Biocon

Unwavering Purpose

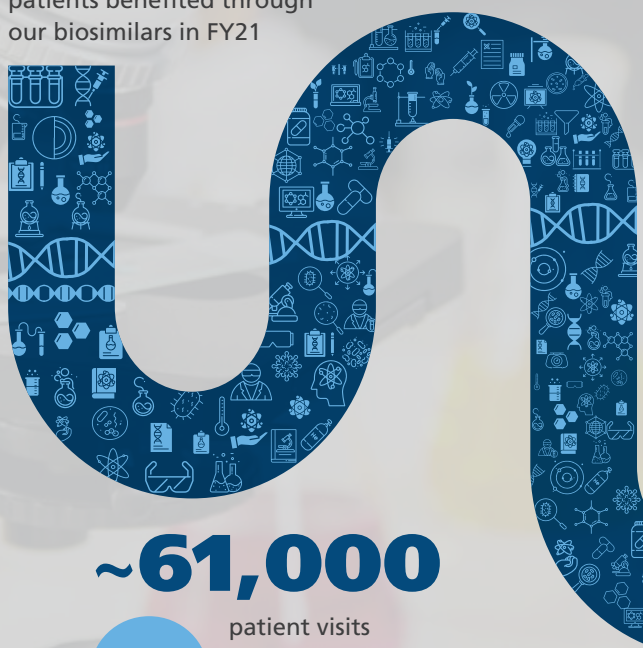
Annual Report 2021

Unparalleled Impact

During FY21, we achieved several milestones on the journey of making a meaningful impact to patient lives globally. Our actions helped ensure better patient care and improved treatment outcomes while reducing costs for wider access to affordable, quality assured, complex therapies. We contributed to national and international efforts to tackle COVID-19 through innovative science and repurposed one of our novel drugs to save the lives of COVID-19 patients suffering from moderate to severe complications in India. We also supported the government and the community in the fight against the coronavirus by using our domain knowledge and capabilities. Moreover, we worked on finding innovative healthcare solutions that go beyond therapies to provide a holistic patient experience.

~3.1[#] Million

patients benefited through our biosimilars in FY21



~61,000

patient visits recorded at Biocon Foundation-run eLAJ smart clinics in FY21

[#]Patient reach numbers are Company estimates based on volumes supplied and standard dosage.

~2.75* **Billion**

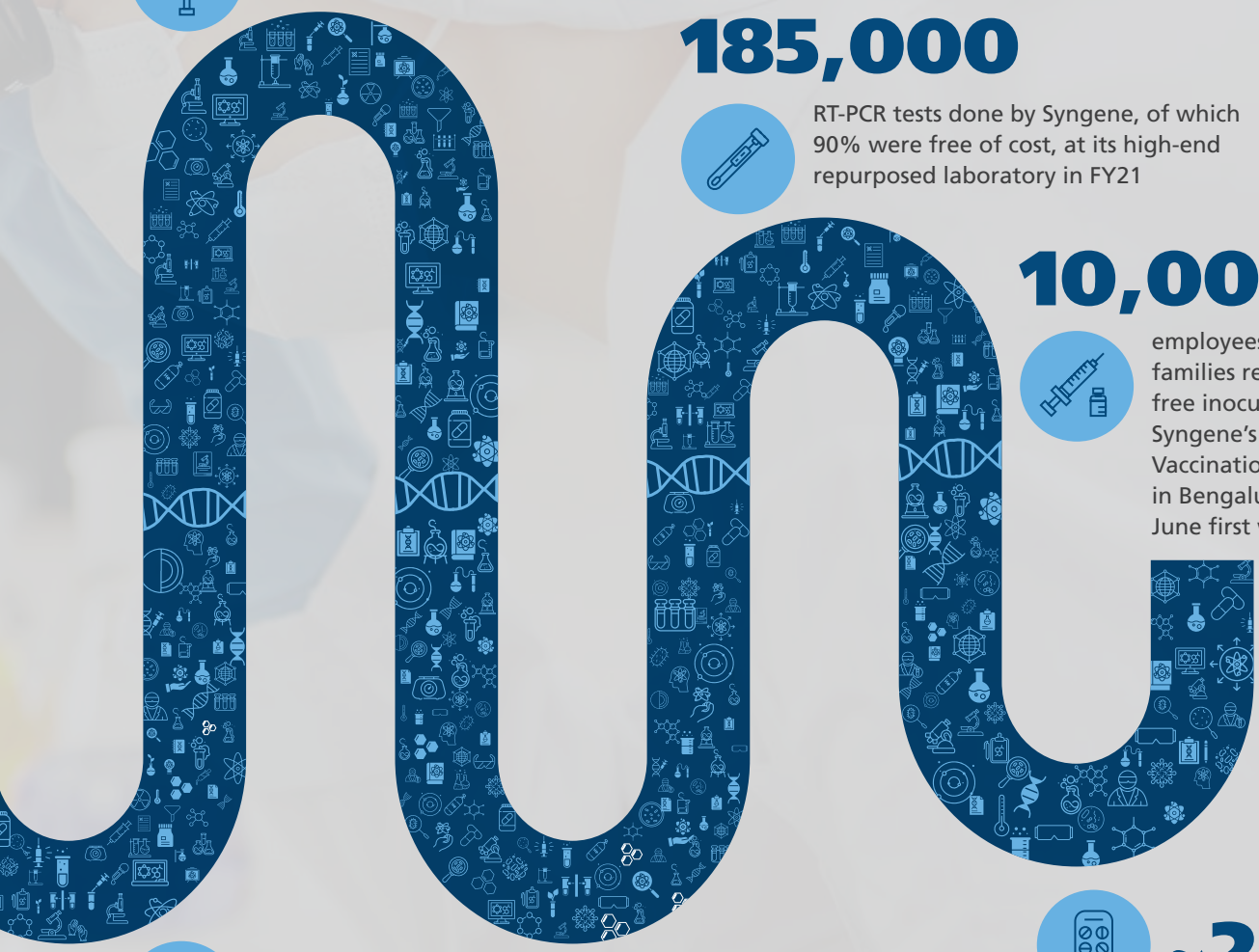
doses of recombinant human insulin supplied globally since 2004

185,000

RT-PCR tests done by Syngene, of which 90% were free of cost, at its high-end repurposed laboratory in FY21

10,000+

employees and their families received free inoculations at Syngene's COVID-19 Vaccination Center in Bengaluru till June first week



5th

rank on prestigious Global Biotech Employers 2020 rankings by U.S.-based Science Careers magazine

27,000+

COVID-19 patients benefited through our repurposed novel biologic Itolizumab till May 2021

~2 Billion

statin pills delivered for the benefit of patients in the U.S. in FY21

**Estimated doses calculated on the basis of drug substance, drug product sales data.*

FY21 At a Glance

Revenue
73,603
₹ Million

Profit for the year*
7,405
₹ Million

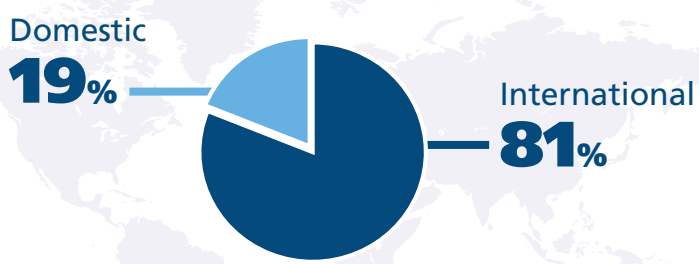
EBITDA Margin
26 %

EPS
6.2
₹

R&D Spend (Gross)
6,270
₹ Million

Employees (TOTAL)
13,500+

Geographic Distribution



Our international revenue contribution grew to 81% in FY21 from 78% in FY20.

* Includes exceptional items and loss from discontinuing operations
\# Includes inter-segment revenue

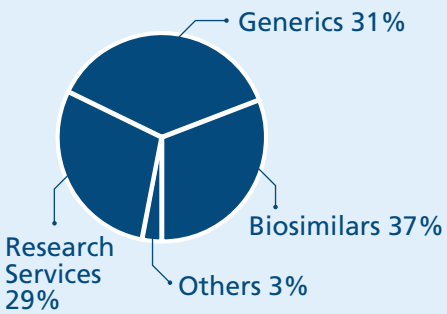
Business Segment Revenue#

Generics
23,359 ₹ Million
6% Growth

Biosimilars
28,002 ₹ Million
21% Growth

Research Services
21,843 ₹ Million
9% Growth

Business Segment Revenue Contribution



FY21 Business Highlights

Undeterred Endeavor

While we took on the pandemic head-on by ramping up drug innovation and production, we remained undeterred in our endeavor to deliver on our commitment to our patients, partners and customers across the world.

GENERICS

- Launched Tacrolimus capsules, Biocon's first immunosuppressant formulation in the U.S., for the benefit of organ transplant patients.
- Received U.S. FDA approval for Everolimus (gAfinitor), an immunosuppressant formulation to prevent rejection of organ transplants, and treat renal cell cancer and other tumors.
- Entered into a partnership with Libbs Farmaceutica, marking the entry of Biocon's Generic Formulations into Latin America, starting with Brazil.
- Partnered with DKSH to expand access to Biocon's Generic Formulations portfolio in key South East Asian markets of Singapore and Thailand.
- Continued to build our Generic Formulations portfolio through new regulatory filings in the U.S., EU and Most of World markets.
- Received a GMP compliance certificate from MHRA, UK, for Generic Formulations manufacturing facility at Biocon Park in Bengaluru.

COVID-19

- Repurposed an in-market novel biologic drug, Itolizumab, to treat COVID-19 patients. 27,000+ patients benefited from the drug.
- Offered a comprehensive portfolio of products for COVID-19 patients – Itolizumab (*ALZUMAb-L*), *CytoSorb*, Remdesivir (*RemWin*) and Favipiravir (*ARAFLU*).
- An ELISA antibody testing kit developed by Syngene enabled efficient, reliable and scalable testing.
- Several novel, high-affinity monoclonal antibody assets developed by Syngene to combat SARS-CoV-2 infection.
- Syngene was a co-recipient of BIRAC grant to discover measles virosome-based COVID-19 vaccine.

NOVEL BIOLOGICS

- Obtained the Drugs Controller General of India's approval for *ALZUMAb-L*, a new 100 mg/vial formulation of Itolizumab, for treating moderate to severe COVID-19 complications.
- U.S. partner Equillium reported encouraging developments on clinical advancement of Itolizumab in treating acute graft-versus-host disease, lupus and lupus nephritis, and uncontrolled asthma.
- BCA101, a first-in-class EGFR / TGFβ-trap bifunctional antibody, entered a Phase 1/2 study at leading U.S. and Canadian cancer centers.

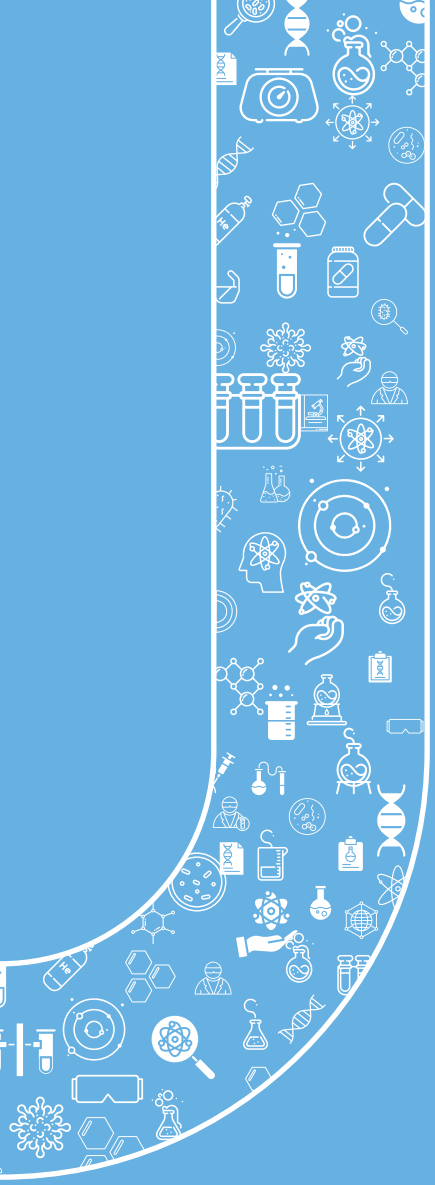
BIOSIMILARS

- Commercialized biosimilar Insulin Glargine (*Semglee**), making Biocon Biologics the only company from India to make three biosimilars available in the U.S. for chronic diseases like diabetes and cancer.
- Commercialized biosimilar Pegfilgrastim (*Fulphila**) in Australia and Canada, enabling access to an affordable supportive cancer care medicine.
- Received marketing authorization approvals from the European Commission for biosimilar Insulin Aspart (*Kixelle**) and biosimilar Bevacizumab (*Abevmy**), widening the choice of biosimilars for diabetes and cancer patients in EU countries.
- Received pre-qualification approval from WHO for our biosimilar Trastuzumab, opening opportunities to serve cancer patients in 46 low- and middle-income countries (LMICs).
- Rolled out 'Mission 10 cents' as a part of our commitment to enable universal access to affordable insulins in low- and middle-income countries of Philippines and Tanzania.
- Raised ~USD 330 million from global marquee investors to expand capabilities that will address rising demand for high quality biosimilars across the globe.

*(*Partnered with Viatris)*

RESEARCH SERVICES

- Extended till 2030, a long-standing partnership with Bristol Myers Squibb (BMS) for drug discovery research.
- Entered a 5-year pact with 3DC, the drug discovery and development unit of Deerfield Management Co, to advance therapeutic discovery projects.
- Helped partner Albireo Pharma advance their compound to regulatory filings in U.S. and Europe, putting it on track to be the first approved drug for treating specific genetic liver diseases, primarily in children.
- Continued to support clients on drug research projects for leukemia, Parkinson's disease, inflammatory disorders, fibrotic disorders and orphan diseases.
- Expanded research facility in Hyderabad by adding capacity for an additional 90 scientists.
- Commissioned a new microbial manufacturing facility to reduce dependency on external service providers.



United in Commitment

The Biocon Group rose to the challenges thrown by the COVID-19 pandemic and the consequent lockdowns. To minimize disruption during the crisis, we went the extra mile to support Patients, Caregivers, Health Care Professionals, our Partners and Customers. We remained united in our commitment to serve patients and enhance global healthcare throughout the pandemic.

Patients

Dr. Belani

Mumbai

When I came off the ventilator, my primary treating physician Dr. Gaurav Gupta at the Breach Candy Hospital, Mumbai told me to be prepared for convalescent plasma therapy. But the need for plasma therapy was mitigated by the administration of *ALZUMAb-L* (Itolizumab), which foiled the life-threatening impact of cytokine storm due to COVID-19.

My turnaround was miraculous after the administration of the drug. Above all, I wish to express my sincere gratitude to Biocon Chairperson, Madam Kiran Mazumdar-Shaw for giving me the elixir of life – *ALZUMAb-L*. Jai Hind!

Vijaya

Senior Nursing Officer, AIIMS, New Delhi

I am a Senior Nursing Officer working in the COVID-19 Department at AIIMS, New Delhi. Despite taking all safety measures, I contracted COVID-19 in 2020 and had to be hospitalized. As plasma for my blood group was not available, the doctors gave me Itolizumab injection. I would like COVID-19 patients to know that Itolizumab is an effective drug for treating COVID-related complications.

Sanjai Rai

Mumbai

COVID-19 resulted in persistent fatigue. When my condition deteriorated, I was admitted in the ICU of Lok Nayak Hospital, New Delhi. It was at this stage that the doctors administered Itolizumab. After receiving this drug my condition improved, and I was moved out of the ICU the next day. From then on, my condition improved so much so that within a few days I could help other patients, even those in wheelchairs.

Caregivers

Taslimarif Saiyed

CEO and Director, C-CAMP, Bengaluru

My immense gratitude towards Biocon and its Chairperson Madam Kiran Mazumdar-Shaw for their phenomenal and continuous support during my mother's COVID-19 treatment at Manipal Hospital, Bengaluru in 2020. My mother developed complications and was administered with Itolizumab immediately, which turned out to be a timely intervention playing a major role in her recovery.

I cannot thank Ms. Mazumdar-Shaw and her team enough for supporting us and many others by ensuring we received Itolizumab on time. Salute for this remarkable act of humanity and social responsibility!

Sumeet Ashok Kotak

Manager, Mahindra Insurance Brokers Limited

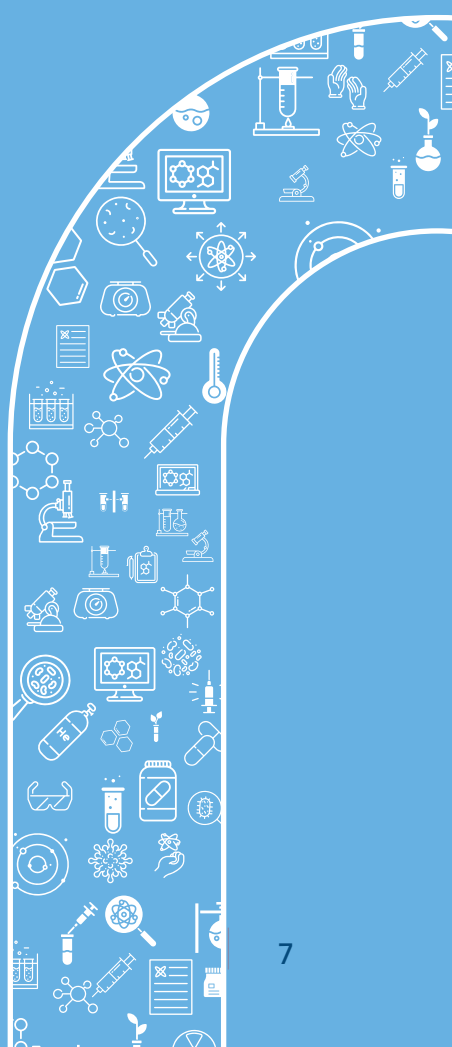
My 75-year-old father tested positive for COVID-19 in April 2021 and had to be admitted to a hospital in Mumbai. The hospital asked me to procure Itolizumab injection for my father as it had run out of stock. I reached out to over 200 people but failed to make any headway. It was then that I contacted the communications team at Biocon Biologics, who with the help of their colleague in Medical Affairs helped me procure this injection well in time.

Thanks to their quick response, I was able to procure the Itolizumab injection on time. After being administered this critical therapy, my father's condition improved, and he recovered completely.

Akash Bhushan

CNBC, Delhi

You people are doing a great job, life saver. Salute to you. Thanks a ton. We will always keep you in our prayers. You are like God to us.



Chairperson's Review

Kiran Mazumdar-Shaw
Executive Chairperson

Chairperson's Review

Unwavering Purpose

Dear Shareholders,

The pharmaceutical and healthcare industry's fight against COVID-19 intensified over the past year as fresh waves of infections hit many countries around the world. As the pandemic left societies and economies in disarray, biotechnology-led companies quickly developed diagnostics, vaccines and therapies to tilt the battle in favor of humanity.

India has been at the forefront of this crusade, producing cost-effective vaccines at scale for millions of people. At the same time, the country has continued to supply a global patient pool with generic and biosimilar therapies to prevent and treat non-COVID health threats such as cancer, diabetes, heart attacks, HIV infections, malaria, tuberculosis etc.

Biocon Group Endures COVID-19 Challenge

As an innovation-led, life sciences group based in India, Biocon and its subsidiaries ensured that we delivered on our promise of providing access to life-saving healthcare solutions during COVID-19.

Our belief that the top priority in a public health crisis is to protect human lives, led all employees of Biocon, Biocon Biologics and Syngene to relentlessly contribute towards ensuring continuity of operations

despite lockdowns in the country and many parts of the world. The unwavering purpose of our people to put 'patients first' enabled us to sustain the supply of life-saving medicines, worldwide.

We also took up the challenge to find solutions to support India's fight against COVID-19, by leveraging our deep scientific expertise and large

scale manufacturing capabilities. From diagnostics to therapies, from testing to vaccinations, we did our best to make a meaningful difference.

As we continued with our operations, we also focused on protecting our people and ensuring their health and well-being. We invested in implementing strict safety protocols and regularly engaged with our people to keep them motivated. The leadership team constantly monitored the fast evolving situation and took data-driven decisions for operational planning across our facilities.

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Realizing The Biosimilars Promise

Our Biosimilars business revenue at ₹ 28,002 million, recorded a growth of 21% in FY21. We commercialized our third biosimilar, Insulin Glargine, in the U.S. and obtained regulatory approvals for key biosimilars Bevacizumab and Insulin Aspart in the European Union. Our biosimilars benefited 3.1 million patients during the year.

With the pandemic overwhelming healthcare systems globally, chronic diseases took a backseat as budgets and resources were diverted to tackle COVID-19. This and other COVID-related challenges affected the growth trajectory of our Biosimilars business. In the post-COVID world, we believe, Biocon Biologics will have a larger opportunity to shape the global biosimilars landscape, as healthcare systems worldwide are compelled to leverage both generics and biosimilars to contain medical costs.

As the only company from India to have three biosimilars commercialized in the U.S. and among the select few globally to have five biosimilars approved in Europe, we are confident of enabling affordable access to expensive biologic drugs for several million patients globally.

Our diverse portfolio of products straddling monoclonal antibodies for cancer and autoimmune diseases and rh-insulin and insulin analogs for diabetes as well as our continued commitment to quality and product safety, position us to deliver robust and enduring growth in the coming years. The market potential for biosimilars remains solid, with biologics worth ~USD 90 billion in originator sales losing exclusivity over the next decade.

The confidence of investors in Biocon Biologics' growth story is reflected in the entity's post-money valuation of ~USD 4.17 billion.

The confidence of investors in Biocon Biologics' growth story is reflected in the entity's post-money valuation of ~USD 4.17 billion during the last round of fundraising from Abu Dhabi-based ADQ. Including the infusion from ADQ, we have raised ~USD 330 million from top global investors like True North, Tata Capital Growth Fund and Goldman Sachs.

Serving Patient Needs Through Generics

The Generics business acted with agility to ensure supplies of much-needed generic APIs (Active Pharmaceutical Ingredients) and formulations from India to the rest of the world, belying fears of large-scale medicine shortages due to the pandemic. We supply statins, immunosuppressants, narrow-spectrum antibiotics and other APIs to over 100 countries, and were able

to serve our partners despite COVID-related disruptions. Revenues from the Generics business grew by 6% over the previous year to ₹ 23,359 million, supported by double-digit growth in Generic Formulations and a modest single-digit growth in APIs.

In FY21, Generics Formulations achieved a key milestone with the launch of Tacrolimus capsules, an immunosuppressant used to treat organ transplant patients, in the U.S. It also entered new partnerships to expand commercial footprint to Singapore, Thailand and Brazil.

We remain committed to investing in building new capabilities and capacities across functions, including R&D, Manufacturing and Quality, and strengthening our product portfolio to deliver long-term, sustainable growth in our Generics business.

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Making A Difference With Our Novel Biologics

Realizing the acute need for an effective treatment for people hospitalized with COVID-19 and those at risk of developing severe illness, we repurposed our 'first in class' anti-CD6 monoclonal antibody, Itolizumab, which has a unique 'mechanism of action' in controlling cytokine release syndrome (CRS). The Drugs Controller General of India (DCGI) granted Restricted Emergency Use approval to Itolizumab in July 2020, to treat CRS in patients experiencing moderate to severe acute respiratory distress syndrome (ARDS) due to COVID-19. We are gathering additional data as part of the Phase 4 post marketing study for Itolizumab, which will further validate the potential of this therapy in COVID-19.

Results from the Phase 2 clinical trial, which established Itolizumab as a promising, safe and effective immunomodulatory therapy for COVID-19 with survival and recovery benefits, have been published in a prestigious, peer-reviewed scientific journal in FY21.

Equillium, our U.S.-based partner, reported encouraging developments on the clinical advancement of Itolizumab in treating acute graft-versus-host disease, lupus, lupus nephritis, and uncontrolled asthma. We are expecting clinical data from all studies later in calendar year 2021.

Boston-based Bicara Therapeutics is spearheading the development of novel bi-functional fusion antibodies in immuno-oncology.

Boston-based Bicara Therapeutics is spearheading the development of novel bi-functional fusion antibodies in immuno-oncology. Its lead program, BCA101, is in Phase 1/2 clinical trials in the U.S. and Canada. Bicara started operating as a standalone company under an independent management team in FY21 after we ceded control to its Board and Management.

Keeping Research Projects On Track

Despite a challenging year, Syngene successfully delivered on its commitment to clients who depend on the Company for their research and development needs. It delivered revenue of ₹ 21,843 million, and an annual growth of 9%. Syngene also built on its integrated drug discovery and development portfolio during the year, signing on new clients and renewing contracts

with existing ones like Bristol Myers Squibb. It also invested and built on its scientific and manufacturing capabilities during the year.

Tackling COVID-19

The Biocon Group was able to very quickly pivot its capabilities to fight against COVID-19 in FY21.

Itolizumab, our novel anti-CD6 monoclonal antibody repurposed for COVID-19, has benefited over 27,000 patients suffering from acute lung inflammation. We have a comprehensive portfolio of products for treating COVID-19 patients at different stages of the disease spectrum, including *RemWin* (Remdesivir) and *ARAFLU* (Favipiravir) for mild to moderate patients, *ALZUMAb-L* (Itolizumab) for moderate to severe patients and *CytoSorb* for critical patients.

The Biocon Group was able to very quickly pivot its capabilities to fight against COVID-19.

Biocon's Research Services subsidiary Syngene manufactured Remdesivir under a license from Gilead and distributed in India through Biocon Biologics and Sun Pharma to address patient needs for this life saving therapy. Syngene leveraged its deep scientific expertise to develop various solutions to support the nation's battle against COVID-19.

Syngene, through its repurposed, high-end laboratory, conducted 185,000 RT-PCR tests, of which 90% were free of cost. The Company also developed an ELISA (Enzyme-Linked Immunosorbent Assay) antibody testing kit for COVID-19. Currently, scientists at Syngene are engaged in developing an mRNA technology platform for vaccines including a novel vaccine against COVID-19 using the measles virosome and working to generate a human-ACE-2 transgenic mouse to support studies on prevention or treatment of SARS-CoV-2 infection. Additionally, it developed and validated several relevant assays for assessing immune response against SARS-CoV-2.

To support the government's efforts to combat and contain the pandemic, Syngene has set up a Vaccination Center to provide free vaccination for Biocon Group employees and their families.

Scientists at Syngene are engaged in developing an mRNA technology platform for vaccines.

Paying Tribute To Our Colleagues Lost To COVID-19

The second wave of COVID-19 in India has tragically impacted us and we have lost some of our dear colleagues across Biocon, Biocon Biologics and Syngene. We express our deepest condolences to the bereaved families. We understand we cannot compensate the loss of a human life, however, we have taken steps to help their families rebuild their lives. Biocon Group has decided to pay the families of the deceased, 50% of the employee's gross salary for two years, up to a maximum payout of ₹ 50 lakhs. We will also extend the education allowance support for two children until the age of 18. We will also assist with job hiring for either the spouse or child, in one of our group companies, or help them find employment elsewhere, depending on their education and eligibility. The above support is in addition to the Group Term Life Insurance and other benefits applicable as

per the Company's policy. We sincerely appreciate the contributions made by our dear colleagues and earnestly share the grief of their families.

Financial Performance

Despite a tough and unpredictable year, Biocon delivered a credible financial performance with consolidated revenue growing 14% to ₹ 73,603 million and EBITDA climbing 8% to ₹ 19,071 million, representing an EBITDA margin of 26%. Net Profit (before exceptional item and discontinuing operations) was at ₹ 7,540 million. Our determination to keep investing in science to stay a step ahead of the pandemic is reflected in the 19% rise in our Gross R&D spends to ₹ 6,270 million in the year.

Dr. Arun Chandavarkar was appointed as Managing Director of Biocon Biologics and entrusted to steer the Company to the next level.

Dividend Postponed

On account of the uncertainty due to the unprecedented second wave of the COVID-19 pandemic in India, Biocon's Board of Directors has deemed it prudent not to declare a dividend for FY21, in order to prioritize cash and maintain liquidity. As the business environment evolves over the coming months, the Board will review the dividend payable for FY22.

Strengthening The Management

The Board of Biocon Biologics appointed Dr. Arun Chandavarkar as the Managing Director (MD) w.e.f. January 21, 2021 and entrusted him to steer the Company to the next level. Shreehas Tambe was promoted from Chief Operating Officer to the position of Deputy Chief Executive Officer (CEO).

We appointed Susheel Umesh as the Chief Commercial Officer for Emerging Markets to drive the Company's business in these markets. Susheel brings over 30 years of experience in the pharmaceuticals industry, having worked in India, France and Sub-Saharan Africa for leading global pharma companies.

I do believe we have a strong leadership team in place now to drive the future growth of our Biosimilars business and return the Company to its high growth trajectory soon. I will also be playing a more active role as the Executive Chairperson of Biocon Biologics Limited.

I am also happy to welcome Prof. Peter Piot, Director of the London School of Hygiene & Tropical Medicine and the Handa Professor of Global Health, to the Board of Biocon Biologics Limited as an Independent Director. His scientific expertise and long experience in global healthcare will be invaluable for the Company.

I am also happy to welcome Prof. Peter Piot to the Board of Biocon Biologics Limited as an Independent Director.

Recently, the Board of Biocon Limited has appointed Indranil Sen as the Chief Financial Officer of Biocon, in place of Anupam Jindal who resigned from the position due to personal reasons.

Looking Ahead

In the face of the biggest health calamity faced by humanity in a century,

Biocon kept its commitment to its patients and partners in FY21. We are continuing to brave the challenges of the second wave of COVID-19 in India and hope that with increasing vaccination coverage the social and economic situation in India will improve. We look forward to an overall improvement in business sentiment.

On the back of investments made so far, we expect to drive revenue growth in our Biosimilars, Research Services and Generics businesses in FY22. We will continue to focus on expanding our product portfolio, strengthening the development pipeline and accelerating capacity enhancement. We will invest in skilling our workforce to prepare for a digital future. These initiatives will bolster our pursuit of enabling affordable access to essential and life-saving medicines for patients worldwide. At a time when the world sadly acknowledges inequitable access to vaccines, we hope that our purposeful business philosophy embedded in health equity and access resonates with our partners and every stakeholder.

I would like to thank our esteemed shareholders, partners and other stakeholders for continuing to repose their faith in us. While the pandemic will bring many further challenges, our unwavering purpose of ensuring equitable access to healthcare gives us the confidence to build a stronger, better Biocon for the future.

Thank You.

Yours sincerely,
Sd/-
Kiran Mazumdar-Shaw
Executive Chairperson
June 18, 2021

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Biocon Biologics
Transforming Healthcare. Transforming Lives.

Our Biosimilars Business

Unfailing Accessibility

Untiring Commitment

During COVID-19 pandemic, we went the extra mile to support Patients, Caregivers, Health Care Professionals, our Partners and Customers. We remained steadfast in our commitment to serve patients and enhance global healthcare throughout the pandemic.

Health Care Professionals

Dr. Suresh Kumar

Medical Director, Lok Nayak Hospital, Delhi

At the time of this COVID-19 pandemic, we do not have any specific treatment for patients who are losing the fight against the disease despite best supportive care. Lok Nayak Hospital was one of the sites of the Itolizumab study. Patients did extremely well even with a single dose of Itolizumab. Patients who were with initial oxygen saturation of less than 80% recovered completely when treated with Itolizumab and got discharged.

I sincerely believe Itolizumab will not only help in reducing morbidity and mortality of COVID-19 patients but will also help us in judiciously managing healthcare resources like ICUs and ventilators for critically ill patients.

Dr. Anand R Sutar

Intensivist, Apollo Hospitals, Bengaluru

In the current pandemic, there were many drugs that were tried, tested and used with varying results in the management of COVID-19. We were glad that Itolizumab was approved by DCGI for managing CRS in COVID-19 at a right time. As an intensivist who has used Itolizumab in many COVID-19 patients, I believe *ALZUMAb*-L has changed the paradigm in COVID-19 management when used in carefully selected patients at the right stage.

Itolizumab reduced the inflammatory markers, reduced the oxygen demand and showed a sustained and significant improvements within 48 - 72 hours of its administration. We could see the ray of hope with this molecule when used in judicious patient at an appropriate time. We really thank Biocon for making a meaningful difference in patients' life.

Dr. Vishal Gore

Physician and Intensivist, Markandeya Hospital and CNS Hospital, Solapur

COVID-19 patients who present co-morbidities such as diabetes and hypertension have a higher chance of experiencing the 'cytokine storm' as a result of the novel coronavirus infection. I administered Itolizumab to a few of my patients who were showing serious COVID-19 complications, and this drug has by far given the best experience.

None of the patients treated with Itolizumab suffered from sepsis or other bacterial infections after using the drug. The drug is also affordable considering that it can reduce three to four days in ICU on a ventilator, which can be far more expensive.

Dr. Mohan Joshi

Formerly with BYL Nair Hospital, Mumbai

We have tried Itolizumab in many COVID-19 patients with moderate to severe ARDS and found significant improvement in clinical, radiological and inflammatory markers after administering Itolizumab. These outcomes were quite evident with one dose of Itolizumab when administered before the 'cytokine storm' set in.

Most of the patients have well tolerated the drug. Given the growing surge of COVID-19 cases, I would recommend use of Itolizumab in moderate to severe complications in COVID-19.

Dr. Rahul Pandit

Director of Critical Care Services, Fortis Hospital, Mumbai

There are not many drugs currently available to block the COVID-19-induced cytokine release syndrome (CRS), which patients typically experience at the start of the second week of the viral infection. I used only a single dose of Itolizumab on my patients at the onset of CRS and the drug's mechanism of action of immunomodulation suppressed the pro-inflammatory cytokines, and the patients showed clinical improvement.

Managing Director's Message

Dr. Arun Chandavarkar
Managing Director,
Biocon Biologics Limited

Biocon Biologics Managing Director's Message

Undaunted Pursuit

As an innovation-led company, Biocon has always taken the path less travelled, seeking new opportunities whilst building on its strong foundation of over four decades in biotechnology. Biocon Biologics was incubated to capture the opportunity in biosimilars, a niche area marked by high entry barriers of complex science, rigorous product quality and stringent manufacturing standards.

The undaunted pursuit of our collective vision of transforming healthcare and transforming patients' lives, led Biocon Biologics to work on a mission mode, demonstrating a strong sense of ownership, to combat ongoing COVID-related challenges and being resourceful in ensuring that our products reached patients worldwide during the year.

Five of our molecules have now obtained approvals in the developed markets. Through our commercialized biosimilars, we served over 3 million patients in FY21.

Making A Difference Through Biosimilars

Through our pioneering spirit, collaborative approach and pursuit of excellence we have built one of the broadest and deepest pipelines in the industry straddling monoclonal antibodies for cancer and autoimmune diseases, insulin and insulin analogs for diabetes and conjugated recombinant proteins. Five of our molecules have now obtained approvals in the developed markets. Through our commercialized biosimilars in India, emerging markets as well as advanced markets, we served over 3 million patients in FY21.

Financial Performance

Our annual revenues grew 21% to ₹ 28,002 million, driven by improved performance in both developed and emerging markets, despite a challenging business environment aggravated in part by the pandemic.

Annual revenues for the Biosimilars business grew 21% to ₹ 28,002 million.

We reported EBITDA margins of 27% despite a 60% jump in Net Research & Development costs to ₹ 2,840 million in FY21. Higher R&D costs reflect progress on several of our biosimilar development programs that will fuel our future growth. Stripped of R&D costs, licensing income and forex, our Core EBITDA margins were 36%. Profit Before Tax stood at ₹ 3,652 million in FY21.

Key Milestones

Biocon Biologics reached several milestones in FY21. These included the Company's third biosimilar approval in the U.S., two recent approvals in the European Union (EU) and product commercialization in both developed and

emerging markets, widening the treatment options available to patients living with diabetes and certain cancers.

Value Unlocking

We have successfully initiated the process of unlocking value from our Biosimilars business and raised ~USD 330 million from marquee private equity investors such as True North, Tata Capital, Goldman Sachs and ADQ. The most recent PE investment in Jan 2021 (by ADQ) had put the post money valuation of Biocon Biologics at ~USD 4.17 billion. The capital raised is being deployed primarily to fund the ongoing expansion and qualification of our manufacturing facilities and to support our R&D programs, besides the redemption of Biocon Limited's preference shares in Biocon Biologics.

We have raised ~USD 330 million from marquee private equity investors such as True North, Tata Capital, Goldman Sachs and ADQ.

Product Launches and Approvals

Commercialization of Insulin Glargine (*Semglee*) in the U.S. in August 2020, through our partner Viatris, is a milestone achievement for Biocon Biologics in making insulin-based therapy accessible for people with diabetes globally. We are proud to provide another quality treatment option for more than 30 million Americans living with diabetes in the U.S.[1]

The European Commission approved our Bevacizumab, developed in partnership with Viatris, close on the heels of approving Insulin Aspart. These approvals give us a robust portfolio of five approved biosimilars in Europe along with an economic interest in two more approved in-licensed products. Moreover, we received approvals from regulators of over 20 Emerging Market countries in FY21 for our portfolio of biosimilars.

Boosting Manufacturing Capacity

We continued to make investments in building global scale, cost-competitive, complex manufacturing capabilities to address market opportunities worldwide and enhance patient access to our high quality biosimilars. Our capital expenditure in FY21 was ~USD 125 million, net of partner funding, primarily for the expansion of our production capacity for monoclonal antibodies (mAbs). In FY22, we are looking at an additional capital expenditure of about USD 100 million.

Our FY21 capital expenditure of ~USD 125 million was primarily on expansion of our production capacity for monoclonal antibodies.

Our new facility, one of the largest mAbs manufacturing facilities in India, has been qualified and is awaiting commercialization. This is the first biopharma facility from India to receive an Honorable Mention as Facility of the Year by the International Society for Pharmaceutical Engineering (ISPE). We have also built another new facility with state-of-the-art single use technology to support our monoclonal antibody portfolio.

Strengthening Research Capabilities

On the Research & Development front, we enhanced our in-house capabilities and capacity, improved the efficiency of the R&D engine and supported the progress of our in-development biosimilars pipeline in line

with the Company's vision to be a leading global player.

Going ahead, we expect to increase our investment as we advance the development of our next wave of biosimilar molecules, which we expect to commercialize over the second half of this decade.

Quality is a part of Biocon Biologics' DNA and we are committed to making available medicines that are safe, effective and of high quality. To strengthen our Quality Control and Quality Assurance systems further we accelerated the adoption and implementation of best-in-class digital processes during the year and will continue to invest in this multi-year effort.

Widening Our Commercial Footprint

We continued to expand our commercial footprint across global markets. We have established a strong foothold in developed markets like U.S., Canada and Australia through our partner Viatris who remain focused on gaining market shares for our key biosimilars and ensuring success in the new launches expected next year.

Biocon Biologics also has a wide commercial footprint across many of the top 20 Emerging Markets, where we have partnered with leading local pharma companies. Our efforts to expand business in these markets led to an increase in market shares for our bTrastuzumab (in Brazil, Malaysia, and Indonesia), rh-Insulin (in Mexico, Thailand, and Vietnam), and bGlargine (in Malaysia and Bangladesh).

We repurposed our novel biologic drug Itolizumab to treat the cytokine release syndrome observed in some COVID-19 patients.

Tackling COVID-19

Since early 2020, COVID-19 has had devastating social and economic consequences worldwide, impacting business across many industries. The pharmaceuticals industry, whilst being at the forefront of the fight against COVID-19, did face several challenges that impacted product development, regulatory inspections and approvals, and commercial demand on account of delays in tenders and reprioritization of healthcare budgets. It was also a challenge sustaining peak operating performance whilst adopting stringent COVID related safety protocols and managing strained supply chains.

Despite the challenges, we continued to serve patients across the world. As an innovation driven organization, we entrusted our research team to find solutions to help combat the raging pandemic. In a short span of time, Biocon Biologics repurposed its novel biologic drug Itolizumab, an anti-CD-6 monoclonal antibody, to treat the cytokine release syndrome observed in some COVID-19 patients. The product, *ALZUMAb-L*, received emergency use authorization from the Indian drugs regulator and proved to be a good therapy option for doctors to treat moderate to severe ARDS patients and enabled them to save lives. In order to address the growing patient needs we rapidly scaled up our production capacities and succeeded in ensuring supplies of Itolizumab to all parts of the country thus benefitting o ver 27,000 patients during the pandemic thus far.

In addition to *ALZUMAb-L*, we offered a comprehensive COVID-19 therapy portfolio encompassing *CytoSorb*, *ARAFLU* and *RemWin*, which cater to patients at different stages of the disease continuum.

Biocon Biologics reinforced its reputation of resilience and reliability through its agility in using its scientific and manufacturing prowess to supply critical therapies for COVID-19 to patients in India.

We succeeded in our core mission of serving patients on the strength of our purpose driven organization, an engaged and visible leadership, an effective communications strategy, quick and agile decision-making, a motivated workforce and technology-enabled digital solutions.

We offered a comprehensive COVID-19 therapy portfolio encompassing *ALZUMAb-L, CytoSorb, ARAFLU* and *RemWin*.

Our People

I commend the courage of our employees in demonstrating their commitment to patients by ensuring continuity of operations despite personal and professional challenges. All teams, both working on site and working from home, embraced the new normal and focused on minimizing any adverse impact to patients who depend on the Company's products. The can-do spirit of our people embodies our culture of collaboration and teamwork, where patients are at the core.

Strengthening Leadership

As part of our focus on organizational change to sustain our future growth, we promoted Shreehas Tambe to the role of Deputy Chief Executive Officer. He has been with the Company for over 20 years in diverse leadership and operational roles and has played a critical role in shaping our Biosimilars business. With his elevation, the Company will be able to draw on his expertise and leadership skills to drive business growth and achieve operational excellence.

All teams embraced the new normal and focused on minimizing any adverse impact to patients who depend on the Company's products.

Prepared for a Post-COVID Future

Whilst enduring the first wave of the pandemic, we put in place robust safety protocols, employee support schemes and business continuity plans that have now stood us in good stead as we confront the enormity of the second wave. We plan to deploy digital technologies in our manufacturing and supply chain to gain real-time control all the way from procurement to production to dispatch to serve patients in diverse markets. With the help of new digital tools we are aiming to enhance compliance and operational efficiencies.

As the COVID-19 pandemic stretches healthcare budgets, the need for affordable medicines for non-communicable diseases such as cancer and diabetes would become increasingly important. Biocon Biologics, as an integrated biosimilars player with a focus on developing therapies for chronic conditions, has the ability to make a difference to patients and healthcare systems across the world. We believe we are well placed to

deliver on our core purpose of developing quality alternatives to expensive biologics and enabling affordable access to these complex therapeutics.

Whilst near term uncertainties linked to the pandemic remain, we are confident of growing our Biosimilars business in a sustained manner, on the back of our robust business fundamentals, scientific know-how, efficient operations, early-mover learnings, and a broad product portfolio.

Best regards,
Sd/-
Arun Chandavarkar, Ph.D.
Managing Director, Biocon Biologics Limited
June 18, 2021

We believe we are well placed to deliver on our core purpose of developing quality alternatives to expensive biologics and enabling affordable access to these complex therapeutics.

Sources:
[1] Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2020. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2020

Undivided Commitment

During COVID-19 pandemic, we went the extra mile to support Patients, Caregivers, Health Care Professionals, our Partners and Customers. We remained undivided in our commitment to serve patients and enhance global healthcare throughout the pandemic.

Partners

Dhananjay Sonawane

Director – Pharma Health Care Division, Mega Lifesciences Limited, Myanmar

Our patients in Myanmar were delighted as we informed patient forums, retail pharmacies and hospitals on the availability of insulin stocks especially premix and Glargine. The lockdown in India during the pandemic had impacted us such that shipments were unable to reach Myanmar and we were facing shortages.

We appreciate Biocon's support in enabling shipments to Myanmar when flights were restricted, and we were dealing with logistics nightmare. This was a tremendous support that helped patients receive treatment and take charge of their health. We thank Team Biocon.

Dr. Manjunath Ramarao

Group Director & Head of Discovery Biology and Translational Sciences, Bristol Myers Squibb

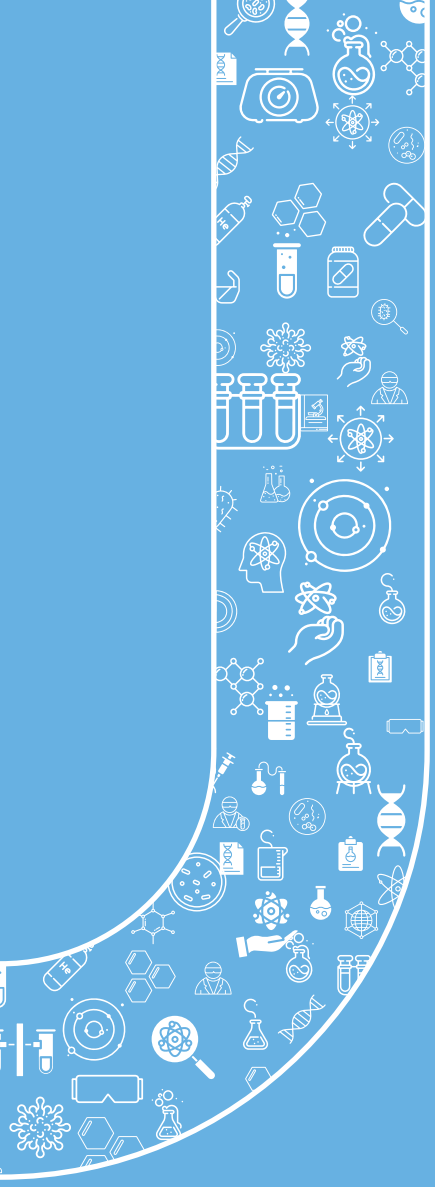
Syngene has been a trusted long-term partner in our endeavor of discovering and developing novel drugs. They have gone beyond our expectations in delivering projects even during the challenging times of the COVID-19 pandemic while keeping the safety of our people as the top priority.

Leonard Ariff Bin Abdul Shatar

Group Managing Director, Duopharma Biotech, Berhad, Malaysia

In these tumultuous times, the leadership shown by Biocon's Chairperson Kiran Mazumdar-Shaw, in accelerating global cooperation during the COVID-19 outbreak resonates with all of us at Duopharma Biotech.

As the pharmaceutical and healthcare industry is among the frontline in the fight against the pandemic, we are heartened as colleagues by the spirit of innovation-driven agility exemplified by several key advances such as Biocon's breakthrough drug Itolizumab, approved mid-2020 for emergency use in moderate to severe COVID-19 patients.



Unmeasurable Commitment

During COVID-19 pandemic, we went the extra mile to serve patients and support the caregivers. We remained united in our commitment to enable access and make a difference to patients' lives throughout the pandemic.

Caregivers

Pravin Sarwankar
CBI, Mumbai

Thank you so much for your help! I could not have managed without you. I don't know about God but there is humanity for sure.

Suryakant Naik
Pune

Thank you so much for Itolizumab injection and special thanks to Biocon Biologics team for being very helpful.

Trisha Sinha Majumdar
Kolkata

I am thankful to state that the lifesaving injection "Itolizumab" was applied to my mother, who was very serious due to COVID-19, under BiPAP support admitted at JN Ray Hospital, Kolkata. To myself and even Doctors got amazed by the action of the injection as my mother started positive recovery sign within 6 hours of application of Itolizumab. She not only survived but recovered within 5 days without any further side effects. I am thankful for this support extended by Biocon and recommend application of Itolizumab to serious condition patients who are undergoing Cytokine storm when the doctor prescribes on time.

Raj Devar
Andhra Pradesh

Kiran Mazumdar-Shaw should be proud of her superb and prompt Biocon Social Media team. Reached out to them for a friend desperately looking for Itolizumab and received a prompt response.

Sanjiv Mishra
SSP, Patna

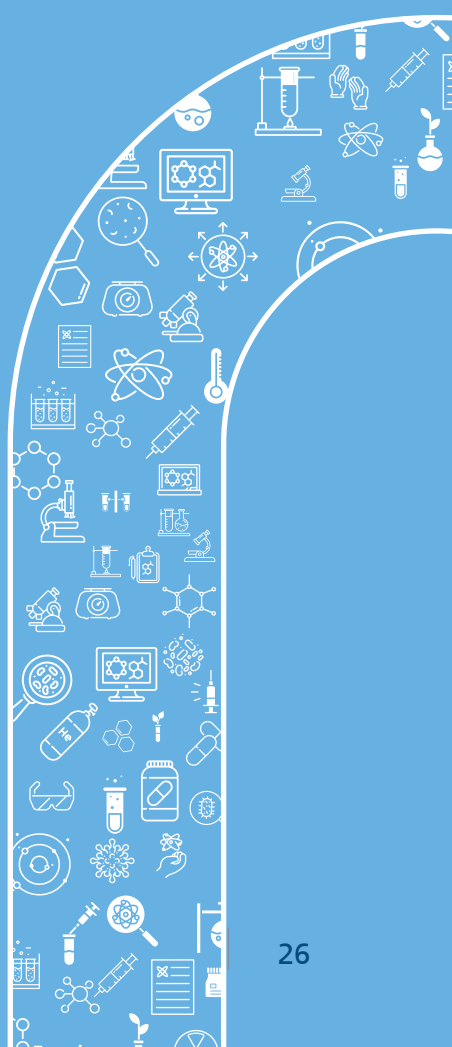
I am extremely happy to inform you that my mother has been discharged from hospital. Your advice of administering her Itolizumab acted as life savior for my mother. Thanks a lot.

Udayan Jain
Manager, Mahindra Insurance Brokers Limited

Your timely help in procuring *ALZUMAb-L* for my mother-in-law has helped her in recovering from COVID-19. Like million others I too have been an admirer of your work but did not know I would get a chance to interact in such a situation. I thank you from the bottom of my heart. I am a lawyer and have a counsel practice in corporate litigation, with all humility at my command, if I can ever be of help in some humble manner, it would be my honour and privilege.

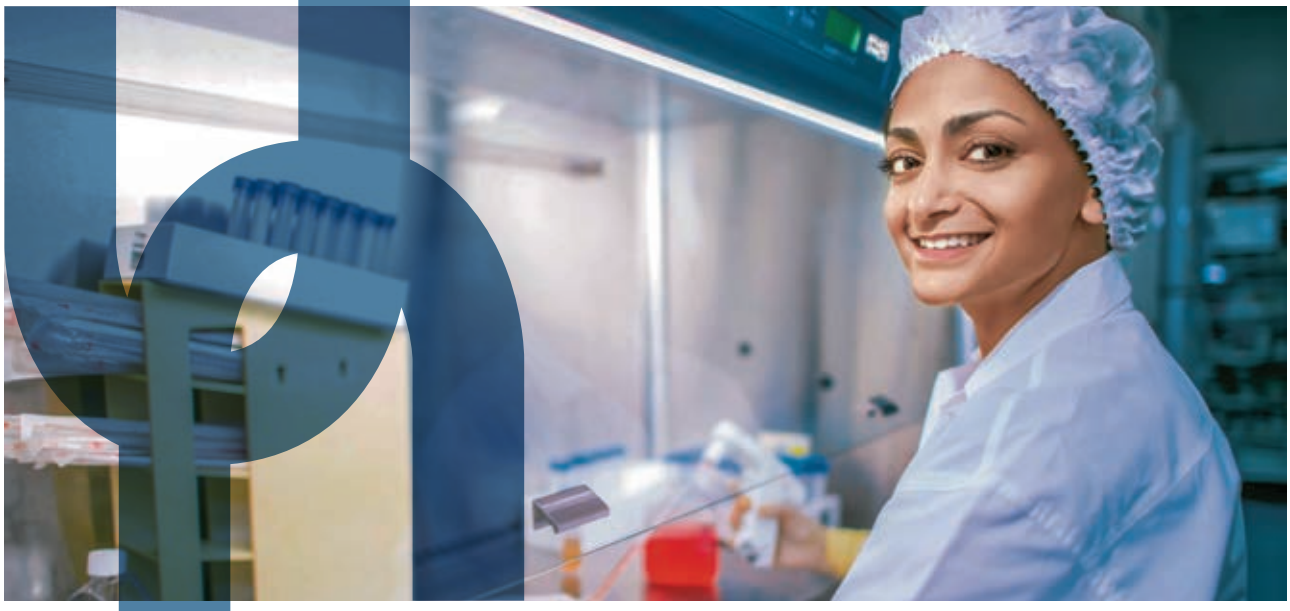
Adarsh Kumar
New Delhi

I would like to thank Madam Kiran Mazumdar-Shaw and Biocon Biologics for the great work they are doing in saving people's life. Special thanks for responding promptly to our plea in the hour of need for providing *ALZUMAb-L*. Keep up the good work.



Our Novel Biologics Business

Unbridled Innovation



Our portfolio of Novel assets, comprising therapeutics for diabetes, autoimmune or inflammatory diseases and cancer, reflects our track record of pioneering cutting-edge innovation. Our Novels program counts reputable organizations such as the U.S. based JDRF and Equillium as partners, which underscores its potential to impact lives globally.

Itolizumab

Itolizumab is playing a crucial role in the fight against COVID-19 in India, having benefited more than 27,000 COVID-19 patients as of May 2021. Itolizumab *ALZUMAb* was initially launched in India for the treatment of chronic plaque psoriasis in 2013. It was repurposed for the treatment of COVID-19 and subsequently made available to patients in July 2020, following an Emergency Use Approval from the Drugs Controller General of India (DCGI).

In September, *ALZUMAb-L*, a new 100 mg/vial formulation of Itolizumab, was approved by the DCGI for the treatment of cytokine release syndrome (CRS) in moderate to severe ARDS (acute respiratory distress syndrome) patients due to COVID-19.

ALZUMAb-L underscores our relentless focus on patient-centricity and affordability. Not only does it replace the need for four vials of the previous formulation with a single dosage but is also priced at less than

half of other comparable therapies. We continue to gather additional data as part of the Phase 4 post marketing study and Real World Evidence (RWE). Itolizumab's unique mechanism of immunomodulation involves binding to the CD6 receptor and blocking the activation of T lymphocytes, which in turn suppresses the pro-inflammatory cytokines, thus reducing inflammation. We believe this could help prevent and treat patients with CRS, which is a major cause of fatality in COVID-19 patients.

Out-Licensing Partnership

We out-licensed Itolizumab to U.S.-based biotechnology company Equillium Inc. in 2017. Itolizumab holds the potential for multiple high-value indications. Equillium is developing Itolizumab for multiple severe immuno-inflammatory diseases, including acute graft-versus-host-disease (aGVHD), lupus and lupus nephritis and uncontrolled asthma. We are expecting clinical data from all the studies in CY 2021.

Insulin Tregopil

Insulin Tregopil is a first-in-class molecule for post-prandial glycaemic (PPG) control. A clinical study report (CSR) of the phase 2 component of a study in India, evaluating higher dosage forms (up to 45 mg TID), has been submitted to the DCGI and the U.S. Food and Drug Administration.

While the data from our Type 2 diabetes studies were encouraging with respect to safety and PPG control, the marketing authorization application was deferred in the wake of the pandemic.

In FY20, we had commenced a multiple ascending dose study for Type 1 diabetes in Germany. The Phase 1 study, held in partnership with JDRF, a leading non-profit organization that funds research on Type 1 diabetes, is expected to be completed in FY22. We will decide on further development activities based on the outcome of this trial.

Bicara

BCA 101, Bicara Therapeutics' lead program, a first-in-class EGFR/TGFβ-trap bifunctional antibody, entered a Phase 1/2 study at leading U.S. and Canadian cancer centers in July 2020. BCA101 is under evaluation, both in combination with the checkpoint inhibitor Pembrolizumab and as a single agent, in patients with advanced Epidermal Growth Factor Receptor (EGFR) driven solid tumors, who stopped responding to the standard of care. We anticipate transitioning to dose expansion studies in the second half of calendar year 2021.

In an important development during the year, Biocon ceded control over the Board and operations of Bicara, which housed our immuno-oncology program focused on novel bifunctional fusion antibodies. As a result of this change, Bicara was classified as an Associate from a Subsidiary under IND-AS accounting standards. With its lead program, BCA101, achieving critical scale, this development will enable Bicara to operate independently under a U.S.-based leadership and raise funds to advance its development programs.

Outlook

We expect results from studies involving our Novel assets, which are currently underway at various stages of progress. The progress made so far signals a strong potential for our portfolio. The advancement of our programs will be driven by our inherent capabilities as well as external collaborations to fund more extensive studies required to bring these novel molecules to the market.

Unrestricted Commitment

During COVID-19 pandemic, we went the extra mile to support Patients, Caregivers, Health Care Professionals, our Partners and Customers. We remain unrestricted in our commitment to serve patients and enhance global healthcare throughout the pandemic.

Employees

Dr. Praveen R

MBBS, MD, Head - Medical Affairs, Metabolics Business, Biocon Biologics

Working on the Itolizumab project was quite interesting and inspiring too. This project is an outstanding example of cross functional team collaboration. Most of the treating doctors were unaware on administration protocol for Itolizumab in COVID-19 patients. As part of the medical affairs team, one of the critical aspects is to train the treating physicians about right administration and usage of Itolizumab in COVID-19 patients.

In fact, we used to get 200+ telephonic calls in a day and the phone kept ringing day & night. These calls were from hospitals, physicians, nursing staff, pharmacy team etc. We worked together with our sales colleagues in making the drug available. To quote an instance, when Cyclone Nisarga hit Mumbai, our team traveled almost six hours from Mumbai to Pune to deliver the drug and saved a patient's life. As a team, we worked with utmost passion in delivering science to save patients' lives. Trust me, it is a life changing experience!

Dr. Sandeep Nilkanth Athalye

Chief Medical Officer, Biocon Biologics

COVID-19 affected my close relatives and I learnt about the disease and treatments closely. I was connected with the doctors and experts throughout and witnessed the evolution of treatment options. To be able to deliver something that could save lives was immensely satisfying.

There was a strong drive to work hard and deliver because of a strong purpose that each team member had. Great team collaboration where patients were at the center and understanding of science was strong. The team feels immensely proud to have delivered. Kiran's personal involvement in this project was also inspiring for the team.

Srinivas Rao Desu

Senior Executive – Production, Biocon Limited, Hyderabad

My role was to execute and ensure batch charging with delivery plan without any delays. At a time when COVID-19 cases were increasing in India, I stayed 21 days in Company's premises to ensure the continuity of my work. I was anxious to work with limited manpower, but our goal of helping the patients was the key motivating factor for us.
I am quite humbled to be able to do my part. I made sure that I was available throughout the crisis and ensured manufacturing activities within the timelines.

Prasanna Sampath

Senior Director - Supply Chain Management, Biocon Limited

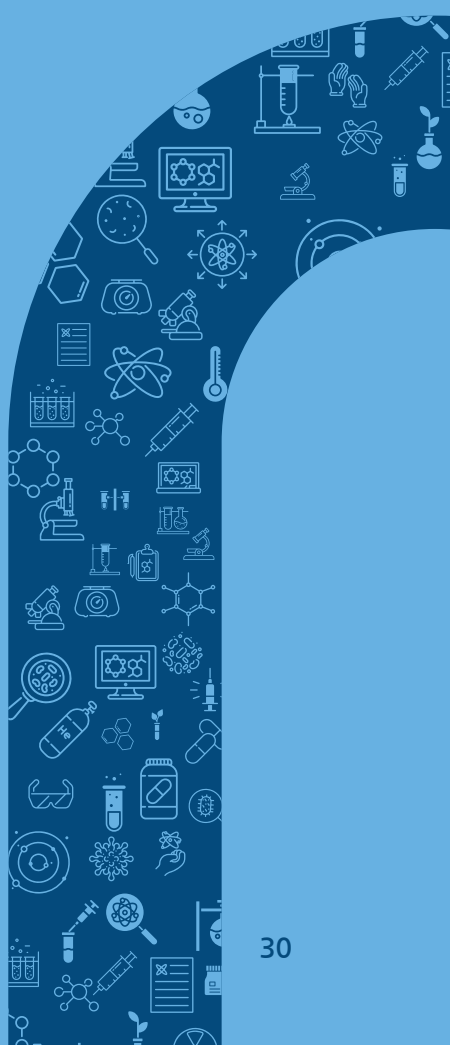
COVID-19 era has brought us newer challenges where out of the box thinking, and inside out approach is the need of the hour. Our teams too faced challenges such as reduced transportation capacity, high air freight cost, capacity limitations in ocean freight, port disruptions and quarantined crews & labour shortage. As a team, we stepped towards the paradigm shift and had to be creative and logical with the solutions that had to be implemented to ensure customer success.

We simply could not afford delays both in our inbounds and outbound. We acted fast, ensured excellent co-ordination between procurement, planning, logistics and warehousing teams. Our process improvements and automations ensured continued and efficient supplies. Our collaboration, drive and dedication helped us in overcoming all types of challenges.

Sunil Koteel

Senior Director - Administration, Biocon Limited

It was hard work, especially since March 2020. For more than 75 days after the lockdown was announced, the transport team literally worked round-the-clock. But looking back, it was worth it because we could ensure business continuity. Also, our leadership was prompt with approvals. They empowered us to take decisions, which helped us execute our plan to perfection.



Our Biosimilars Business

Executive Leadership Team

Dr. Arun Chandavarkar
Managing Director

Shreehas Tambe
Deputy Chief Executive Officer

Chinappa M B
Chief Financial Officer

Susheel Umesh
Chief Commercial Officer, Emerging Markets

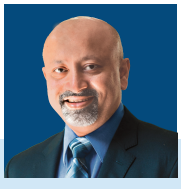
Paul Thomas
Chief Commercial Officer, U.S. & Portfolio Strategy & Business Development, Advanced markets

Dr. Anuj Goel
Chief Scientific Officer

Dr. Sandeep N Athalye
Chief Medical Officer

Dr. Sundar Ramanan
Chief Regulatory Officer

Akhilesh Nand
Company Secretary and Chief Legal, Risk & Compliance Officer



Amitava Saha
Chief Human Resources Officer

Seema Ahuja
Chief Communications Officer

"Our proven track record of scientific credibility, large scale manufacturing capability and a strong supply & distribution network in compliance with the highest standards of quality and governance gives me the confidence that we can successfully deliver on our vision to transform healthcare. As a fully integrated innovation-led biologics company, we continue to make significant investments in advancing our R&D portfolio, expanding our manufacturing capacity and enhancing our reach to patients. At Biocon Biologics we remain committed to making healthcare affordable and importantly accessible to the benefit of millions of patients and their families across the world.

FY21 was unprecedented in many ways and it brought with it severe hardship, grief and personal loss to many families. Despite the various challenges, I am proud that even during the peak of the pandemic we worked together as one team to keep our manufacturing plants operational, research and testing laboratories functional and the overall supply chain efficient. It is this strong sense of purpose and the unwavering commitment that allowed us to serve over 3 million patients who look up to us for a reliable supply of these life-saving drugs. It is this culture of collective ownership and team spirit that sets Biocon Biologics apart."

Shreehas Tambe
Deputy Chief Executive Officer
Biocon Biologics Limited

Our Biosimilars Business

Unfailing Accessibility

The COVID-19 pandemic has magnified societal and healthcare disparities globally and underlined the need for expanding affordable access to advanced therapies like biologics.

Biosimilars, which are safe and effective alternatives to innovator biologics, can provide relatively lower cost access to advanced therapeutics for treating non-communicable diseases such as diabetes and cancer. Increased penetration of biosimilars is leading to an expansion of access to biologic treatments for patients who could not afford these expensive therapeutics otherwise.

Biocon's early entry into this segment, more than 15 years ago, has enabled it to become a frontrunner in biosimilars. We deploy highly efficient technology platforms to develop monoclonal antibodies (mAbs) for cancer and autoimmune disease, insulin and insulin analogs for diabetes, and conjugated recombinant proteins.

We are among the select few globally to have co-developed five biosimilars, bTrastuzumab, bBevacizumab, bPegfilgrastim, bGlargine and bAspart, which have received approvals in key advanced markets and three of these are also commercialized in these markets through our partner Viatris.

We are also among the few to have successfully commercialized five biosimilars, bTrastuzumab, bBevacizumab, bPegfilgrastim, bGlargine, rh-Insulin, in many emerging markets though our strong network of partners.

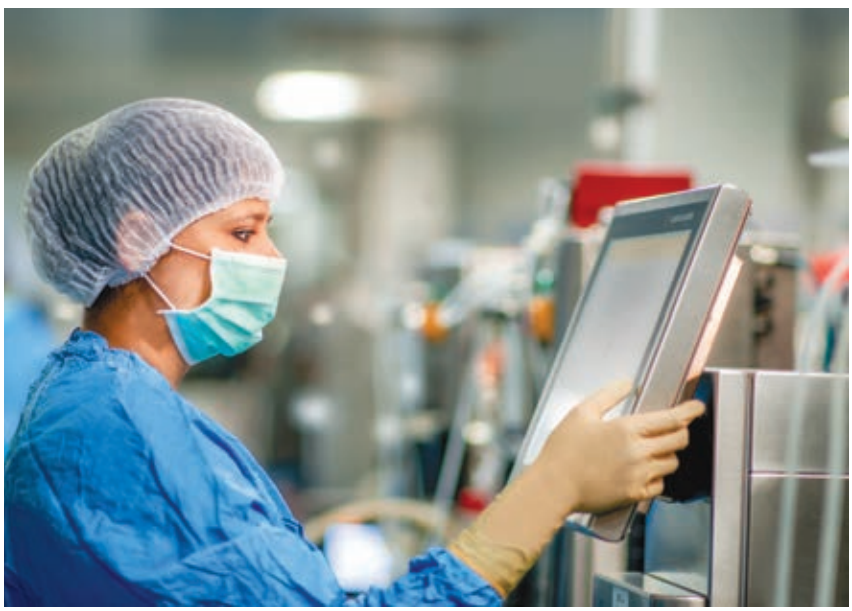
The biosimilars opportunity is expected to grow as biologics worth USD 90 billion in originator sales lose exclusivity over the next decade, as per industry estimates. Biosimilars have the potential for substantial system savings. Therefore, biosimilars spending is expected to reach USD 16-36 billion^ by 2024. Given the expertise we have developed over the years, Biocon Biologics aims to capitalize on this unfolding biosimilars opportunity to enable access to patients globally.

Financial Performance

Biocon Biologics' revenues grew 21% over last year to ₹ 28,002 million, driven by improved performance in both developed and emerging markets. This segment now accounts for 37% of our group revenues. We reported EBITDA margin of 27% and Core EBITDA margin of 36% (i.e., EBIDTA margin, net of licensing, forex, and R&D).

Biocon Biologics' revenues have **grown by 21%** over last year to **₹ 28,002 million.**

Net Research & Development costs increased 60% to ₹ 2,840 million, representing 10% of our annual revenue. The higher R&D costs reflect progress on several of our biosimilar development programs, which will support our future growth. Profit before Tax for the year stood at ₹ 3,652 million.



Business Performance

Biocon Biologics reached several milestones in FY21, including its third biosimilar approval in the U.S. and two new approvals in EU. We also extended our commercial footprint in new emerging markets and key developed markets.

Insulins

As a leading global insulins player, Biocon Biologics is already benefiting people with diabetes in many emerging and developed markets through improved access to its more affordable recombinant human Insulin (rh-Insulin) and bGlargine. Our rapid acting insulin analog, bAspart, received regulatory approvals in developed markets like EU and emerging markets like Malaysia in FY21. We now have a broad portfolio, comprising basal, mixed and rapid acting insulins, which will enable us to meet varied patient needs and make a difference globally.

Progress of Insulins

Biocon Biologics became the first company from India to have three biosimilars commercialized in the U.S. after launching bGlargine (*Semglee**) through Viatris in the second quarter of FY21. *Semglee* witnessed a gradual ramp-up in market share in U.S. in FY21.

We now have the unique distinction of having a biosimilar monoclonal antibody, a conjugated recombinant protein and an insulin analog commercialized in the U.S.

In the EU, we have been able to increase the market share of *Semglee* in select markets, as well as, launch it in additional markets through Viatris.

Sales of our bGlargine also witnessed good traction in key markets in Asia-Pacific and Africa such as Malaysia and Algeria.

We continued to expand sales of our rh-Insulin across emerging markets in the Latin America, Asia Pacific, Middle East & Africa regions through our partners. This included improving our share in existing markets as well as entering new ones. Biocon Biologics has supplied ~2.75 billion doses of rh-Insulin globally since its launch in India in 2004.

To enable better patient outcomes and reduce costs to healthcare systems, we collaborated with Voluntis for Insulia, a unique digital therapeutic solution that has U.S. FDA clearance and a CE mark to help manage the treatment of Type 2 diabetes with bGlargine.

Increasing Access to Insulin Biosimilars in LMICs

Given our extensive experience in providing affordable insulins globally, we aspire to drive policy changes to increase access and transform patients' lives. To translate intention into action, we rolled out our 'Mission 10 cents' program in Philippines and Tanzania in FY21. Under this program, we offer governments in low- and middle-income countries (LMICs) our rh-Insulin for less than 10 U.S. cents a day. Through our local partners, we engaged in diabetes awareness campaigns to promote early diagnosis and better diabetes management.

To contribute to a stronger global voice for diabetes patients globally, we entered a partnership with the International Diabetes Federation (IDF) this year, coinciding with the start of the centenary celebrations of the discovery of insulin.

mAbs And Therapeutic Proteins

Trastuzumab

Biocon and Viatris were the first to get approval for bTrastuzumab (*Ogivri**) in the U.S. in 2017, and the drug was commercialized in December 2019. *Ogivri* has witnessed a steady increase in market share in U.S. and has become the leading bTrastuzumab brand in Canada and Australia. It has also gained market share in several EU countries.

Our bTrastuzumab recorded a strong uptake in several emerging markets. *Zedora* is the leading bTrastuzumab in Brazil's private market with high double-digit market share; *Canmab* is the market leader in Algeria; and *Zuhera* leads in Malaysia's private market.

Adalimumab

Biosimilar Adalimumab, in-licensed by Viatris from a third party, received U.S. FDA approval in July 2020 and reported a steady sales performance in selected EU countries. We retain an economic interest in the biosimilar and will gain a share of profits from global markets.

Pegfilgrastim

Our bPegfilgrastim (*Fulphila**) maintained steady market share throughout the year in the U.S. despite competitors entering the market.

Etanercept

Biosimilar Etanercept, in-licensed by Viatris from a third party for Europe and other markets, was launched in the EU in August 2020. We retain an economic interest in the biosimilar and will gain a share of profits from global markets.

We provide access to best-in-class therapies for cancer that are currently out of reach for patients in low- and middle-income countries.

Increasing Access to Cancer Biosimilars in LMICs

Biocon Biologics is enabling access to biosimilars for cancer patients in LMICs, where the economic and epidemiological burden of cancer is considerably worse due to high morbidity and mortality owing to limited access to advanced treatment.

In February 2021, Biocon Biologics partnered the Clinton Health Access Initiative (CHAI) and the American Cancer Society (ACS) to expand access to life-saving cancer biosimilars for healthcare systems in over 30 countries in Sub-Saharan Africa and Asia under the Cancer Access Partnership (CAP).

Sharpening Focus On Emerging Markets

A disproportionately high chronic disease burden in emerging markets is accentuated by patients' inability to afford long-term treatment and healthcare systems' budget limitations. By ensuring the availability and accessibility of our high quality biosimilars to as many people as possible, we are expanding access to affordable biologics. In line with our mission to make a global impact, we have built our business through strong relationships with regional partners over the years. We are now preparing to be closer to patients, prescribers and our partners in these markets. Accordingly, we have set up commercial offices in Brazil, Malaysia, UAE and Saudi Arabia.

We have recently appointed Susheel Umesh as the Chief Commercial Officer for Emerging Markets. With his strong global experience and expertise in diabetes and other chronic diseases, our focus on emerging markets will further strengthen.

Regulatory Approvals

The European Commission (EC) approved our bBevacizumab (*Abevmy**) in April 2021. Our biosimilar also received approval from Malaysia's National Pharmaceutical Regulatory Agency.

Our bAspart (*Kixelle**) got EC approval in February 2021. It received an approval in Malaysia. The Biologics License Application (BLA) for bAspart is under review in the U.S.

The U.S. FDA has been unable to travel to our India site for a pre-approval inspection due to the pandemic and hence the agency's approval of Viatris' BLA for our co-developed bBevacizumab has been delayed. There are no additional observations or outstanding data requests from the agency related to the application.

To get around travel restrictions, some regulators started conducting remote inspections virtually. In FY21, Biocon Biologics successfully underwent nine virtual inspections of its biosimilars manufacturing facilities in India and Malaysia by regulators from Russia, the World Health Organization (WHO), as well as, several key customers.

The WHO pre-qualified our bTrastuzumab, opening opportunities to serve cancer patients in 46 LMIC countries.

Our biosimilars received regulatory approvals in over 20 emerging markets in FY21.

We received EU GMP certification for some of our Biologics Drug Substance and Drug Product manufacturing facilities at Bengaluru's Biocon Park.

We received approval for Bevacizumab from the National Pharmaceutical Regulatory Agency (NPRA) in Malaysia.

These approvals are an outcome of great team effort and years of hard work and underline our commitment to expand affordable access to life-saving biosimilars and make an enduring impact on global health.

*(*In Partnership with Viatris)*
(^IQVIA Institute, Jan 2021)

Policy Shaping

During the year, we engaged with key stakeholders globally to advocate for policies that will broaden biosimilars access.

Contributing to Evolution of Biosimilars Regulatory Framework in the U.S.

Biocon Biologics made a presentation on the reauthorization process for the Biosimilar User Fee Act (BsUFA III) program at the U.S. FDA's public meeting held to collect a wide variety of stakeholder perspectives on the broad goals laid out by the agency for the FY23-27 period.

We were among the select presenters, which included representatives from pharma trade associations, patient groups and physician groups who shared their wish lists for the third iteration of the agency's biosimilars review program.

Starting with BsUFA I and subsequently through BsUFA II, the U.S. FDA has improved the biosimilar regulatory process by providing greater clarity around the regulatory framework, as well as, expectations from the industry through timely guidance and communications. The agency has done a great job of evolving the regulatory requirements with emerging scientific evidence.

Biocon Biologics' suggestions were that in BsUFA III, the agency should further evolve the regulatory framework based on emerging cumulative scientific evidence. The Company recommended a patients-first, science-based approach to enhance regulatory predictability and efficiency of biosimilar development.

Investing In Research & Development

We continued to invest in the development of our next wave of biosimilar molecules, which we expect to commercialize over the second half of this decade. In FY21, our Net R&D spends were ~10% of annual revenues.

Biocon Biologics Management and Research & Development leadership invested in evolving robust processes and "future ready" technology that ensured business continuity and safety of employees while delivering on many key product approvals in FY21.

Replacing paper-based processes with electronic workflows helped improve efficiency, collaboration, compliance and data security.

A highly motivated team of scientists drove the momentum towards achieving organizational objectives through sustained efforts on all fronts in order to manage and advance the Company's pipeline of biosimilars.

The technical diligence of the Research & Development team resulted in successful regulatory approvals in EU for the bBevacizumab and bAspart.

Equipment installation and qualification of our newly established 60,000 sq. ft., state-of-the-art biologics development facility at TICEL Bio Park in Chennai was completed successfully during the year. The facility, which has end-to-end capabilities from cell line development to pilot scale, will support the development of our growing pipeline of biosimilar mAbs.

Incisive IP Strategy

Biocon Biologics also worked on developing and implementing a robust in-house Intellectual Property (IP) strategy designed to constrain key patents and enable early market penetration of next-in-line molecules. By invalidating certain patents covering Insulin Glargine, we accelerated the route to market for *Semglee*, making it accessible to millions of patients across the U.S. We also obtained process patents as well as trademarks for other biosimilar products in multiple jurisdictions during FY21.

Clinical Development & Medical Affairs

As an innovation-led global biopharmaceutical organization, Biocon Biologics repurposed its first-in-class, anti-CD6 monoclonal antibody, Itolizumab, to treat moderate to severe ARDS (acute respiratory distress syndrome) by preventing and treating the Cytokine Release Syndrome (CRS) in COVID-19 patients. Itolizumab, a novel biologic with a unique mechanism of action, is an approved and in-market drug that has been available in India for treating plaque psoriasis since 2013.

Biocon conducted a multi-centric, open label, randomized, controlled trial to study the efficacy and safety of Itolizumab in COVID-19 complications at four top public health institutions and medical colleges in Delhi and Mumbai under strict GCP standards.

We conducted the Phase 2 trial in accordance with a comprehensive plan, which outlined the types of patients who could enter the trial, the schedule of tests and procedures, drugs and dosages, necessary follow up and the length of the study. The trial also described the endpoints that would be measured and the type of information to collect, which we then shared with regulatory authorities to obtain approval. The clinical trial was designed to answer certain questions, while taking steps necessary to safeguard the patients taking part.

In July 2020, the Drugs Controller General of India (DCGI) issued a 'Restricted Emergency Use' approval for Itolizumab in the treatment of CRS in moderate to severe ARDS patients due to COVID-19, based on the results of the Phase 2 study. Itolizumab received label extension approval for restricted emergency use in additional indication in COVID-19.

Repurposed Itolizumab addressed an area of unmet need, providing doctors with a safe, effective treatment option that is saving lives and helping reduce the mortality rate in our country.

Going Digital

A digital platform using various digitization tools was deployed to manage ongoing clinical trials in the midst of the pandemic. eConsent used in Phase 4 of the Itolizumab study enabled patients or caregivers to provide consent remotely. It empowered patients to take informed decisions through interactive multimedia engagement. The platform also enabled remote monitoring of the trial.

An Electronic Trial Master File system, which allows for real-time management of all Trial Master File documents and processes and helps sponsors, CROs and sites work together to accelerate trials, is also being implemented.

Unquestioned Commitment

During COVID-19 pandemic, we went the extra mile to support Patients, Caregivers, Health Care Professionals, our Partners and Customers. We remain steadfast in our commitment to serve patients and enhance global healthcare throughout the pandemic.

Partners

Rajiv Malik

President,Viatris

One of the most critical components of the Viatris and Biocon collaboration over the past year has been open and transparent communication. When physical borders started to quickly close in early 2020, we knew our top priority needed to remain the same – providing a reliable supply of biosimilar treatments to patients in need.

We're proud to say that we have been able to deliver on this goal by finding new ways to stay virtually connected, meeting more frequently through video calls and remaining nimble to provide additional support and resources to those impacted by COVID-19 including our own colleagues and their families around the world. Together we have been able to overcome many unprecedented challenges to meet patient needs. Thank you to the entire Biocon team for being a strong, committed and steadfast partner to ensure access to biosimilar medicines during these challenging times.

Wilfredo Colunga

Oncology Division Manager, Abbott EPD – Perú

The Peruvian Government considers that cancer care must be comprehensive and that it is essential to improve access to safe, effective and quality medicines. In this regard, Abbott and Biocon took on the challenge of improving breast cancer patients' access to high-cost, life-saving treatment, making it more affordable. The entry of BISINTEX (Trastuzumab) in Peru, allowed the State to save 2.9 million dollars, guaranteeing accessibility to patients who are part of the National Plan for the Prevention and Control of Breast Cancer, these resources were used in the fight against COVID-19.

Alcebíades de Mendonça Athayde Junior

Executive President, Libbs Farmaceutica, Brazil

Times like the one we are living show the importance of relationships based on ethics, in the commitment and respect to people. Since the beginning of COVID-19 pandemic, Libbs has been searching for technical alternatives, with scientific basis, for the reduction of virus transmission among its collaborators and to prevent the lack of drugs for those who need them. And it is the same commitment with the patients that we expect from our partners.

Over three years, Biocon has been a great partner of Libbs and, in a time when canceled flights and closed airports could compromise the supply of *Zedora* (Trastuzumab) to thousands of Brazilian patients, it was not different. We knew that we could, once again, count on Biocon efforts to get around this issue. Transparency, readiness in decision-making, and agile communication have been constant between the companies in order to ensure the access to patients to what they have the right to, their treatment. And it is this trust that reinforces our belief in the strengthening of our partnership in the long term.

Nakkiran Saravanakumar

Director, Innogene Kalbiotech, Philippines

Biocon has provided excellent services in supporting us to face the market dynamics and challenges in this pandemic era. We really appreciate how they are so accessible & committed. They have been working so hard to provide punctual product delivery despite of current circumstances. Our mutual and long-term partnership reflects the value of good collaboration, openness and innovation.

Nagesh NC

Director, R&D, Herbalife India

The Syngene team did a great job in completing all projects on schedule helping us launch new products despite the COVID-19 situation. Thanks to Syngene, we launched five new products this year: Skin Booster, ShakeMate, F1 Banana Caramel, Brain health & Immune Health.

Scientific Publications

Biocon Biologics featured in key scientific publications and peer-reviewed journals during FY21.

Two critical publications on Itolizumab, our novel mAb, have been published in the *Expert Opinion on Biological Therapy*, including a mini-review (Loganathan et al 2020) and results of the Phase 2 study (Kumar et al, 2021). A mini review titled 'Itolizumab, an anti-CD6 monoclonal antibody, as a potential treatment for COVID-19 complications' garnered ~6,500 views and is on *EoBT's* list of most-read articles. The review has been cited six times and has a high Altmetric Attention Score of 50.

The publication of Itolizumab's Phase 2 clinical study results show the efficacy and safety of the drug in treating moderate to severe acute respiratory distress syndrome (ARDS) due to cytokine release in COVID-19 patients. In this multi-centric, open-label, two-arm, controlled, randomized study Itolizumab has come across as a promising, safe and effective immunomodulatory therapy for treating COVID-19 patients, with survival and recovery benefits.

Emerging real world evidence (RWE) has fast substantiated the immunomodulatory role of Itolizumab in management of COVID-19 complications (Gore et al 2021; Thacker et al 2021a, 2021b, 2021c). A single dose of Itolizumab accelerated recovery in 25 adult patients with COVID-19 by controlling immune hyperactivation. Clinical improvement was demonstrated through reduction in inflammatory markers, weaning-off from oxygen, reduced length of hospital stay and improvement of ordinal score (Gore et al, 2021). Another instance of RWE showed that Itolizumab reduced inflammatory markers and improved oxygen saturation levels in 27 ARDS patients. Further, Itolizumab accelerated recovery time in hospitalized patients with no serious adverse events and no mortality (Thacker et al 2021).

A study of RWE for bTrastuzumab by a team from Christian Medical College, Vellore, India (Joel et al 2021) was published in the e-CANCER journal. The data generated so far, largely, had been in a metastatic setting and this is the first data in early breast cancer showing comparable pathological complete response rates. This is also the first of its kind RWE of any bTrastuzumab in a neo-adjuvant setting with data compiled over three years.

List Of Citations In FY21

Authors	Subject	Publication
ITOLIZUMAB		
Gore V, Kshirsagar DP, Bhat SM, Khatib KI, Mansukhani B.	Itolizumab Treatment for Cytokine Release Syndrome in Moderate to Severe Acute Respiratory Distress Syndrome Due to COVID-19: Clinical Outcomes, A Retrospective Study.	J Assoc Physicians India. 2021 Feb;69(2):13-18. PMID: 33527804.
Thacker HP, Dhekane A, Wadhwa N, Patil S. I.	Itolizumab in addressing symptoms of acute respiratory distress syndrome (ARDS) with weaning off oxygen requirements in a COVID-19 patient: A case study.	IP Indian Journal of Immunology and Respiratory Medicine 2021;6(1):58–61
Thacker HP, Halnor D, Dhekane A, Wadhwa N, Patil S, Gandhi B, Nimbolkar J, Avhad A.	An early experience of Itolizumab with best supportive care in the treatment of moderate to severe COVID-19 patients: A retrospective study.	IP Indian Journal of Immunology and Respiratory Medicine 2021;6(1):24–28
Thacker HP, Dhekane A, Wadhwa N, Patil S.	Anti-CD6 humanized monoclonal antibody itolizumab, halts disease progression and severity of acute respiratory distress syndrome in COVID-19 disease: A case study.	Indian Journal of Respiratory Care. 2021 Jan 1;10(1):112.
Loganathan S, Athalye SN, Joshi SR.	Itolizumab, an anti-CD6 monoclonal antibody, as a potential treatment for COVID-19 complications.	Expert Opinion on Biological Therapy. 2020 Sep 1;20(9):1025-31.
Kumar S, de Souza R, Nadkar M, Guleria R, Trikha A, Joshi SR, Loganathan S, Vaidyanathan S, Marwah A, Athalye SN.	A two-arm, randomized, controlled, multi-centric, open-label Phase-2 study to evaluate the efficacy and safety of Itolizumab in moderate to severe ARDS patients due to COVID-19.	Expert Opinion on Biological Therapy 2021 (In press)
TRASTUZUMAB		
Anjana J, Thomas GJ, Divya Bala T, Oommen JA, Raju Titus C, Grace R, Elanthenral S, Jagan C, Marie Therese M, Anish Jacob A, Deepak Thomas A, Jacob Paul M, Patricia S, Selvamani B, Ashish S	Neoadjuvant chemotherapy with biosimilar trastuzumab in human epidermal growth factor receptor 2 overexpressed non-metastatic breast cancer: patterns of use and clinical outcomes in India.	ecancer 15 1207. https://doi.org/10.3332/ecancer.2021.1207

Expanding Manufacturing Capacities

Despite a national lockdown, Biocon Biologics was able to sustain operations at all our plants to meet committed supplies to partners and ensure patients were unaffected. During the nationwide lockdown in India, we faced many challenges and had to adopt innovative planning and implementation strategies to run our manufacturing facilities without compromising on the safety and well-being of our employees.

We progressed well on new projects to expand our mAbs manufacturing capacities to address projected volume growth from increased market shares and to support the development of our biosimilars pipeline.

We also augmented our existing Drug Substance and Drug Product capabilities, which enabled us to expand our capacities multi-fold. We also tied up additional capacity to meet demand for our insulin and insulin analogs. The Manufacturing teams successfully managed to scale up production of Itolizumab through effective planning and execution to ensure timely supplies of *ALZUMAb-L* for treating COVID-19 patients.

In FY21, Biocon Biologics for the first time completed the tech transfer and scale up of a high cell density process using alternating tangential flow (ATF) technology.

New mAbs Facilities in Bengaluru

We completed the qualification process for the first phase of our new mAbs Drug Substance (B3) facility in Biocon Park. At 350,000-

sq. ft., this is one of the largest mAbs manufacturing facilities in India in terms of the built up area of a single building/site. Built at an investment of ~USD 120 million, this is India's first biopharma facility awarded by the International Society for Pharmaceutical Engineering (ISPE) and is on track for commercialization in FY22. When completed the B3 facility would boost our mAbs production capacity substantially.

We also completed qualification of our first single-use mAbs facility (B5) in Bengaluru. Scale-up and manufacturing of our pipeline molecules is ongoing at this 150,000 sq. ft. facility. Both B3 and B5 facilities will support our future growth and drug development pipeline.

Malaysia: Center of Excellence (CoE) for Insulins

In Malaysia, our focus has been to create a Center of Excellence (CoE) for insulins. This CoE achieved two key milestones this year, with the commercialization of bGlargine in the U.S. and the approval of bAspart in EU.

Enabling this CoE is a strong team spanning personnel from the R&D, Manufacturing, Quality, Regulatory and Commercial functions. With the EU approval for bAspart, we are now manufacturing a broad portfolio of regular, basal and rapid insulins end to end at our state-of-the-art insulins facility in Malaysia.

Through our scientifically validated, high quality products manufactured at Malaysia, we are providing affordable access to life-saving insulins to patients in developed markets as well as many emerging markets, including Malaysia.

Through our biosimilar insulin analog portfolio we have enabled the local healthcare system to save over 50% of its spending on diabetes in Malaysia. The Ministry of Health, Malaysia is deploying these savings to expand insulin access to a larger patient population. Over time, we expect to enable substantial savings for people with diabetes across the globe.

Unified Commitment

During COVID-19 pandemic, we went the extra mile to support Patients, Caregivers, Health Care Professionals, our Partners and Customers. We remain unified in our commitment to serve patients and enhance global healthcare throughout the pandemic.

Employees

Devasish Sahoo

Deputy Manager - Generics APIs Maintenance, Biocon Limited

Our team ensured seamless supply of power to entire Biocon site amidst the frequent power failures due to thunderstorms during the COVID–19 pandemic lockdown period.

Vishnu Vardhan V

Deputy Manager - Biosimilars Production - mAbs Drug Substance, Biocon Biologics

As a planning coordinator, I undertook the herculean task of resource planning and communication for a team of 250 people during the pandemic. I also extended my support to regular QMS for start-up of the B3 facility during these challenging times.

Mohammad Suhail

Assistant Manager - Generic Formulations, Biocon Limited

By putting in extended hours and odd hour availability at work, I prepared and executed the qualification activity to lock the bottle line conveyor speed for packing validation.

Mohamad Fadzli Bin Mohamed Yassin

Production-Drug Product Packaging, Biocon Malaysia

To ensure business continuity by coordinating with various team members, I ensured all packing activities are completed as per the committed timeframe. This in turn is a firm commitment towards our patients. Along with my supervisor, we took on the duty to assure there are enough members at the shop floor to complete the task at hand and worked as a team for meeting stringent deliverables.

Sadananda Naik

Senior Executive - Operations, Science & Technology Innovation Center, Biocon Biologics

As a part of the in-house preventive maintenance activity for critical equipment, I have taken care of continuous temperature monitoring for more than 90 equipment and preventive maintenance of 30 critical equipment, during the lockdown.

Vinitha K R

Executive, Fill Finish, Packaging Operations, Biocon Biologics

As a team we contributed to the closure of QMS elements like change control, CAPA and annual planer related to visual inspection during the COVID-19 lockdown by personally visiting the plant every single day.

George Thomas P

Associate Scientific Manager-I, SM-API, Biocon Limited

Our entire team has put in extensive efforts in addressing the regulatory queries for vertically integrated synthetic projects. The analytical data required to send response was made available to regulatory science within the timeframe for the filings.

Biocon Biologics Branded Formulations In India

Our Branded Formulations business in India continues to make a significant impact through a wide portfolio of branded biosimilars, novel biologics and specialty products in chronic and acute disease segments such as diabetes, cancer, end-stage renal illnesses, immune disorders, and other life-threatening conditions.

Given our patient-centric focus, our teams remained committed to providing high quality, life-saving medicines even during adverse times like this pandemic. This year, we saved several thousand lives of COVID-19 patients through our repurposed Itolizumab, *ALZUMAb-L*.

Committed to Serve Patients

The team employed innovative solutions to support physicians and ensure patients continued to receive our insulins, cancer therapies and other essential drugs. Despite supply issues and COVID-related disruptions, we could touch the lives of ~1.7 million patients in India across therapies in FY21.

Our comprehensive COVID-19 portfolio addressed the needs of patients at different stages of the disease spectrum -- mild, moderate, severe and critical. The portfolio included *ALZUMAb-L* (Itolizumab), *RemWin* (Remdesivir), *ARAFLU* (Favipiravir) and *CytoSorb*. We set up helplines for patients and our field staff worked diligently to facilitate medicine supplies.

Over 16,000 COVID-19 patients were treated across the country with Itolizumab during the second wave of the pandemic. So far, over 27,000 patients have benefited from Itolizumab (till May 2021). This was made possible due to the unrelenting commitment of various teams across the organization, including the field force, who ensured Biocon's product reached patients.

Key Brands Addressing Patients' Needs

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 bGlargine in the country. *KRABEVA* (bBevacizumab) increased its market share in the ovarian cancer segment. Despite the pandemic we continued to provide Oncotherapy support to a large number of patients. Our range of immunosuppressants catered to ~7,000 post-transplant recipients and ~12,000 patients on dialysis / pre-dialysis to manage anemia.

Our COVID-Care Portfolio

Building Brand Equity

The Branded Formulations business further built on the considerable brand equity it enjoys with doctors and patients by highlighting the Company's strengths in cutting-edge science.

We shared the results of Biocon Biologics' landmark INSTRIDE-3 study for bGlargine among the medical community. The remarkable outcome about the interchangeability of our bGlargine with that of the reference product was communicated to thousands of healthcare professional across the country through a series of webinars as well as the on-ground SWITCH campaign.

We continued our education in diabetes management through our flagship p rograms s uch a s ABIDE, Insulin & CGM workshops as our insulins served close to half a million patients.

To strengthen stakeholder engagement, we transitioned from a 'phygital' to a fully digital communication ecosystem, reorienting to a virtual world. This enabled us to step up our engagement with over 55,000 health care professionals and 250 therapeutic area experts, despite the restrictions imposed by the pandemic.

Digital Initiatives

In FY21, Biocon Biologics progressed towards re-imagining the ways of working with the right set of technologies and innovations to usher in digital transformation within the organization.

We initiated several key digital projects during the year across various functions, including Quality Assurance, Quality Control, R&D, Supply Chain, Manufacturing Operations, Clinical Trial Management and Learning & Development.

We believe this digital transformation will add speed and efficiency to the processes at Biocon Biologics. Digital tools will help reduce human errors, enable easy remote document reviews and approvals, and improve adherence to SOPs (standard operating procedures). Additionally, application of data analytics will provide superior insights for better decision making with an objective of creating a highly patient-centric organization.

Global Biosimilars Pipeline

Therapeutic Areas	Molecule	Product Status: U.S.	Product Status: Developed Markets: ex-U.S	Product Status: MoW^^
Oncology	Pegfilgrastim#		EU, CANZ	
	Trastuzumab#		EU, CANZ	
	Bevacizumab#		EU, AUS	
	Pertuzumab#			
Immunology	Adalimumab*		EU, CA, Japan	
	Etanercept*		EU	
Diabetes	Glargine** 100U#		EU, ANZ, Japan	
	Glargine 300U#		EU	
	Aspart#		EU	
	RHI^			
Undisclosed	7 Assets			

Early Dev./ Preclinical | Clinical | Filed | Approved

#In partnership with Viatris.

**Partner Viatris has in-licensed product (Biocon benefits from economic interest).*

***Japan is outside of Viatris partnership.*

^RHI non-partnered asset completed Ph 1 and considering potential Ph 3 waiver to be confirmed with U.S. FDA advice, shown as Planned submission.

^^MoW represents Most of the World markets. Chart represents the status of the country where the product is in most advanced stage.

Every country has a different status.

CANZ stands for Canada, Australia and New Zealand. CA - Canada, AUS - Australia and NZ - New Zealand.
Status of Biosimilars Portfolio as of May 2021.

Value Unlocking

The valuation of Biocon Biologics has increased by USD 1.2 billion over the last 12 months. The first private equity infusion USD 75 million by Activ Pine LLP, an affiliate of True North Fund, had valued the Company at USD 3 billion on a pre-money basis in January 2020. In FY21, we received additional investments of USD 255 million from Tata Capital Growth Fund, Goldman Sachs and ADQ. In July 2020, Tata Capital Growth Fund invested ~USD 30 million for a 0.85% stake in Biocon Biologics at an equity valuation of ~USD 3.5 billion. Goldman Sachs issued Optionally Convertible Debentures (OCDs) worth ~USD 150 million at a post-money equity valuation of USD 3.94 billion. Abu Dhabi-based ADQ invested ~USD 75 million for a 1.80% stake, valuing Biocon Biologics at a post-money valuation of ~USD 4.17 billion. Biocon Limited will hold an 89.89% stake in Biocon Biologics on a fully diluted basis after completion of these transactions.

Braving The Storm

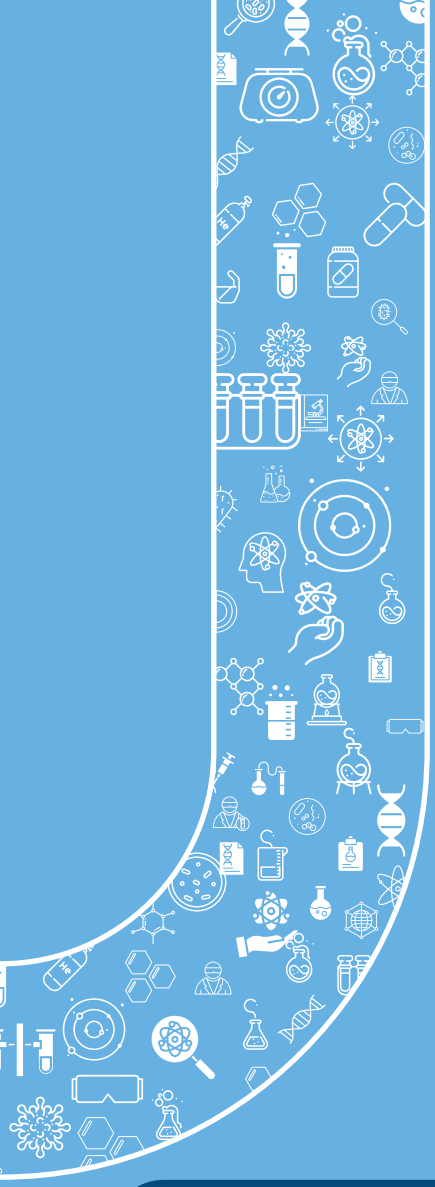
Though FY21 was a challenging year on many fronts, we steered through it on the collective strength of our people, our partners, and our unwavering commitment to serve patients. Our agility in making decisions and flexibility in rescheduling operations and embracing technology enabled business continuity. While a large section of the employees from the Production, R&D, Quality and Engineering functions reported for work at various sites, a significant number of people worked from home with complete dedication to their goals, thus fully enabling our business operations.

While we had recovered from the first wave of the pandemic with little impact, uncertainties with the second wave continue to pose new challenges with an expected impact in the near term. So far, we have not seen any major impact on our operations, but we are closely tracking the evolving situation. We have initiated a vaccination drive for all our employees and their family members.

Outlook

While becoming increasingly competitive, the biosimilar market continues to offer attractive opportunities for vertically integrated players like us. We expect to continue the momentum and improve market share for our current commercial products and expect to launch bBevacizumab and bAspart in some developed markets in FY22. We also expect to make good progress on the development of our robust R&D pipeline.

We believe that we are well-positioned to grow our Biosimilars business globally on the back of our robust business fundamentals, scientific knowhow, low-cost manufacturing setup, early-mover learnings, and a broad product portfolio. We are confident that we will continue to expand access to millions of patients across the world.



Unmistakable Commitment

During COVID-19 pandemic, we went the extra mile to support Patients, Caregivers, Health Care Professionals, our Partners and Customers. We remain steadfast in our commitment to serve patients and enhance global healthcare throughout the pandemic.

Employees

Esha Bagi

Assistant Manager - Operations, Biocon Biologics

As part of the upstream operations team for mAbs at B1 for biosimilars - Trastuzumab and Bevacizumab, I undertook the role of inoculum generation till the final production scale manufacturing. Despite the limited manpower, we as a team ensured that the operations ran as per regular schedule without any loss of a batch along with the smooth progress of Process Validation for the newly commissioned bioreactors.

Harihara Moorthy K

Deputy Manager - Operations, Insulin Production, Biocon Biologics

I along with my team ensured business continuity by accepting the challenges posed by the COVID-19 pandemic and planning well by 'expecting the unexpected' in critical circumstances. We adopted the model of maximum utilization of available resources to achieve the strategic objectives while simultaneously ensuring our team's safety.

Mayura Hegde

Associate Manager – Generics - APIs, Biocon Limited

Our Team ensured continuity of manufacturing operations by efficiently managing manpower availability to achieve our production targets and I personally ensured that every team member traveled comfortably & safely amidst the lockdown.

Anita Rao

Principal Scientific Manager – R&D, Biocon Biologics

The COVID-19 crisis tested the resilience of the R&D team, that had to complete multiple Biologics License Applications (BLAs), as well as respond to another molecule dossier. Despite thin staffing to ensure people's safety, the scientists at the bench learned to work smart. We used available online collaboration tools to meet each of our quality benchmarks while completing all deliverables on time.

When information requests started arriving from the U.S. Food and Drug Administration, we took on the increased workload, rethought procurement and thrived in the face of adversity. The entire analytical team's heroic efforts paid off as we were able to successfully respond to all information requests from the regulators.

Saravanan P

Senior Executive, Operations – GPP Production, Biocon Biologics

I undertook additional responsibilities of my teammates who could not be on-site and ensured autoclave requalification without any delays. To ensure a seamless production and dispatch of our products for serving our patients during the pandemic, our team made sure the pilot plant manufacturing facility, quality management system tasks, and equipment re-qualifications were on time.

Muthuvel I

Deputy Manager - Generics - APIs, Biocon Limited

I contributed by ensuring the availability of the raw materials, timely preparation and approvals of U.S.FDA CAPA related documents in conjunction with QA, PETT, and R&D. I also collaborated with the EHS team for distribution of masks, zoning badges, etc. and helped the pandemic response team during the lockdown.