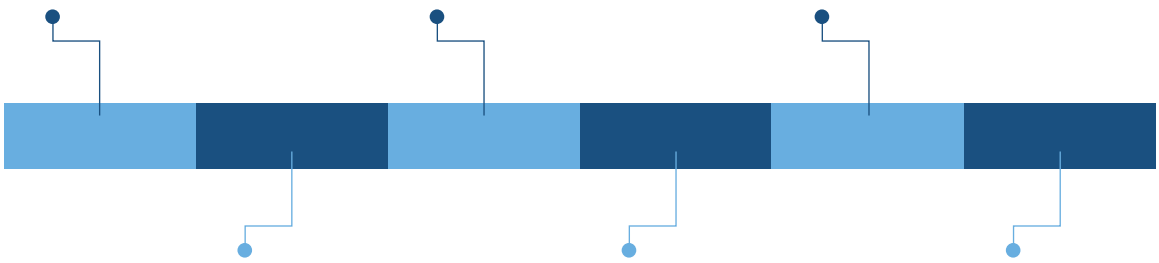
Mylan extended the commercial footprint for **Hulio®** to additional markets in Europe during FY20, and Biocon Biologics benefited from higher sales and market shares of the product across key markets.

Steady stream of biosimilar launches in developed markets till FY25^

FY20
Trastuzumab*: U.S., EU, Australia, Canada
Adalimumab@: EU
Insulin Glargine*: Australia

FY21
Bevacizumab*: U.S.
Insulin Glargine*: U.S.
Pegfilgrastim*: EU
Etanercept@: EU

FY22
Insulin Aspart*: U.S., EU
Recombinant Human Insulin#: U.S.
Bevacizumab*: EU



FY23
Undisclosed: U.S., EU

FY24
Adalimumab@: U.S.

FY25
Undisclosed: U.S.
Undisclosed: U.S.

^The launch timelines are estimates of Biocon Biologics subject to potential risks & delays
**Partnered with Mylan #*Acceleration options linked to recent U.S. FDA guidance are under review
@Partner Mylan has in-licensed product, Biocon Biologics continues to have economic benefit

Product filings and approvals

We have one of the broadest and deepest pipelines in the industry straddling insulins, monoclonal antibodies and recombinant proteins in a portfolio targeting diabetes, autoimmune diseases and oncology in various presentation formats, including devices for self-administration. Until now, five molecules from our portfolio of 28 have been commercialized globally (Trastuzumab, Pegfilgrastim, Glargine, rh-Insulin, Bevacizumab). During FY20, we gained additional approvals for some of these five biosimilars across North America, Latin America, CIS, Middle East & North Africa, Asia-Pacific, South Asia and EU regions.

We are on track with the development of Insulin Aspart. We have filed the Marketing Authorization Application for the molecule in the EU, where it is currently under review.

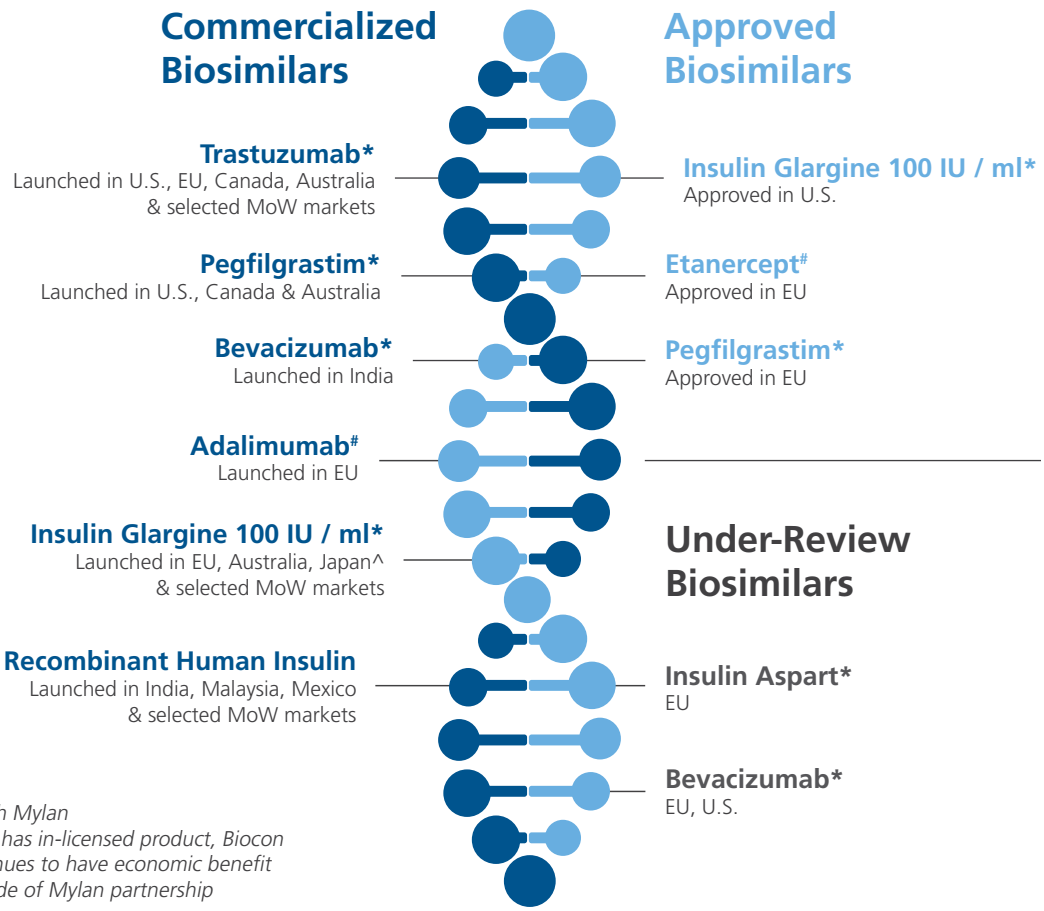
We continue to work with the U.S. FDA on the development of rh-Insulin for the U.S., taking into account the draft guidance for insulin biosimilars under the 351(k) pathway.

In addition, we expect Mylan to launch biosimilar Etanercept in Europe in the second half of CY20. Biocon has shared economics in this program.

On the monoclonal antibodies front, the Biologics License Application (BLA) filed by Mylan for biosimilar Bevacizumab is currently under review by both the U.S. FDA and European Medicines Agency.

At the end of FY20, we had approvals for our biosimilar Trastuzumab in 60 countries, Pegfilgrastim in 36 countries, Bevacizumab in two countries, Insulin Glargine in 60 countries and rh-Insulin in over 40 countries.

Major global biosimilars player



**Partnered with Mylan*
#Partner Mylan has in-licensed product, Biocon Biologics continues to have economic benefit
^Japan is outside of Mylan partnership

U.S. FDA approves our Insulin Glargine

In June 2020, the U.S. FDA approved our partner Mylan's New Drug Application (NDA) for Semglee under the 505(b)(2) NDA pathway. Semglee is now deemed a biologic under section 351(a) with approval for vial and pre-filled pen presentation to control high blood sugar in adults with Type 2 diabetes as well as adult and pediatric patients with Type 1 diabetes.

The approval of our Insulin Glargine by the U.S. FDA marks the culmination of a long journey. As an organization committed to making insulin-based therapy increasingly accessible for people with diabetes globally, this approval will enable us to serve the needs of patients in the U.S., where millions of patients need more affordable insulin analogs to control their diabetes.

Globally, Insulin Glargine represents an opportunity of over USD 6 billion. Sanofi's total IQVIA sales for the 12 months ending April 30, 2020 were approximately USD 1.68 billion for Lantus 100 Units/mL Vial and approximately USD 4.33 billion for Lantus SoloSTAR Pen.

Along with Mylan, we also continue to be engaged in active discussions with the FDA on a viable pathway to obtain an interchangeable designation.

Capacity expansion

Biocon Biologics' key strengths is its reliability in supplying high-quality products to patients globally. We have adequate manufacturing capacity to support our market share projections in all geographies. We have continued to make steady investments in manufacturing capacity as our products make further inroads in markets globally expanding access to high-quality biosimilars. These investments will also enable the development and launch of the next wave of biosimilars from our rich pipeline.

Towards the end of FY20, we commissioned our new state-of-the-art biologics drug substance facility, which will enhance our manufacturing capacity for monoclonal antibodies manifold and improve our ability to serve many more patients across the globe. We expect this facility to begin commercial operations in early FY22, subject to regulatory approvals in various markets.

During this fiscal, we also expanded our manufacturing capacity for Pegfilgrastim drug substance. This new manufacturing facility in Bengaluru received U.S. FDA approval in November 2019 and has started commercial operations since. This facility was also inspected and approved by the European Medicines Agency (EMA). We upgraded our Drug Product manufacturing capacity substantially with the commercialization of a new sterile injectables facility. This new aseptic processing unit enhances our liquid and lyophilized vial capacity and was inspected and approved by several global regulatory agencies including ANVISA, EMA and U.S. FDA to list a few.

Our state-of-the-art Insulins manufacturing facility in Malaysia has been serving patients over the past four years. This facility, hosted multiple regulatory inspections successfully during FY20 and received EU GMP certification. The facility also successfully closed a U.S. FDA inspection enabling the supply of our rh-Insulin and Insulin Glargine to various markets.

These approvals enhance Biocon Biologics' capability multi-fold and will enable us to take our biosimilars to more patients worldwide.

We also expanded our R&D footprint in the quarter by acquiring Pfizer Healthcare India Ltd.'s R&D capital assets to set up a 60,000 sq. ft. world-class integrated R&D facility at TICEL Bio Park in Chennai. The high-end facility will enable Biocon Biologics to expand its R&D capability and fast-forward development of its biosimilars from lab to pilot scale. Post qualification, the facility will house over 250 scientists.

New state-of-the-art biologics drug substance facility for monoclonal antibodies, Biocon Park

Our Branded Formulations Business

Offering patients high quality, differentiated therapies

Biocon's Branded Formulations business is making an impact in India through its wide portfolio of branded small molecule generics, biosimilars and novel biologics in the chronic disease segments of diabetes, cancer, end-stage renal illnesses, immune disorders and other life-threatening conditions.

Segmental revenue at ₹ 5,362 million, which contributed 8% to FY20 consolidated revenue, declined 18% primarily due to significant downward pricing pressures in our leading assets and increased competition for some of our key brands in India. Supply issues and COVID-19-related disruptions at the end of the year further compounded these challenges. The positive performance of the Nephrology, Immunotherapy and Critical Care divisions of the India business was offset by pressure in Metabolics, Oncology and Market Access divisions.

Our Branded Formulations team rose to the challenges thrown by the COVID-19 pandemic and the consequent lockdown in India. To minimise disruption during the crisis, we adopted innovative ways to support physicians and ensure that patients continued to receive our life-saving medicines, including insulin and cancer therapies.

We set up helplines for patients and our field staff worked diligently during the lockdown to facilitate medicine supplies to far-flung areas ensuring the well-being of patients who rely on Biocon's products.

Top brands continue to shine

Among our flagship brands, Insugen® continued to hold its position among the Top 3 human insulin brands in India while Basalog® was the No. 2 brand of Insulin Glargine in the country. CANMAb™ retained its position as the No.1 brand of biosimilar Trastuzumab in India, giving us a firm foothold in Oncotherapeutics.

The Branded Formulations business further built on the considerable brand equity it enjoys with doctors and patients by highlighting Biocon's strengths in cutting-edge science. We shared the results of Biocon Biologics' landmark INSTRIDE-3 study for biosimilar Insulin Glargine among the medical community. The remarkable outcome about the interchangeability of our biosimilar Insulin Glargine with that of the reference product was communicated to thousands of healthcare professional across the country through a series of webinars as well as on-ground SWITCH campaign.

Digital push

During the lockdown, the Branded Formulations team switched to a technology-enabled digital operations model. Webinars, e-detailing, video-based marketing and social media outreach replaced traditional methods of reaching out to customers.

The team is preparing to adopt digital outreach as the new normal. It is gearing up to use new communication platforms with a firm focus on Patients, People, Partners and Business.

Outlook

The COVID-19 pandemic has given us an even larger opportunity to shape the global biosimilar landscape. Healthcare systems worldwide will be compelled to leverage both generics and biosimilars to contain medical costs. As a fully integrated, 'pure play' global biosimilars company, Biocon Biologics has the scientific expertise and manufacturing scale to deliver complex biosimilars to patients across the globe. Our strong portfolio of in-market and in-development biosimilars covering oncology, diabetes & immunology and other therapeutic areas, offer one of the industry's largest and most diverse global biosimilars pipelines.

At the same time, all regions are showing strong promise with high single- to strong double-digit growth underlining the tremendous potential that biosimilars offer.

The total global market of all biosimilar monoclonal antibodies and therapeutic proteins is anticipated to grow from ~USD 25 billion today to USD 55 billion in 2025 *(Source: IQVIA data and the Company's analysis).*

We target to have at least eight of our biosimilars available in developed markets through our partner by the end of FY22 viz. Trastuzumab, Pegfilgrastim, Adalimumab, Bevacizumab, Etanercept, Insulin Glargine, Insulin Aspart and rh-Insulin^, addressing an estimated market opportunity of up to USD 33 billion*. Our pipeline is expected to deliver three molecules between FY23 and FY25. We are currently focused on developed markets such as U.S., Europe, Australia, Canada and Japan through strong partners, but are also preparing to tap the opportunity from the rapid rise in demand for biosimilars in rest of the world markets. We already have a presence in the majority of the Top 20 markets, and we plan to expand our geographic footprint even further.

**Combined annual sales of originator brands*
^rh-Insulin is outside of Mylan partnership

Value unlocking of the Biosimilars business

An important development during the financial year was the investment of USD 75 million by Activ Pine LLP, an affiliate of True North Fund, in Biocon Biologics. This was a primary equity infusion for a 2.44% stake at an equity valuation of USD 3 billion and an enterprise valuation of USD 3.5 billion on a pre-money basis.

The pre-money equity valuation of Biocon Biologics by True North, which has an investment focus on the Healthcare and Life Sciences sector, reflects the market's confidence in our current business and future prospects.

The equity infusion by True North will enable expansion of our R&D and manufacturing capabilities to meet the growing demands of patients worldwide. It will fuel the future growth of the business as we pursue our mission to establish Biocon Biologics as a leading global player in biosimilars.