

# Meta morphosis **Biocon 5.0**

**ANNUAL REPORT 2022** 

## Meta in morphosis

The metaverse, which will encompass a set of interconnected virtual worlds, is going to radically transform every aspect of the human experience. This collective vision of the future, where digital innovation and human interaction intersects, presents an immense innovation opportunity for the healthcare sector. The convergence of powerful technological platforms will give birth to disruptive new healthcare ecosystems with the potential to lower costs, widen access and vastly improve patient outcomes.

## **Biocon 5.0**

With the metaverse poised to reshape the world, enterprises will need to undergo the kind of metamorphosis that prepares them to thrive in this brave new future.

This organizational metamorphosis will be multi-dimensional, from acquiring and integrating new skills to creating a culture of continuous innovation, from achieving operational excellence to increasing risk taking agility, from reimagining business models to digital reinvention. The focus of organizational metamorphosis will be on ensuring sustainable performance across operational, financial, environmental, societal, governance and humanitarian facets of our enterprise.

Biocon is an organization that thrives on change. Since our foundation in 1978, we have witnessed a transformational event every decade, enabling us to expand our business and unlock value across segments. From our founding business of enzymes, we gradually evolved into a company making fermentation-based small molecule generics, followed by a rapid metamorphosis into a diversified biopharmaceuticals group with businesses spanning bulk drugs and finished formulations at our Generics vertical, novel biologics and biosimilars at Biocon Biologics, and research services at Syngene.

FY22 marks the beginning of a process of accelerated transformation that will not only take us closer to patients but also steer us into new growth paths. It heralds the emergence of Biocon 5.0 – a technology-enabled, future-ready biopharmaceuticals leader and a well-recognized, global brand, touching a billion lives.

## The Emergence of **Biocon 5.0**

## **Biocon 3.0**

Working Towards Health Equity

## **Biocon 2.0**

Evolving from Enzymes to Research Services to Biopharmaceuticals

## **Biocon 1.0**

Innovating Enzyme Technologies

## Biocon 5.0

Building a Company of the Future

## **Biocon 4.0**

Building Scale for Global Impact



**Biocon 1.0** Innovating Enzyme Technologies

### Biocon started in 1978 as a joint venture with an Irish biotech company to manufacture and export enzymes for the brewing industry globally through its partner.

Subsequently, we developed a solid-state fermentation technology for producing novel bio-enzymes for global customers in the food and pharmaceutical industries. Our focus on innovation led us to develop PlaFractor technology using a unique bioreactor which allowed us to acquire our first patent. We progressed to develop other proprietary fermentation technologies, such as a Pichia pastoris yeast based expression system, for producing a range of specialty enzymes. These enzymes were a new technological intervention to replace polluting chemical processes with eco-friendly enzymatic bio-processes in textiles, paper, leather and starch processing industries. In 1989, Unilever Plc acquired our Irish partners and made Biocon India a part of the Unilever system, allowing us to professionalize rapidly by adopting international best practices. The association with this global conglomerate enabled us to build world-class manufacturing capabilities and a strong guality culture. We also learnt the nuances of building intellectual property. We became the first life sciences company in India to get the ISO 9001 Certification from RWTUV, Germany in 1993. Biocon in its first avatar was an export-driven enzymes company supplying to customers worldwide.

BIOCON WAS LARGELY AN EXPORT-DRIVEN ENZYMES COMPANY SUPPLYING TO CUSTOMERS WORLDWIDE.



## Biocon 2.0

**Evolving from Enzymes** to Research Services to **Biopharmaceuticals** 

### Biocon had attained leadership in a variety of specialty enzymes by the Nineties.

As the enzymes business grew steadily, we explored the opportunity of starting another business that would emulate the success of India's information technology (IT) services model. We set up a new subsidiary, Syngene, as a 'pure play' research services company catering to the R&D needs of the global pharmaceutical industry. We then applied our recombinant technologies for enzymes to biopharmaceuticals, starting with our proprietary fungal solid-state fermentation technology to produce statins. We used our microbial fermentation platforms to develop immunosuppressants and harnessed our proprietary yeastbased platform to develop the world's first Pichia pastorisderived recombinant human Insulin. This heralded our entry into biopharmaceuticals. Going beyond insulins, we ventured into developing monoclonal antibodies. The combination of research services and biopharmaceuticals made Biocon a unique and diversified biotechnology enterprise.

GOING BEYOND INSULINS, WE VENTURED INTO DEVELOPING MONOCLONAL ANTIBODIES.



**Biocon 3.0** Working Towards Health Equity

### As early movers in the domain of biologics, we realized that patients in most of the developing world could not afford these advanced therapeutics.

This catalyzed our early entry into biosimilars. We wanted to bring in competition for expensive innovator biologics through our biosimilars for diabetes and cancer. However, the long gestation period for development and the capital intensity of creating new capacity for biosimilars entailed effective management of scientific and regulatory uncertainty and financial risk. To fuel our mission, we unlocked value through an IPO in 2004 and divested our enzymes business in 2007. To bring in complementary skills and experience as well as share risks and rewards, we entered into a global partnership with Mylan (now Viatris) for a range of biosimilar antibodies and insulin analogs. Biocon was aligned to the global imperative of driving greater health equity through its diversified and differentiated pipeline of fermentation-derived complex generics, biosimilars that included insulins & monoclonal antibodies, and novel biologics.

TO FUEL OUR MISSION, WE UNLOCKED VALUE THROUGH AN IPO IN 2004 AND DIVESTED OUR ENZYMES BUSINESS IN 2007.



**Biocon 4.0** Building Scale for Global Impact

### To benefit from our first-mover advantage, we embarked on building global scale and credibility.

We invested in cutting-edge R&D and commercial scale, globally compliant manufacturing facilities across diverse technology platforms spanning insulins, monoclonal antibodies and conjugated recombinant proteins. We established global credibility as a serious biosimilars player through several ground-breaking achievements, starting with the Indian approval for the world's first bTrastuzumab in 2014 and the Japanese approval for bGlargine in 2016. We were the first in the world to obtain U.S. approvals for bTrastuzumab in 2017 and bPegfilgrastim in 2018. Our investments in building global scale have led us to rank among the world's Top 15 biomanufacturing companies. We are among the leading insulin producers worldwide and have one of the largest antibodies manufacturing capacities in South Asia. Our Generics business forward integrated into formulations for our differentiated APIs to capture a bigger share of the value through a direct commercial presence in U.S. and Europe. Syngene's emergence as India's leading contract development and manufacturing company (CDMO) triggered its successful public listing in 2015.

> OUR INVESTMENTS IN BUILDING GLOBAL SCALE HAVE LED US TO RANK AMONG THE WORLD'S TOP 15 BIOMANUFACTURING COMPANIES.



## **Biocon 5.0**

Building a Company of the Future

Having emerged as one of the leading global biopharmaceutical companies with consolidated revenues of USD 1.1 billion and a ~15,000-strong workforce, we have started building an organization of the future. We are building Biocon into an innovative and trustworthy global brand. We are leveraging our scale and cost advantages to gain world leadership. We are creating a business with impeccable quality compliance, world-class ethics and a robust corporate governance structure. We are harnessing digital and data analytics to get closer to patients, as well as reach a larger patient population. Each of our three business segments, Generics, Biosimilars and Research Services, is well positioned for future growth.

> The acquisition of Viatris' biosimilars business by our subsidiary Biocon Biologics will create a fully, vertically integrated biosimilars company with a direct commercial presence in the developed and emerging markets. The strategic alliance with Serum Institute Life Sciences provides us an 'asset-light' and accelerated entry into vaccines. These strategic developments will catapult us to a higher growth orbit, setting us up for significant value unlocking through Biocon Biologics' future IPO.

> Our Generics business is scripting the next leg of its growth story through portfolio and geographical expansions, capacity additions, improved cost competitiveness and operational excellence.

Syngene is moving beyond a traditional research services outsourcing model expediting innovation for its customers towards true end-to-end discovery, development and manufacturing collaborations. It is building expertise in immuno-oncology, CAR-T, mRNA and small interfering RNA (siRNA) platforms for researching next-generation therapies.

> IN OUR BIOCON 5.0 AVATAR, WE ENDEAVOR TO FOCUS ON CONSCIOUS CAPITALISM, ENVIRONMENTAL STEWARDSHIP, DIVERSITY, EQUITY & INCLUSION, COMPLIANCE & GOVERNANCE AND PATIENT-CENTRICITY. WE ARE BUILDING A TECHNOLOGY-LED, ESG-CONSCIOUS COMPANY THAT WILL CREATE EXPONENTIAL AND ENDURING VALUE FOR ALL OUR STAKEHOLDERS WHILE IMPACTING HUMANITY IN PROFOUND WAYS.

## FY22 at a Glance



\* Includes exceptional items

#### **Business Segment Revenue**<sup>#</sup>



## CHAIRPERSON'S MESSAGE

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#### Kiran Mazumdar-Shaw

Executive Chairperson Biocon Limited & Biocon Biologics Limited

## Metamorphosis: Biocon 5.0

#### Dear Shareholders,

Biocon's pioneering journey of over four decades in biotechnology has an underlying theme of metamorphosis. From enzymes to biopharmaceuticals, from research services to integrated drug development and from active pharmaceutical ingredients (APIs) to finished formulations, the evolution has sustained and is now accelerating to an inflection point of transformational advancement. Biocon 5.0 denotes our fifth decade which is poised for breakthrough growth derived from two decades of investing in advanced scientific research and global-scale bio-manufacturing. Each of our businesses is uniquely differentiated and has attained a leadership profile that prepares us for an exciting future.

Our endeavor to build global health equity through affordable access to essential and lifesaving therapeutics has brought in a patient-centric focus in all that we measure. From a fledgling biotech company in 1978, we are today among the largest in Asia with ~15,000\* employees and consolidated revenues of USD 1.1 billion.

Biocon is exclusively positioned with three distinctive and diverse businesses that balance the headwinds of one business with tailwinds in others. Pricing pressure on generics, for example, is mitigated with preferential pricing both from contract manufacturing and market exclusivity.

Our relentless strategic intent to stand out and stand apart through research and innovation has steered us into new growth paths that include a mega acquisition and multiple new investments that will generate both inorganic and organic growth momentum in the decade ahead.

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EACH OF OUR BUSINESSES IS UNIQUELY DIFFERENTIATED AND HAS ATTAINED A LEADERSHIP PROFILE THAT PREPARES US FOR AN EXCITING FUTURE.

#### **A Transformative Acquisition**

Our landmark decision to acquire the global biosimilars business of our longterm partner Viatris for USD 3.335 billion in cash and stock, is a transformational inflection point that steers us into accelerated, inorganic business expansion.

This game-changing transaction will create a world leader in a space that is extremely attractive for investors. Biologic brands worth over USD 70 billion<sup>^</sup> will lose exclusivity over the next five years, presenting multiple new opportunities for the biosimilars sector.

This acquisition by Biocon Biologics will enable the Company to seamlessly move from the current collaboration model to full ownership of Viatris' rights in partnered and in-licensed biosimilars assets, allowing recognition of 100% of revenues and profits. Furthermore, it will enable full vertical integration across the biosimilars value chain from lab to market and take us closer to patients, payors and healthcare providers in developed and emerging markets.

The deal is a strategic fit for Biocon Biologics and valued fairly. By giving us visibility on the growth trajectory of our Biosimilars portfolio over the next decade, this deal is going to be highly value accretive to both Biocon and Biocon Biologics shareholders. Viatris' biosimilar business is expected to generate over USD 1 billion in revenue in calendar year 2023.

#### **Foraying into Vaccines and Infectious Diseases**

Biocon's quest to impact global healthcare has steered us towards a strategic expansion into adjacencies such as vaccines.

Biocon Biologics has entered into an alliance with Serum Institute Life Sciences (SILS) to join the effort of addressing the inequitable access to vaccines.

We expect a very attractive return on investment from this strategic transaction.

#### **Strong Biosimilars Business Performance**

Prudent investments over the years in advanced R&D and global manufacturing scale have led Biocon Biologics to build a unique biosimilars portfolio comprising basal and rapid acting insulins, as well as antibodies for cancer and inflammatory diseases.

The performance of our portfolio of commercialized biosimilars in both developed and emerging markets yielded a 24% growth in our Biosimilars business revenues this year.

The highlight of the year was the historic approval of the world's first interchangeable biosimilar, our bGlargine, in the U.S. The launch of our interchangeable bGlargine in the U.S. by our partner Viatris is in line with our



THE VIATRIS DEAL IS GOING TO BE HIGHLY VALUE ACCRETIVE TO BOTH BIOCON AND BIOCON BIOLOGICS SHAREHOLDERS.

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THE HISTORIC APPROVAL OF THE WORLD'S FIRST INTERCHANGEABLE BIOSIMILAR, OUR bGLARGINE, IN THE U.S. WAS A KEY HIGHLIGHT OF FY22.

aspiration to provide our biosimilar insulins to 'one in five' insulin-dependent people with diabetes, globally. Post this launch, the market share of our bGlargine in the U.S. has moved up from a low single-digit share last year to a double-digit market share in March 2022.

As we commemorate 100 years of the discovery of Insulin, we are positioning ourselves to build global leadership through unlocking equitable access to insulin and meeting varied patient needs through our comprehensive portfolio.

We have also focused on best-in-class therapies for cancer patients worldwide through our biosimilars such as bTrastuzumab, bPegfilgrastim and bBevacizumab. Our bTrastuzumab, which was the first to receive U.S. FDA regulatory approval in the world, continued to witness good demand in both developed and emerging markets. We commercialized our bBevacizumab in selected European markets during the year to bolster our oncology franchise.

#### **Saving Lives During the Pandemic**

At the height of the pandemic, we were able to realize the potential of biotherapeutics in the fight against COVID-19 induced cytokine storm. Our repurposed novel biologic ALZUMAb-L (Itolizumab) has benefited over 40,000 COVID-19 patients so far.

#### **Good Progress in Generic Formulations**

Our investments in our Generics business have translated into new DMF and ANDA filings as well as approvals globally, which led to our first 'Day 1' launch in the U.S. for generic Everolimus 10 mg tablets. We also have made steady progress in establishing a strong global footprint for our Generics business during the year.

We continue to build a strong pipeline of niche formulations such as injectables, as well as peptides and potent APIs. A key element of our investment is a large greenfield fermentation-based manufacturing plant, largely for immunosuppressants, in the Visakhapatnam SEZ that will be operational in FY23.

We believe our API business stands to benefit from the 'China Plus One' strategy at a time when pharma MNCs are trying to diversify their supply chains to include sourcing from India to mitigate their dependence on China.

#### A Strong Year for Research Services

Our Research Services business, Syngene, which delivered a revenue growth of 19%, is well poised to capture opportunities arising from the growing global demand for CRO and CDMO services through its offering of integrated research, development and manufacturing services. Syngene is leveraging its existing relationships to provide forward integration on the discovery and

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OUR REPURPOSED NOVEL BIOLOGIC ALZUMAb-L (ITOLIZUMAB) HAS BENEFITED OVER 40,000 COVID-19 PATIENTS SO FAR.

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THE GENERICS BUSINESS MARKED ITS FIRST 'DAY 1' LAUNCH IN THE U.S. WITH THE COMMERCIALIZATION OF GENERIC EVEROLIMUS 10 MG TABLETS.

development continuum by catering to its clients' requirements for earlystage, late-stage and commercial launch supplies.

Syngene extended its long-standing research collaboration with Amgen this year. These contract extensions confirm the stability of the relationship with both key clients and provide a very clear perspective on the future of Syngene's Dedicated Centers.

To capture a higher share of biologics manufacturing opportunities, Syngene is also investing in expanding both microbial and mammalian manufacturing capacities.

#### **Embedding ESG at the Core of our Business**

At Biocon Group, our key priorities of 'patient centricity' and 'access to all' drive our strategy and the way we operate. Our philosophy of ensuring health equity resonates with our Environmental, Social and Governance (ESG) aspirations, which have assumed a greater prominence in our business objectives. By serving patients, protecting the environment and promoting business integrity, we are reinforcing our commitment to building a sustainable future. Our recent entry in the prestigious Dow Jones Sustainability Index (DJSI) Emerging Markets Index, where we achieved a 93rd percentile position with a Total Sustainability Score of 45, is a testimony to our responsible and sustainable business practices.

We were also certified by Great Place to Work® India as a Workplace with Inclusive Practices, acknowledging our investment in our people and our inclusive culture. We are refining our policies and increasing career opportunities for women to improve gender diversity at the Group, where women currently constitute 21% of our workforce.

As a Group, we believe that health equity is synergistic with restoring the ecological balance. This belief is driving us in continuously identifying opportunities to increase the share of renewables in our energy mix, improving energy efficiency, innovating to drive productivity across our value chain, implementing the principles of a circular economy and adopting digital solutions that minimize inefficiencies. Onsite solar installations and sourcing of power from renewable sources have increased the share of 'green power' to 54%\* of our total energy consumption for FY22 across Biocon Group. We reduced our total carbon footprint by 186,500\* tCO2 during the year. Through our water conservation initiatives across the global manufacturing operations of Biocon and Biocon Biologics we achieved 680,000 liters of incremental water savings per day.

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OUR RECENT ENTRY IN THE DJSI EMERGING MARKETS INDEX, WHERE WE ACHIEVED A 93<sup>rd</sup> PERCENTILE POSITION WITH A TOTAL SUSTAINABILITY SCORE OF 45, IS A TESTIMONY TO OUR RESPONSIBLE AND SUSTAINABLE BUSINESS PRACTICES.

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WE ACHIEVED 680,000 LITERS OF INCREMENTAL WATER SAVINGS PER DAY FROM WATER CONSERVATION INITIATIVES ACROSS THE GLOBAL MANUFACTURING OPERATIONS OF BIOCON AND BIOCON BIOLOGICS.

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<sup>\*</sup>Biocon Group: Biocon + Biocon Biologics + Syngene

#### **Ensuring Sustainable Social Change**

Biocon Group's corporate philanthropy aims to build resilient solutions that enable and empower disadvantaged communities to live better. In FY22, we implemented several initiatives targeted at increasing access to healthcare for underserved communities, improving the nutritional standing of school-age children, promoting science & technology and sponsoring urban afforestation initiatives.

Biocon Foundation supported the Government of Karnataka in the implementation of its 'test, treat, track and vaccinate' strategy at 20 Primary Health Centers across seven districts. We helped strengthen hospital infrastructure by installing a 2,000-liter Liquid Medical Oxygen (LMO) storage tank at the Anekal General Hospital in Karnataka. As a part of our healthcare initiatives, we contributed to the capacity building of frontline health workers and screened over 4,000 people using the mHealth oral cancer screening tool.

Continuing our partnership with the Akshaya Patra Foundation, we contributed to raising the nutrition profile of students in over 70 government schools through the PM Poshan, Mid Day Meal Scheme.

As a part of our environmental outreach program, the Foundation is developing a second Miyawaki micro-forest in Mangaluru.

The Foundation is funding construction of the proposed Biocon-Hebbagodi Metro Station. Metro connectivity will reduce traffic congestion in Bengaluru and help lower the environmental impact from vehicular pollution.

As a part of our commitment to strengthen the medical science ecosystem in the country, the Foundation signed a memorandum of understanding with the Indian Institute of Science to contribute funds for the construction of a notfor-profit, 490-bed multi-specialty hospital and medical school in Bengaluru. This hospital will offer an integrated dual degree MD-PhD program in clinical research. In recognition of the funding support, the General Medicine Block will bear the name of Biocon-Syngene.

Our flagship initiative, Biocon Academy, which aims to build the talent ecosystem for biotech-related skills, saw over 180 young life sciences students graduate this year.

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BIOCON FOUNDATION HELPED STRENGTHEN HOSPITAL INFRASTRUCTURE BY INSTALLING A 2,000-LITER LIQUID MEDICAL OXYGEN STORAGE TANK AT THE ANEKAL GENERAL HOSPITAL IN KARNATAKA.



BIOCON ACADEMY, WHICH AIMS TO BUILD THE TALENT ECOSYSTEM FOR BIOTECH-RELATED SKILLS, SAW OVER 180 YOUNG LIFE SCIENCES STUDENTS GRADUATE THIS YEAR.

#### A Technology-Enabled Organization for the Future

The digital transformation journey we embarked on in 2020 was further accelerated as we maneuvered through the COVID-19 pandemic.

The significant investments we are making in organization-wide digital transformation initiatives are going to transform the Biocon Group into a data and digital-led global biopharmaceuticals organization, spearheading Biocon 5.0. Digitalization, we firmly believe, can build higher standards of governance and deliver greater levels of trust to all our stakeholders.

#### **Good Financial Performance**

Biocon's consolidated revenues grew 14% to ₹83,967 million for the full year, led by Biosimilars and Research Services revenues increasing 24% and 19%, respectively. For the year, the Biosimilars business posted revenue of ₹34,643 million, Generics reported ₹23,409 million and Research Services turned in ₹26,042 million. Our EBITDA increased 14% to ₹21,829 million for the year, representing a healthy margin of 26%. Adjusted for licensing, forex, gain on dilution in Bicara, mark-to-market loss on investments and R&D expense, Core EBITDA for the year grew 18% to ₹26,690 million, representing a margin of 32%. Our Net Profit for the year was ₹6,484 million. Net Profit was impacted on account of certain exceptional items, mark-to-market losses on investments and gain on dilution in Bicara. Adjusted for these items, Net Profit grew by 23% for the full year.

#### **Management & Board Updates**

We have appointed Naina Lal Kidwai, an accomplished banker and business leader, as an Additional Director on the Board of Biocon Limited, with effect from April 28, 2022 for a period of three years. We also appointed Dr. Eric Mazumdar as a Non-Executive Director to the Board, with effect from November 1, 2021.

I would like to express my deep appreciation and gratitude to John Shaw for his stewardship and judicious guidance as a key member of the Board and the management team since 1999. He has contributed significantly to the transformation of Biocon from a small enzymes company to a globally recognized biopharmaceutical enterprise. He has played a critical role in building Biocon, ensuring the highest levels of corporate governance, as well as contributing to the financial and strategic development of the Group in his role as Vice Chairman for over two decades.



BIOCON'S CONSOLIDATED REVENUES GREW 14% TO ₹83,967 MILLION FOR THE FULL YEAR, LED BY BIOSIMILARS AND RESEARCH SERVICES REVENUES INCREASING 24% AND 19%, RESPECTIVELY.





#### Dividend

The Company and its Board of Directors acknowledge with deep appreciation, the support received from the shareholders during the pandemic over the last two years. As we come out of the pandemic with a strong financial performance, the Board of Directors has recommended a dividend of 10% of the face value of each share for FY22.

#### **Ushering in Transformative Change**

We have demonstrated a clear commitment to the highest standards of corporate governance as we pursue our purpose and deliver on our promise to protect patients from both communicable and non-communicable diseases. We have invested with a clear focus on efficiency and end-to-end digital transformation, coupled with ambitious targets in exciting new growth avenues, namely, a comprehensive portfolio of generic formulations, complex APIs, biosimilars, vaccines and research services.

The year ahead holds tremendous promise for all our business segments. We expect strong growth from our Biosimilars business on the back of the strategic transactions with SILS and Viatris, which are progressing towards various regulatory approvals. We expect these deals to close by the second half of calendar year 2022.

I would like to appreciate the contribution of our employees, executives and Boards who have worked tirelessly and passionately throughout the pandemic to realize our core purpose of serving patients and partners.

I would also like to thank all our shareholders for trusting our uniquely differentiated Company, over the years. With your unstinted support, we will continue to make progress towards ushering in transformative change that will make our world a healthier place.

Thank You.

Yours sincerely, Sd/-**Kiran Mazumdar-Shaw** Executive Chairperson May 27, 2022

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AS WE COME OUT OF THE PANDEMIC WITH A STRONG FINANCIAL PERFORMANCE, THE BOARD OF DIRECTORS HAS RECOMMENDED A DIVIDEND OF 10% OF FACE VALUE OF EACH SHARE FOR FY22.



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**Our Biosimilars Business** 

Changing to Win; Transforming to Lead

## MANAGING DIRECTOR'S MESSAGE

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**Dr. Arun Chandavarkar** Managing Director, Biocon Biologics Limited

## A Year of Transformation

We are living through a time of rapid transformation. Climate disruption, changing geopolitics, technological transformation and digital convergence are challenging our fundamental assumptions about work, the world, and our place in it. The COVID-19 pandemic has made us realize that the next big disruption may just be around the corner. It has also made it clear that dealing with change requires a strong sense of ownership, agility of decision-making, process innovations, operational excellence and forward thinking.

Biocon is no stranger to change. We built our Biosimilars business by effectively navigating a fast-evolving regulatory landscape, rapid scientific advancement and accelerated technological progression. Biocon Biologics is now adapting to a swiftly maturing industry, where agencies like the U.S. FDA are setting precedents, such as deeming biosimilars to be interchangeable with the innovator products.

Up until now, we have maneuvered change through shared risk-reward partnerships that brought in complementary skills and experience, such as our long-standing, successful global partnership with Viatris for a range of biosimilar antibodies and insulin analogs.



BIOCON BIOLOGICS IS NOW ADAPTING TO A SWIFTLY MATURING INDUSTRY, WHERE AGENCIES LIKE THE U.S. FDA ARE SETTING PRECEDENTS, SUCH AS DEEMING BIOSIMILARS TO BE INTERCHANGEABLE WITH THE INNOVATOR PRODUCTS.

Going forward, Biocon Biologics intends to be a fully, vertically integrated company supplementing its established capabilities in development, operations and presence in emerging markets with commercial infrastructure in advanced markets. We have demonstrated success with a proven track record of multiple successful biosimilar approvals in U.S., Europe and several other developed and developing countries. We have created global scale capacities for insulins and antibodies that meet the most stringent of regulatory norms to support our near-term growth. Our commercial footprint for biosimilars straddles the developed and developing countries by leveraging strong regional and global partnerships.

The tectonic shifts afoot in the global healthcare industry calls for bold and transformational changes to adapt to the evolving market dynamics, and drive sustainable growth.

#### **A Transformative Acquisition**

In FY22, Biocon Biologics announced a transformative acquisition of its longterm partner Viatris' biosimilars business for USD 3.335 billion in cash and stock. This acquisition, upon closing, will accelerate our strategy to create a fully, vertically integrated company with direct commercial presence in the developed markets.

This acquisition is unique as it brings together the two companies' teams, which have been collaborating on common projects, into a single, integrated organization driven by a common vision and mission.

Through this deal, we intend to integrate Viatris' biosimilars commercial infrastructure globally. We will gain from Viatris' experience on navigating the formulary positioning, contracting, front end sales, regulatory interface and distribution in these markets.

As a vertically integrated enterprise, we will be able to drive efficiencies in the system with quicker decision-making, improved market insights and common focus across functions. This deal gives us better strategic agility to improve overall cost of supply chain, capital allocation and distribution, among others.  $\bullet \bullet \bullet \bullet \bullet$ 

THE ACQUISITION OF VIATRIS' BIOSIMILARS BUSINESS IS UNIQUE AS IT BRINGS TOGETHER THE TWO COMPANIES' TEAMS, WHICH HAVE BEEN COLLABORATING ON COMMON PROJECTS, INTO A SINGLE, INTEGRATED ORGANIZATION.

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#### Viatris Biosimilars Business Acquisition: Deal Dynamics

Post completion of the transaction, Viatris will receive consideration of up to USD 3.335 billion, including cash up to USD 2.335 billion and Compulsorily Convertible Preference Shares (CCPS) in Biocon Biologics valued at USD 1 billion, equivalent to an equity stake of at least 12.9% on a fully diluted basis.

Cash consideration will be distributed over the next few years with USD 2 billion payable on closing of the transaction and up to USD 335 million as additional payments expected to be paid in 2024. The deferred considerations include USD 175 million to be paid for the acquisition of Viatris' rights in its bAflibercept. Viatris will pay USD 50 million to Biocon Biologics to fund certain capital expenditures.

Cash payment of USD 2 billion will be funded by ~USD 800 million raised through equity infusion in Biocon Biologics and the remainder will be funded by debt. The equity infusion will see participation from Serum Institute Life Sciences (SILS), Biocon Limited and other private equity investors.

Our long-standing relationship with Viatris will help us integrate smoothly and rapidly. To ensure seamless transition and continued service to our patients and partners, Viatris will provide commercial and other transition services to Biocon Biologics for up to two years.

#### **Entering Vaccines & Infectious Diseases Segment**

The COVID-19 pandemic brought home to us the serious threat posed by viral and other infectious diseases and the role that biologics such as vaccines and antibodies have in addressing this threat. We had responded to the crisis by repurposing Biocon's novel biologic drug, Itolizumab, to treat COVID-19 patients, especially those with moderate to severe Acute Respiratory Distress Syndrome (ARDS).

Realizing the difference we could make to patient lives, Biocon Biologics entered into a strategic alliance with SILS this year to make a meaningful impact in fighting infectious diseases.

Vaccines and antibodies for infectious disease are a natural adjacency to Biocon Biologics' existing capabilities in biologics for non-communicable diseases. The structure of the alliance provides us with an 'asset-light' and accelerated entry into this segment.  $\bullet \bullet \bullet \bullet \bullet$ 

VACCINES AND ANTIBODIES FOR INFECTIOUS DISEASE ARE A NATURAL ADJACENCY TO BIOCON BIOLOGICS' EXISTING CAPABILITIES IN BIOLOGICS FOR NON-COMMUNICABLE DISEASES.

Together, we believe we can address the needs of patients in various infectious diseases, including COVID-19.

The companies will complement each other by leveraging each other's commercial strengths in existing and new markets. The greater objective is to address inequitable access both in emerging and developed markets for lifesaving vaccines and biologics.

Biocon Biologics will have access to the entire portfolio of SILS including vaccines already commercialized and the ones in development. Additionally, the partnership will have access to SILS' current development pipeline to address unmet needs in other communicable diseases like mosquito-borne infections.

The 15-year supply arrangement of 100 million vaccine doses annually from SILS provides Biocon Biologics with an additional assured revenue stream and associated margins from the second half of FY23.

The partnership provides a framework to explore several other opportunities that would be value accretive to both our organizations and make a difference in the often-overlooked infectious diseases segment. Developing both vaccines and biologics for communicable diseases will provide us long-term growth drivers.

#### Partnering for a COVID-19 Antibody

Furthermore, we partnered with U.S.-based Adagio Therapeutics to bring a novel monoclonal antibody for the prevention and treatment of COVID-19 to patients in India and select emerging markets. ADG20 is a novel monoclonal antibody targeting the spike protein of SARS-CoV-2 and related coronaviruses. This treatment potentially offers a convenient outpatient administration as a single intra-muscular injection for both prevention and treatment of COVID-19.

The preliminary results from Phase II / III clinical trials of ADG20 showed that in the pre-Omicron population, ADG20 administered as a single 300mg intramuscular dose met primary endpoints with statistical significance. However, given the lack of neutralizing activity against the BA.2 variant, Adagio has paused the submission of an Emergency Use Authorization (EUA) request to the U.S. FDA.  $\bullet \bullet \bullet \bullet \bullet$ 

THE 15-YEAR SUPPLY ARRANGEMENT OF 100 MILLION VACCINE DOSES ANNUALLY FROM SILS PROVIDES BIOCON BIOLOGICS WITH AN ADDITIONAL ASSURED REVENUE STREAM AND ASSOCIATED MARGINS FROM THE SECOND HALF OF FY23.

#### **Historic Interchangeability Approval**

Following the landmark commercialization of bGlargine in the U.S. in FY21, we marked another milestone by obtaining interchangeable designation from the U.S. FDA for our bGlargine in FY22. We are the first to obtain approval for an interchangeable biosimilar product, Semglee\*, in the U.S. This approval sets the stage for approvals of our other biosimilars. The interchangeability approval, which allowed substitution of our product for the innovator brand at the pharmacy counter, demonstrated our scientific, quality and regulatory capabilities. The interchangeability status allowed us to get a preferred formulary status from some large formularies, which helped us to rapidly ramp-up market share in the U.S. These developments augur well not only for the future growth of our business but also for our ability to offer people living with diabetes in the U.S. more treatment options, rationalize cost of therapy and generate savings for the overall healthcare system.

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WE ARE THE FIRST TO OBTAIN APPROVAL FOR AN INTERCHANGEABLE BIOSIMILAR PRODUCT, SEMGLEE, IN THE U.S. THIS APPROVAL SETS THE STAGE FOR APPROVALS OF OUR OTHER BIOSIMILARS.

#### \*Our partner Viatris' brand



#### **Building a Robust Product Portfolio**

We continue to invest on research and development to support our biosimilars pipeline. We have built a sizeable portfolio of over 20 biosimilar assets, including some which are unpartnered, that are at various stages of development. This year, two of our antibodies, bUstekinumab and bDenosumab, entered the clinical phase, which represents a large part of the overall cost that goes into developing a molecule.

We are developing various presentations of rh-Insulin for the U.S. Our biosimilar referencing Eli Lilly's Humulin-R, a short-acting rh-Insulin, demonstrated equivalence in a pharmacokinetic and pharmacodynamic study published in the journal, *'Diabetes, Obesity and Metabolism'*, in January 2022.

We exercised the option to acquire Viatris' rights in bAflibercept, which is an advanced asset and has the status of 'first to file' with the U.S. FDA.

Our second wave of biosimilars will address a market opportunity of ~USD 20 billion in innovator sales to drive growth in the medium-term.

#### **Expanding Insulins Manufacturing Capacity**

The investments in manufacturing infrastructure in Malaysia to support our insulins franchise have given us the capacity to supply our insulins, including interchangeable bGlargine, to meet patients' needs in many developed and emerging countries. We have been expanding access to life-saving insulin therapy in Malaysia, too. Recently, we won a three-year contract for rh-Insulin in Malaysia, valued at ~USD 90 million. With sales from Malaysia ramping up, our operations there turned profitable in the fourth quarter of FY22.

Encouraged by the demand for our insulins and in anticipation of new opportunities opening in terms of product approvals and geographic expansion, we have initiated the expansion of our facility in Malaysia. We expect to invest in a phase-wise manner with the investments being within the overall USD 100-150 million range for annual capex over three years.

#### Making a Difference in India

The Branded Formulations India business recorded a 35% growth in FY22. Whilst our COVID-19 portfolio, including ALZUMAb-L, contributed to our growth in Q1FY22 during the second wave of the pandemic in India, we performed well across therapeutic divisions during the rest of the financial year. We continue to strengthen our patient-centric programs and engagement initiatives with healthcare professionals. This year, we expanded our insulins access program to address the needs of young people with Type 1 diabetes in India in collaboration with the Research Society for the Study of Diabetes in India (RSSDI).



WE WON A THREE-YEAR CONTRACT FOR RH-INSULIN IN MALAYSIA, VALUED AT ~USD 90 MILLION.

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THE BIGGEST DRIVER OF GROWTH FOR FY22 WAS OUR bGLARGINE IN THE U.S., WHICH EXPANDED ITS MARKET SHARE FROM 2% TO 10% IN SIX MONTHS DUE TO THE INTERCHANGEABLE STATUS.

#### **Robust Financial Performance**

Biocon Biologics has delivered strong revenue and profit growth this fiscal. Revenues grew by 24% over last year to ₹34,643 million. The biggest driver of growth for FY22 was our bGlargine in the U.S., which expanded its market share from 2% to 10% in six months due to the interchangeable status. Consequently, our revenues moved up from ₹7,581 million in Q1FY22 to ₹9,823 million in Q4FY22. This clearly demonstrates the success that can be achieved by adopting the right strategy when approaching markets that allow a switch from innovator to biosimilar products. Our other products, including bTrastuzumab and bPegfilgrastim, gained market share or held steady. We witnessed good growth for our biosimilars in emerging markets too. Our Core EBITDA margin, which is EBITDA less licensing, forex, mark-to-market loss on investments and R&D expense, was at 39% versus 36% in FY21. The improved margins are a reflection of our strong operating performance. The business delivered EBITDA margins of 29% in FY22.

#### Stage Set for Long-Term Growth

We expect Biocon Biologics' earnings momentum to sustain on the back of strong performance in advanced markets like the U.S., with our bGlargine's market share expected to go up to mid-teens by the end of calendar year 2022. We are awaiting approval for two more products, bAspart and bBevacizumab, in the U.S. which would add significantly to revenues from this market.

FY22 has been a transformational year for Biocon Biologics on account of the two strategic deals with Viatris and SILS. These transactions, which are progressing through regulatory approvals, are expected to close by the second half of calendar year 2022. On their closing, Biocon Biologics will see a significant ramp-up in revenues, enabling continued investments for longterm growth.

At Biocon Biologics, we look forward to leveraging our early successes, robust business fundamentals, technical excellence, high quality operations and global scale to usher in transformational change to global healthcare through our affordable, high quality biologics.

Thank You.

Yours sincerely,

Sd/-**Dr. Arun Chandavarkar** Managing Director Biocon Biologics Limited May 27, 2022  $\bullet \bullet \bullet \bullet \bullet$ 

ON THE COMPLETION OF THE TWO STRATEGIC TRANSACTIONS, BIOCON BIOLOGICS WILL SEE A SIGNIFICANT RAMP-UP IN REVENUES, ENABLING CONTINUED INVESTMENTS FOR LONG-TERM GROWTH.



WE LOOK FORWARD TO USHERING IN TRANSFORMATIONAL CHANGE TO GLOBAL HEALTHCARE THROUGH OUR AFFORDABLE, HIGH QUALITY BIOLOGICS.

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## Biocon Biologics Limited Board of Directors



Kiran Mazumdar-Shaw Executive Chairperson



Daniel Bradbury Independent Director



Dr. Arun Chandavarkar Managing Director



**Russell Walls** Independent Director



**Bobby Parikh** Independent Director



Peter Piot Independent Director



Thomas Roberts Non-Independent Non-Executive Director



Nivruti Rai Independent Director

**Biocon Biologics Limited** 

## Executive Leadership Team



Dr. Arun Chandavarkar Managing Director



Dr. Sandeep N Athalye Chief Medical Officer



Shreehas Tambe Deputy Chief Executive Officer



Susheel Umesh Chief Commercial Officer, Emerging Markets



**Chinappa MB** Chief Financial Officer



Matthew Erick Chief Commercial Officer, Advanced Markets



**Dr. Anuj Goel** Chief Scientific Officer



Paul Thomas Chief Commercial Officer U.S., Business Development & Licensing



Ganesh Reddy Global Head, Biologics Manufacturing



**Kiran Kumar Gandhirajan** Site Head, Malaysia



Amitava Saha Chief Human Resources Officer, Biocon Group



Seema Ahuja Chief Communications Officer



Naveen Narayanan Chief Human Resources Officer



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

## DEPUTY CEO's REVIEW

Shreehas Tambe President & Deputy CEO, Biocon Biologics **Deputy CEO's Message** 

## Laying the Runway to Growth

Just when we had begun to think that we had got the better of the coronavirus, it hit back with a vengeance. This time, even harder than it did in 2020. FY22 began under the gloom of the second wave of the COVID-19 pandemic. The devastation it left behind was unprecedented, with a cascading impact on global health, economy and life in general. It changed the world as we knew it. It was against this backdrop, that we, at Biocon Biologics, set out our Three Top Priorities – Strengthen the Core, Accelerate Growth and Invest in the Future.

#### Strengthen the Core

A key focus area was to ensure that the business delivered a profitable growth on a year-on-year basis and a steady sequential increase over each preceding quarter. In FY22, Biocon Biologics' revenues grew by 24% over the previous year to ₹34,643 million. Focus on business priorities and operational performance led to an improvement in the quality of our earnings. This was reflected in our Core EBITDA, which is EBITDA less licensing, forex, mark-to-market loss on investments and R&D expense, which grew 30% over FY21. With an increase in market share of our commercialized biosimilars and launches in over 25 new markets, we were able to further our mission to broaden access to essential therapies. In FY22 alone, Biocon Biologics served over 5 million patients through our lifesaving drugs.

Investing in our biosimilars development pipeline has been a top focus and we continue to invest in R&D to advance our portfolio. In FY22, two of our Wave 2 biosimilar assets, bUstekinumab and bDenosumab, entered the clinic. Having now exercised the option to acquire Viatris' rights in bAflibercept, which is 'first to file' with the U.S. Food and Drug Administration (FDA), we have opened a market opportunity of ~USD 20 billion in innovator sales for our Wave 2 biosimilar assets.

#### Accelerate Growth

On July 28, 2021, the U.S. FDA made a historic decision when it approved bGlargine (Semglee\*), co-developed by Biocon Biologics and Viatris, as the first interchangeable biosimilar insulin product to improve glycemic control

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IN FY22, BIOCON BIOLOGICS SET OUT THREE TOP PRIORITIES – STRENGTHEN THE CORE, ACCELERATE GROWTH AND INVEST IN THE FUTURE.

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in adults and pediatric patients with Type 1 diabetes mellitus and in adults with Type 2 diabetes mellitus. Semglee (insulin glargine-yfgn) was approved both as biosimilar to and interchangeable with (can be substituted for) its reference product Lantus (Insulin Glargine), a long-acting insulin analog. Semglee (insulin glargine-yfgn) is the first interchangeable biosimilar product approved in the U.S. for the treatment of diabetes. Acting FDA Commissioner Janet Woodcock, M.D. called it a "...momentous day for people who rely daily on insulin for treatment of diabetes..." Our bGlargine sales in the U.S. have been the most significant contributor in accelerating growth in FY22. The interchangeability status allowed us to get a preferred listing at some of the largest formularies, which helped us to rapidly ramp-up market share in the U.S.

Business in Emerging Markets also saw significant acceleration with our insulins and bTrastuzumab leading the way. Recently, we won a three-year contract for rh-Insulin in Malaysia, valued at ~USD 90 million, continuing our long-standing relationship with the Ministry of Health (MoH), Malaysia. With sales from Malaysia ramping up, our Malaysia operations turned profitable in the fourth quarter of FY22. Insulins and bTrastuzumab sales in several Latin American markets and the Africa and Middle East region also contributed to growth in the business.

The Branded Formulations India business made us proud as the team went out of the way to ensure continuity in supply of our lifesaving drugs all through the pandemic. Our Critical Care division, armed with ALZUMAb-L (Itolizumab) and other products, worked tirelessly with doctors across the country to help manage COVID-19 patients. This made a significant contribution to the India business in the first half of FY22. Most importantly, they touched ~40,000 patients' lives during the year. In FY22, our Branded Formulations India business recorded a growth of 35% over last year on the back of strong performance across therapeutic areas.

#### **Invest in the Future**

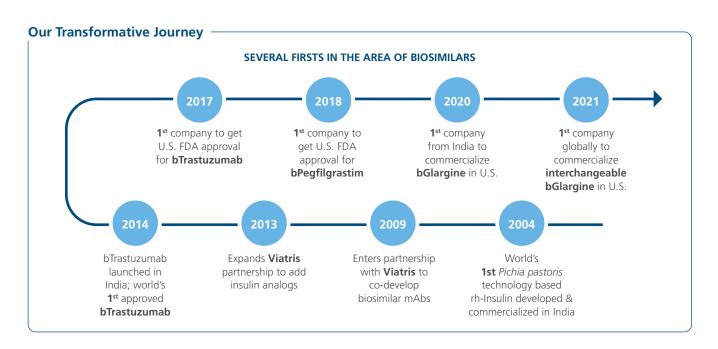
Even as we have continued to strengthen our biosimilars portfolio to broaden access to patients, our investments so far have focused on debilitating non-communicable diseases. The COVID-19 pandemic and the ensuing crisis exposed the inequity in access to global health, particularly when combating communicable diseases. Biocon Biologics has demonstrated scientific credibility, global-scale manufacturing and a proven track record of commercial success across geographies. Our strategy of "Expanding on Adjacencies" is about leveraging our strengths to invest in growth drivers for the future. The strategic alliance with Serum Institute Life Sciences (SILS) is an important step in that direction as we expand into developing vaccines as a potential future growth driver. The 'asset-light' deal structure of this alliance with the world's largest vaccine maker has ensured that Biocon Biologics has access to assured vaccine manufacturing capacity for the next 15 years. This investment becomes accretive to the P&L from the second half of FY23 as we work through the statutory approval process.  $\bullet \bullet \bullet \bullet \bullet$ 

WITH SALES FROM MALAYSIA RAMPING UP, OUR MALAYSIA OPERATIONS TURNED PROFITABLE IN THE FOURTH QUARTER OF FY22.



BIOCON BIOLOGICS HAS DEMONSTRATED SCIENTIFIC CREDIBILITY, GLOBAL-SCALE MANUFACTURING AND A PROVEN TRACK RECORD OF COMMERCIAL SUCCESS ACROSS GEOGRAPHIES.

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The acquisition of Viatris' global biosimilars business accelerates our vision of building a unique, vertically integrated biologics company. In addition to the immediate accrual of economic benefit to the P&L, this deal enables Biocon Biologics with direct presence in the advanced markets of U.S., Canada, EU, Australia and New Zealand, in addition to several emerging markets. With biosimilars gaining ground globally, particularly in the U.S., and several products from our portfolio lined up for market entry in the near term, the timing of this deal couldn't have been better. This deal will provide Biocon Biologics greater agility in decision-making and help improve operational efficiencies in supply chain, capital allocation and distribution, and will also bring us closer to patients.

#### The Way Ahead

The coronavirus has morphed to a new variant today and it is possible that there may be more in future, but our achievements show that we have learnt and adapted quickly and are now stronger than ever before. Our track record of endurance, tenacity and more importantly a strong sense of purpose continues to differentiate us and has allowed us to win. With the core business back on track and key products accelerating growth, Biocon Biologics is well placed to leverage its strengths and realize the full potential of the strategic investments that we have made, in the coming years.

Thank You.

Yours sincerely, Sd/-Shreehas Tambe President & Deputy CEO Biocon Biologics May 27, 2022

#### **Our Biosimilars Business**

## Changing to Win; Transforming to Lead



\* Market opportunity size of Biocon Biologics' portfolio based on reported CY 2021 sales of originator brands and biosimilars Biologics represent the cutting-edge of biomedical research, and biosimilars present an enormous opportunity to provide affordable access to these advanced therapies. Biosimilars can bring in a transformational shift in the treatment paradigm of life-threatening conditions for patients worldwide. We are witnessing a gradual increase in biosimilar adoption, and greater clarity around scientific expectations and the regulatory pathway will further drive a higher uptake of biosimilars globally. To provide patient access to affordable biologics and enable health equity, Biocon Biologics is developing a strong portfolio of biosimilars that will address a USD 70 billion<sup>#</sup> global market opportunity by FY27.

FY22 was a transformative year for Biocon Biologics as we acted to Strengthen the Core, Accelerate Growth and Invest in the Future. We announced the acquisition of Viatris' global biosimilars business to get closer to patients and entered a strategic alliance with Serum Institute Life Sciences (SILS) in line with our strategy of 'Expanding on Adjacencies.'

We believe these strategic moves will fundamentally transform the Company's position and growth trajectory for sustainable value creation in the coming years.

# Creating a Unique, Fully Integrated Biosimilars Leader



## Strategic Move to Acquire the Global Biosimilars Business of Viatris

The strategic decision to acquire the global biosimilars business of our long-term partner Viatris for USD 3.335 billion in a 'cash and stock' deal is a historic inflection point in Biocon Biologics' journey to become a world leading, fully integrated biosimilars enterprise.

### **Building Out Commercial Capabilities in Developed Markets**

Our collaboration with Viatris for over a decade led us to combine our advanced R&D strengths and robust manufacturing capabilities in biosimilars with our partner's regulatory and commercialization expertise in developed markets to together achieve many 'firsts' and set new global benchmarks.

By bringing together the complementary capabilities and strengths of both partners, this acquisition will help us add regulatory, supply chain and commercialization competencies in U.S., UK, EU, Canada, Australia and New Zealand, as well as key emerging markets.

Direct commercial presence in these markets will support our existing and future pipeline of products. It will take us closer to patients, payors and healthcare systems and strengthen our position as a global biosimilars player.

### Fortifying our Biosimilars Portfolio

The deal with Viatris will allow us to have full rights on our partnered assets and Viatris' rights for in-licensed products like bAdalimumab and bEtanercept.

As a part of this deal, Biocon Biologics has also exercised the option to acquire Viatris' rights for its bAflibercept asset, a proposed biosimilar to Regeneron's Eylea, which is indicated for use in multiple ophthalmology indications. Viatris has been the 'first to file' for a biosimilar Aflibercept in the U.S.

This acquisition of bAflibercept will expand our portfolio.



### Improving our Financial Health

Currently, Viatris enjoys majority of the economic benefit from our partnered biosimilars portfolio. Upon closing of the transaction, Biocon Biologics will realize the full revenue and associated profits from these products; a step-up from the existing arrangement.

Biocon Biologics expects Viatris' biosimilars business to contribute over USD 1 billion in revenue in CY23.

The deal will expand Biocon Biologics' EBITDA base and strengthen our overall financials, enabling investments in product portfolio and geographical expansion for sustained long-term growth.

## **Financial Details of the Transaction**

Viatris will receive consideration of up to USD 3.335 billion, including cash up to USD 2.335 billion and Compulsorily Convertible Preference Shares (CCPS) in Biocon Biologics valued at USD 1 billion, equivalent to an equity stake of at least 12.9% on a fully diluted basis.

The cash consideration for the acquisition comprises USD 2 billion payable on closing of the transaction and up to USD 335 million deferred payments expected to be paid in 2024.

The deferred considerations include USD 175 million to be paid for the acquisition of Viatris' rights in its bAflibercept. Viatris will pay USD 50 million to Biocon Biologics to fund certain capital expenditures.

Biocon Biologics will enter into a Transition Service Agreement with Viatris, for an expected two-year period, encompassing commercialization and other services.

Cash payment of USD 2 billion will be funded by ~USD 800 million raised through equity infusion in Biocon Biologics and the remainder will be funded by debt. The equity infusion will see participation from existing and potential investors.

We have firm commitments from lenders for debt financing.

Viatris will designate Rajiv Malik, President of Viatris, to serve on the Biocon Biologics Board of Directors.

### **Creating Long-Term Value**

Our longstanding relationship with Viatris positions us well to integrate seamlessly and rapidly. Vertical integration will drive operational efficiencies and business agility, thereby underpinning cost competitiveness. This acquisition will make us future-ready and help us accelerate our strategy of building a direct commercial presence in developed markets for our next wave of biosimilars.

As a fully integrated global company, we will be able to enhance patient access, reduce healthcare inequities worldwide and drive immense value for all our stakeholders.



### Transaction to Add Financial Depth, Commercial Capabilities





\*CCPS : Compulsorily Convertible Preference Shares equivalent to equity stake of at least 12.9% on a fully diluted basis



# **Positioned for Value Creation Through Vaccines**

## Strategic Alliance with Serum Institute Life Sciences

The COVID-19 pandemic has led the world to acknowledge the serious threat posed by viral and other infectious diseases and the role that biologics such as vaccines and antibodies have in addressing this danger.

Realizing the acute need for an effective treatment for people hospitalized with COVID-19 and those at risk of developing severe illness, Biocon had repurposed its novel antibody, Itolizumab, to treat patients experiencing moderate to severe Acute Respiratory Distress Syndrome (ARDS) due to COVID-19. We also in-licensed a novel monoclonal antibody therapy from U.S.-based Adagio Therapeutics for the prevention and treatment of COVID-19.

Vaccines and antibodies for infectious disease are a natural adjacency to Biocon Biologics' existing capabilities in biologics for non-communicable diseases. The strong synergies between our existing capabilities and the evolving demand for biologics or vaccines against infectious diseases led Biocon Biologics to enter into a strategic alliance with Serum Institute Life Sciences (SILS) for vaccines and infectious disease antibodies in September 2021.

Under the terms of the agreement, Biocon Biologics will offer ~15% stake to SILS, at a post-money valuation of ~USD 4.9 billion\*. Serum Institute CEO, Adar Poonawala, will join Biocon Biologics' board following the closing of the Viatris / SILS deal.

### 'Asset-Light' Entry into Vaccines

The structure of the alliance provides Biocon Biologics with an 'asset-light' and accelerated entry into the vaccines segment.



\*Calculated as on the date of signing of the deal

Serum Institute is the world's largest vaccine manufacturer by volume of doses produced and sold globally. It has world-class vaccines production facilities, capable of producing multi-billion doses of high quality vaccines.

Upon closing of the transaction, Biocon Biologics will get committed access to a 100 million doses of vaccines annually for ~15 years along with commercialization rights to the entire vaccines portfolio of SILS.



### Adding a Growth Pillar

Biocon Biologics will have global commercialization rights for SILS' vaccine portfolio, including COVID-19 vaccines.

Beyond the COVID-19 vaccines portfolio, the partnership provides access to SILS' current development pipeline to address unmet needs in the areas of infectious and vector-borne diseases.

The SILS alliance will provide a committed annual revenue stream of nearly USD 300 million to Biocon Biologics. This will reflect in our P&L from the second half of FY23, post closing of the deal.

### Leveraging Complementary Capabilities

Biocon's investments in biologics over the decades have provided us a strong foundation to contribute to the global fight against infectious diseases.

Biocon Biologics' manufacturing and R&D strengths in biologics will complement SILS' capabilities in vaccines. The two companies will leverage each other's commercial strengths in existing and new markets.

The deal would not only give Biocon Biologics an entry into vaccines, but it would also allow Serum Institute to participate in the global biologics space through its ~15% stake in Biocon Biologics.

Complementing each other's capabilities and capacities will enable both companies to address the issue of access to cost-effective vaccines and biologics in emerging and developed markets and make a meaningful impact in the infectious diseases space globally.

### **Future Plans**

We have agreed to establish a vaccine R&D division to support the development of both vaccines and biologics for communicable diseases, providing long-term growth drivers for this business.

Biocon Biologics will issue shares and receive the rights through a merger with Covidshield Technologies Pvt. Ltd. (CTPL), a wholly-owned subsidiary of SILS, on customary closing conditions and receipt of regulatory approvals. The Competition Commission of India (CCI) has approved the merger.

# **Achieving Efficient Business Growth**

## **Financial Performance**

Biocon Biologics delivered a very strong financial performance in FY22, reporting a robust top line growth with continuous profitability improvement. Revenues grew by 24% to ₹34,643 million in FY22. The growth was driven by a strong uptake of our interchangeable bGlargine in the second half of the year, improved market share of bTrastuzumab in the U.S. and an improved performance in other developed and emerging markets. Core EBITDA margin, which is EBITDA less licensing, forex, mark-

to-market loss on investments and R&D expense was at 39% versus 36% in FY21. The business delivered EBITDA margins of 29% in FY22. The improved margins reflect our strong operating performance.

### **Business Performance**

# Developed Markets: Setting New Benchmarks

A key milestone in FY22 was the U.S. Food and Drug Administration's (FDA) approval of our bGlargine 100U as the first interchangeable biosimilar product under the 351(k) regulatory pathway. There has been strong demand for our interchangeable bGlargine in the U.S. and its market share has ramped up from low singledigits at the end of 2021 to double digits in early 2022.



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## Historic U.S. approval for interchangeable bGlargine

In July 2021, the U.S. Food and Drug Administration deemed our bGlargine to be interchangeable with the innovator product (Lantus) under the 351(k) regulatory pathway, marking another global 'first' for Biocon Biologics. The decision set the precedent for approvals of other interchangeable biosimilars.

Interchangeability allows pharmacists to substitute the reference drug with the interchangeable biosimilar, thus providing a convenient and affordable alternative. It has the potential to bring significant cost savings for patients and the healthcare system as a whole. It can also maximize access to an important therapy like bGlargine, regardless of financial circumstances, insurance or channel.

U.S. FDA Commissioner Janet Woodcock hailed it as a "momentous day for people who rely daily on insulin for the treatment of diabetes".

The interchangeability approval for our bGlargine in the U.S. is a testament to our scientific excellence and robust comparability data. It has improved the confidence of prescribers, patients and payors in our product in the U.S. and beyond.

Our interchangeable product has been listed as a preferred insulin brand on the national formularies of two leading pharmacy benefit managers (PBMs) in the U.S., Express Scripts and Prime Therapeutics, which together have a reach of over 60 million members. It will also be offered through the Walgreens Prescription Savings Club, saving members up to 80% on the cash price of comparable long-acting insulins purchased at Walgreens.

We launched our interchangeable bGlargine in the U.S. in November 2021, paving the way for interchangeable biosimilars in the region.

### Making a Difference in Oncology Treatments

Our bTrastuzumab (Ogivri\*), which has made a difference to cancer patients worldwide, witnessed a gradual increase in market share in the U.S. throughout the year. It also reported a strong performance in Canada and Australia.

Our bPegfilgrastim (Fulphila\*) was resilient against the competition in the U.S. market, recording an uptick in its market share versus FY21. In Europe, both these products reported gradual improvement in performance.

Our bBevacizumab (Abevmy\*) was commercialized in EU and Canada, further bolstering our oncology franchise in these markets.

# Emerging Markets: Widening & Deepening our Presence

Biocon Biologics has been making biosimilars available to patients

in key emerging markets through partnerships with leading local pharmaceutical players, as well as through Viatris' commercial engine. In FY22, we ramped up our presence in emerging markets by signing 44 new partnerships across 50 countries for our products, opening growth opportunities in new and existing markets. These will be an important near-term growth driver for our emerging markets franchise. To build a direct commercial footprint in

\*Our partner Viatris' brand



emerging markets for our biosimilars, we added field force in UAE and Saudi Arabia.

During the year, our Emerging Markets business reported impressive growth, driven by higher sales of our biosimilar insulins and bTrastuzumab in the Africa Middle East and Turkey (AFMET) region.

We continued to see strong demand for a majority of our commercialized

biosimilars. Our oncology portfolio led by bTrastuzumab reported strong double-digit growth, capturing close to half the market in Brazil, Indonesia and Algeria. We also commercialized our bTrastuzumab in few new markets through our partners.

We launched our bBevacizumab in Malaysia and received regulatory approvals for the product in several other emerging markets. Our insulins, which include bGlargine and rh-Insulin, continue to retain a significant share of the market in several countries such as Malaysia, Egypt, Morocco and Mexico.

Going ahead, we expect a greater play in emerging markets following integration of the biosimilars business of Viatris.

### India: Picking up Momentum

In FY22, the Branded Formulations India (BFI) business recorded a year-on-year growth of 35%. Even after excluding the sales from the COVID-19 portfolio, the Core BFI business reported a strong doubledigit growth in FY22. The good performance came on the back of significant ramp-up in prescriptions for Basalog (bGlargine), improved patient acquisition and key account penetrations for oncology biosimilars such as CANMAb (bTrastuzumab) and KRABEVA (bBevacizumab), targeted with healthcare engagement professionals through judicious use of both digital and physical marketing channels. Our strategy of focusing on building strong brands is showing results. The Top 5 power brands, Basalog, Insugen, ALZUMAb-L, CANMAb and BIOMAb EGFR, identified by the India business recorded strong double-digit growth in FY22.

Our commercial team has served over 60,000 COVID-19 patients so far through our comprehensive COVID Care portfolio, including ALZUMAb-L (Itolizumab).

# Expanding Insulins Access to T1D Patients

Biocon Biologics tied up with the Research Society for the Study of Diabetes in India (RSSDI), Asia's largest organization of researchers and healthcare professionals for diabetes, to identify and train ~400 physicians in different districts across the country on the management of Type 1 diabetes. We will enable them with a free supply of our insulins portfolio to help over 1,000 children with Type 1 diabetes (T1D) from the marginalized communities who otherwise cannot afford this therapy.

### **Empowering Clinicians**

In FY22, we trained over 5,000 physicians through over 180 workshops as part of our ABIDE 2.0 program aimed at empowering clinicians in India with continuously updated in-depth training on diabetes, through a case-based interactive approach.

# Contributing to the Battle against Cancer

Our novel biologic, Nimotuzumab, was included in the Indian Cancer Guidelines and National Cancer Grid for the treatment of head & neck cancer.



## Malaysia: Making an Impact



Our interchangeable bGlargine, produced at our Center of Excellence (CoE) for Insulins in Malaysia, received a historic U.S. approval as the first interchangeable biosimilar under the 351(k) regulatory pathway. The strong uptake of our interchangeable bGlargine in the U.S. helped our Malaysia operations to deliver an operating profit for the first time.

In line with our aspiration of taking our biosimilar insulins to 'one in five' insulin-depended people with diabetes worldwide, we have been partnering with the Malaysian government since 2016. Since our entry to Malaysia in 2011, prices of human insulin have dropped by over 20% and insulinization has also improved by 30%. As the only insulin manufacturer in Malaysia, we have been able to achieve insulin selfsufficiency and improved access while providing savings to our partner, Ministry of Health (MoH), Malaysia. MoH, Malaysia recently awarded our Malaysia subsidiary a 3-year tender worth USD 90 million (MYR 370+ million) for the supply of Insugen (rh-Insulin) products.

Encouraged by the demand for our current insulin portfolio globally and the pipeline ahead of us, we have initiated investments to expand our insulins manufacturing facility in Malaysia.



## Biosimilars Pipeline: Forging Ahead

Biocon Biologics has one of the deepest and widest biosimilars pipelines globally. We have a portfolio of 20 biosimilar assets, including those partnered with Viatris and Sandoz, as well as the ones we are developing independently.

During the year, we received regulatory approvals for our key biosimilars in several advanced markets. Health Canada approved our bAspart and bBevacizumab during the year. We also received marketing authorization approval from the European Commission, TGA, Australia and MHRA, UK for our bBevacizumab.

We continued to invest further to advance our pipeline programs. Our net R&D spending in FY22 was ₹3,100 million, representing 9% of revenues.

We are developing various presentations of rh-Insulin for the U.S. Our biosimilar referencing Eli Lilly's

Humulin-R, a short-acting rh-Insulin, demonstrated equivalence in a Pharmacokinetic / Pharmacodynamic (PK/PD) study published in the journal, Diabetes, Obesity and Metabolism, in January 2022.

In FY22, we also commenced clinical trials for two of our unpartnered assets, bUstekinumab for inflammatory conditions and bDenosumab to treat osteoporosis and cancer.

The acquisition of bAflibercept from Viatris fits well with our next wave of biosimilar programs, including bUstekinumab and bDenosumab, which will address a market opportunity of over USD 20 billion<sup>#</sup> and are expected to be commercialized in the medium term.

These will supplement our commercialized portfolio of eight products.

Our portfolio will be further fortified by 10 early-stage programs, including bPertuzumab and bGlargine U300, allowing us to consistently fuel the commercial engine acquired as a part of the Viatris deal.

Biocon Biologics is trying to reimagine the traditional approach to biosimilars development to get these therapies to patients faster and reduce development costs. Our efforts come at a time when rapid scientific and technological advances are generating new insights and data, helping reduce clinical development timelines without taking undue risks or compromising insight generation.

We have sharpened our development and regulatory strategy to expedite the review and approval of Marketing Authorization Applications for our biosimilars. We have successfully leveraged the approvals received in developed markets to fast-track the review and approval of those biosimilars in several emerging markets.

The efforts of the Regulatory Affairs team led to Biocon Biologics receiving over 50 approvals across the world for its basket of biosimilars in FY22.

#### Our Pipeline

Today	< 2 years	2-4 years	> 4 years
louay			> 4 years
Pegfilgrastim	• Bevacizumab (US)	• Aflibercept <sup>2</sup>	• Pertuzumab
• Trastuzumab	• Aspart (US)	Ustekinumab	• Glargine 300 IU
• Bevacizumab (EU)	• Adalimumab (US)	• Denosumab	Seven undisclosed
• Glargine 100 IU	• rh-Insulin (US)		programs
• Aspart (EU)			
• Adalimumab (EU)	<ul> <li>Vaccines<sup>1</sup> (SILS deal expected to close</li> </ul>	Wave 2 biosimilars to address ~ USD 20 billion	
• Etanercept (EU)	in H2 2022)	market opportunity <sup>3</sup>	

<sup>1</sup> Subject to completion of the acquisition of Covidshield Technologes Private Limited (CTPL) | <sup>2</sup> Expected to be included in BBL portfolio post the completion of BBL's acquisition of Viatris' biosimilar business (Viatris has global rights to the program partnered with Momenta) | <sup>3</sup> Based on reported CY 2021 sales of originator brands

# Market opportunity based on reported CY 2021 sales of originator brands

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### Building Robust Intellectual Property

Biocon Biologics' robust in-house Intellectual Property (IP) strategy is helping overcome patent issues in the courts as litigation remains one of the key defence tactics used by branded developers to delay biosimilar entry. We successfully enabled access to bGlargine for millions of patients across the U.S. by invalidating certain patents related to the device and formulation of the originator. In FY22, we received favorable rulings from the U.S. Federal Circuit related to patents covering the originator's device and formulation for administering bGlargine. Biocon Biologics' IP portfolio currently comprises ~1,000 granted patents.

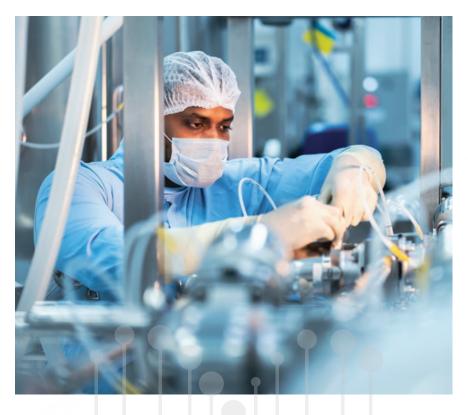
### Ushering in Operational Excellence through Digital Transformation

Biocon Biologics has drawn on the latest global technology trends in the health and life sciences industry to draw up its digital transformation strategy and dovetailed it with the Company's strategic business goals. We are deploying digital initiatives



to enhance quality and compliance, augment productivity through enhanced operational excellence and enable data integrity through technology-led data transparency.

In FY22, we made significant progress on several key digital projects across various functions, including Quality Assurance, Quality Control, R&D, Supply Chain, Manufacturing Operations, Clinical Trial Management and Learning & Development. We intensified the use of digital tools to manage ongoing clinical trials. Electronic data capture tools were used in all our clinical trials to collect data in a timely manner from multiple sites globally. Data analytics ensured real-time data review while ensuring high data quality. We deployed an electronic patient-reported outcome (ePRO) tool, allowing patients to fill up questionnaires remotely. This has not only increased adherence to clinical trial protocols but also yielded higher quality data compared with



paper-based questionnaires and entries.

We conducted several pilot projects to evaluate Augmented Reality and Artificial Intelligence / Machine Learning technologies in our manufacturing and R&D operations. The results were encouraging and are being evaluated for production scale deployment.

Our Center of Excellence (Quality Systems Digital Transformation & Operation Excellence) has enabled the identification and execution of digital and process solutions through structured root cause analysis. The vision of the CoE is to transform the quality culture of Biocon Group through the adoption of Lean Six Sigma Principles to enable continuous innovation, consistent right-firsttime delivery, enhanced efficiency, productivity and agility.

The CoE is developing an overarching operational excellence framework through the deployment of digital solutions to enhance quality and compliance, augment productivity, enable data integrity. It will create an enterprise where everybody works unitedly to build higher standards of governance and deliver greater levels of trust to all our stakeholders.

### **Caring for Our People**

At Biocon Biologics, we pride ourselves on our people-centric approach. We have built a meritocratic and valuedriven culture, which is appreciated by our over 5,000-strong workforce.

During the year, we implemented talent strategies to foster learning and growth for our employees thus ensuring a high-performance culture through education, exposure and experiences. We deployed a comprehensive training program to re-skill and cross-skill our employees. We initiated working on designing a Career Pathing Framework for our employees, which will further enable internal talent mobility and help employees to learn and grow.

We continue to make progress on our commitment to Diversity, Equity and Inclusion (DEI) in line with our ambition of becoming a gender equal organization by 2030. We have developed a DEI framework and strategy that will be implemented throughout the organization going forward. We also launched various career development programs for women leaders and institutionalized the DEI Council. In FY22, women comprised 21% of Biocon Biologics workforce, signaling an improvement in our gender diversity ratio compared to last year.

## Outlook

Biocon Biologics delivered a healthy performance backed by strong demand and seamless execution in FY22. Continued improvement in the performance of our existing products coupled with potential U.S. launches of bAspart, bBevacizumab and bAdalimumab will enable us to deliver robust growth in developed markets. We continue to see strong demand for our products in emerging markets and expect a greater play in these markets post integration of Viatris' biosimilars business. As we make progress on the development of our next wave of biosimilars, we expect R&D expenses to increase further. Our consolidated biosimilars portfolio, which targets a USD 70 billion<sup>#</sup> global opportunity, will provide us with sustainable growth in the years ahead. The two strategic agreements signed with Serum and Viatris will propel us on our path to be a fast-growing, global biologics player with an expected revenue of ~USD 1.8 billion in FY24.

<sup>#</sup> Market opportunity size of Biocon Biologics' portfolio based on reported CY 2021 sales of originator brands and biosimilars

