

**Biocon Limited**

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CIN : L24234KA1978PLC003417

www.biocon.com

February 17, 2023

To, The Secretary BSE Limited Department of Corporate Services Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai – 400 001 Scrip Code - 532523	To, The Secretary National Stock Exchange of India Limited Corporate Communication Department Exchange Plaza, Bandra Kurla Complex Mumbai – 400 050 Scrip Symbol- BIOCON
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Dear Sir/Madam,

Subject: Investor Presentation – Q3 FY23.

With reference to the captioned subject, please find enclosed the Investor Presentation under Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 ("SEBI Listing Regulations").

The above information will also be available on the website of the Company at www.biocon.com.

Kindly take the above said information on record.

Thanking You,

Yours faithfully,

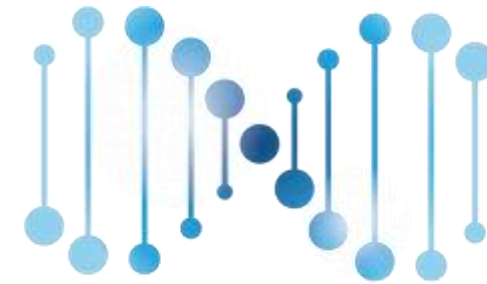
For **Biocon Limited**

Mayank Verma
Company Secretary & Compliance Officer
Membership No.: ACS 18776

Enclosed: Investor Presentation

Q3 FY23 Investor Presentation

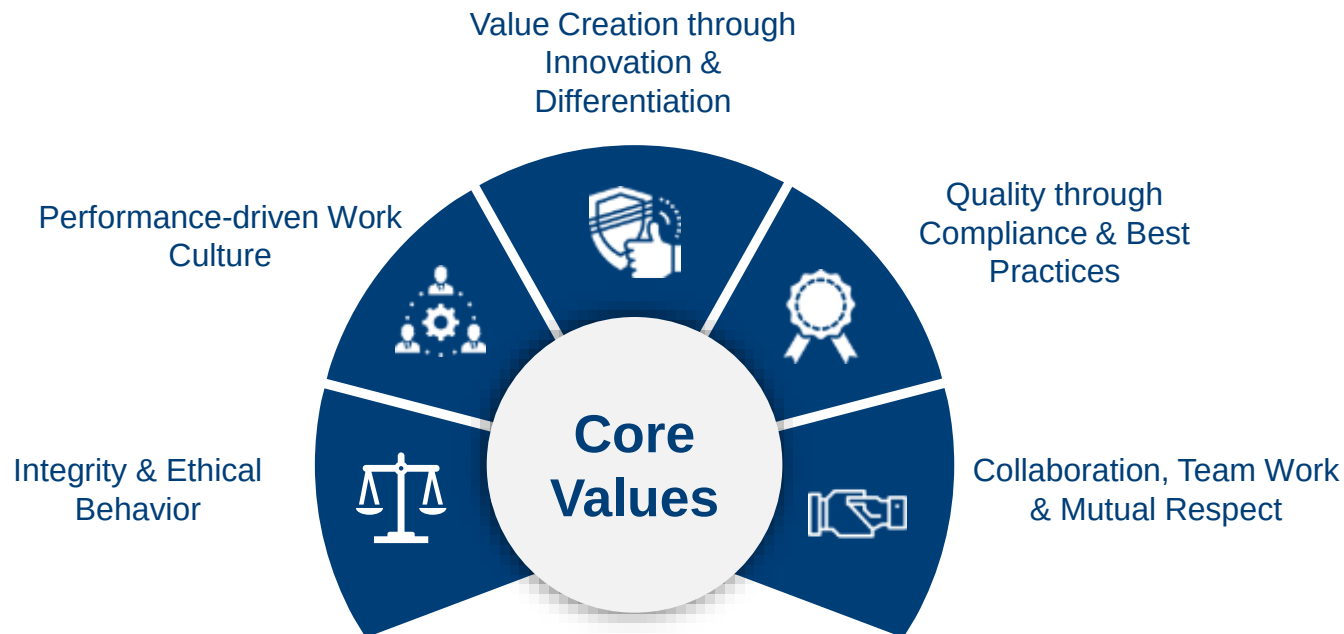
February 2023



Meta morphosis

Biocon 5.0

Biocon is a technology-enabled, future-ready, global biopharmaceuticals leader driven by an unwavering purpose to enhance healthcare worldwide through high-quality, affordable therapies that can lower costs, increase access and improve treatment outcomes.



Biocon at a Glance



**₹ 8,397 Cr |
\$ ~1.1 bn**
Revenue*



~15,000+
Total Employees*



Rank #8
Among Top 10 Global
Biotech Employers**



1,300+
Patents*



100+
cGMP approvals from
International regulatory agencies



7
Manufacturing
units*



120+
Countries where our
products are
available*



15 of top 20
pharma companies
served by service
portfolio *



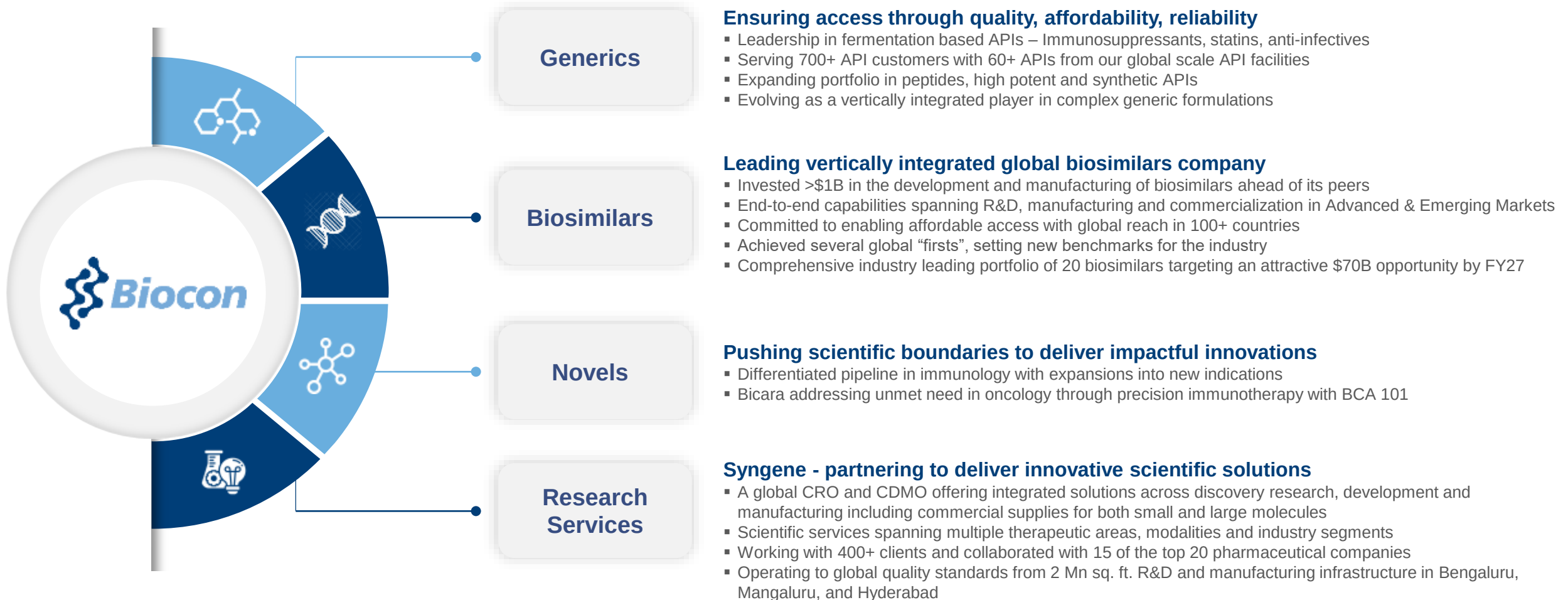
Top 28
Products within
portfolio***

* Numbers as of FY22, ** 2022 Ranking by Science Magazine, *** As per IQVIA MIDAS Oct'22 MAT, top 50 molecules by revenue

Building Biocon



From pipeline to production, from drug discovery to drug delivery,
we bring differentiated, high-quality & affordable healthcare products & services, globally



Generics Business at a Glance



Presence in
100+
countries including U.S.,
Europe & large EMs



5
State-of-the-art
facilities



90+
cGMP approvals
received from international
regulatory agencies



R&D team of
450+
scientists



750+
global
customer reach



Portfolio comprises
60+ APIs
75+ Generic
formulations



90+
Generic
formulation
dossiers
submitted



500+
DMFs filed in various
jurisdictions



300+
patents obtained

Strengths built over the years

- Expertise in fermentation technology, large scale chromatography & synthetic chemistry
- Leveraging in-house API to forward integrate and move up the value chain
- Balanced portfolio across therapeutic segments

Product Portfolio Expansion

- API - Expanding portfolio beyond fermentation and synthetic molecules to peptides, high potent APIs
- Formulations – Complex injectables, device dependent products, potent oral solids, modified-release and extended-release oral solids
- Augmenting portfolio through in-licensing strategy

Capacities Additions & Expansion

- Immunosuppressants API (Visakhapatnam)
- Other Fermentation APIs (Bengaluru)
- Peptides (Bengaluru)
- Synthetic API (Hyderabad)
- Injectables (Bengaluru)

Business Development initiatives

- Strategic partnerships with select customers
- Local manufacturing mandate opportunities in global markets - Technology transfer/ API supply / finished dosage formulations
- API: Expansion of business in key select markets
- Formulations: Expand commercial footprint beyond U.S, either directly or through partners

Other initiatives

- Continued focus on cost improvement and quality compliance
- De-risk critical intermediates sources
- Digital transformation initiatives to support key strategic priorities
- Focus on ESG initiatives like use of renewable energy, promoting gender diversity (incl. women in the shop-floor)

Generics : Our Key APIs and Formulations

APIs *

Therapeutic Area	Molecule	Therapeutic Area	Molecule
Cardiovascular	Apixaban	Immunosuppressants	Mycophenolate Mofetil
	Atorvastatin		Mycophenolate Sodium
	Dabigatran		Pimecrolimus
	Fluvastatin		Sirolimus
	Ivabradine		Tacrolimus
	Pravastatin	Oncology	Dasatinib
	Rivaroxaban		Everolimus
	Rosuvastatin		Lenalidomide
	Simvastatin		Temsirolimus
	Lovastatin	Peptides	Liraglutide
	Sacubitril Na	Multiple Sclerosis	Fingolimod
	Valsartan Disodium		Teriflunomide
Anti-Diabetics	Dapagliflozin	Others	Anidulafungin
	Empagliflozin		Micafungin
	Linagliptin		Posaconazole
	Repaglinide		Orlistat
	Sitagliptin		Deferasirox
	Vildagliptin		Brinzolamide
	Pioglitazone		Mirabegron
			Fidaxomicin

FORMULATIONS

Therapeutic Area	Molecule	US	Dev. Markets: ex-US	MoW ¹
Cardiovascular	Rosuvastatin Calcium	Launched	EU	Launched
	Simvastatin	Launched		
	Atorvastatin	Launched		
	Pravastatin	Launched		
	Labetalol HCl	Launched		
	Prazosin	Launched		
Oncology	Everolimus	Launched	EU ^{\$}	
	Pemetrexed	TA [#]		
Immunosuppressants	Tacrolimus	Launched		Launched
	Mycophenolic Sodium	Launched		
Multiple Sclerosis	Fingolimod	Launched		Launched
Others	Aminocaproic acid (Antifibrinolytic)	Launched		
	Dapagliflozin (Anti Diabetic)	TA [#]		
	Esomeprazole DR (Gastrointestinal)	Launched		
	Dorzolamide (Ophthalmic)	Launched		
	Posaconazole (Anti-Fungal)	Launched	UK, EU ^{\$}	
	Vigabatrin Oral Solution (CNS)	Launched		

Launched Approved

* Filed DMFs | 1 MoW - Most of the World markets | ^{\$}Select EU countries | TA – Tentative approval

Biosimilars Business at a Glance



Global reach in
100+
countries including U.S.,
Europe and EMs



3
State-of-the-art
manufacturing
sites



25+
cGMP approvals
received from key regulatory
agencies



R&D team of
450+
scientists



965+
patents granted



Portfolio comprises
20 biosimilars
and **Vaccines**

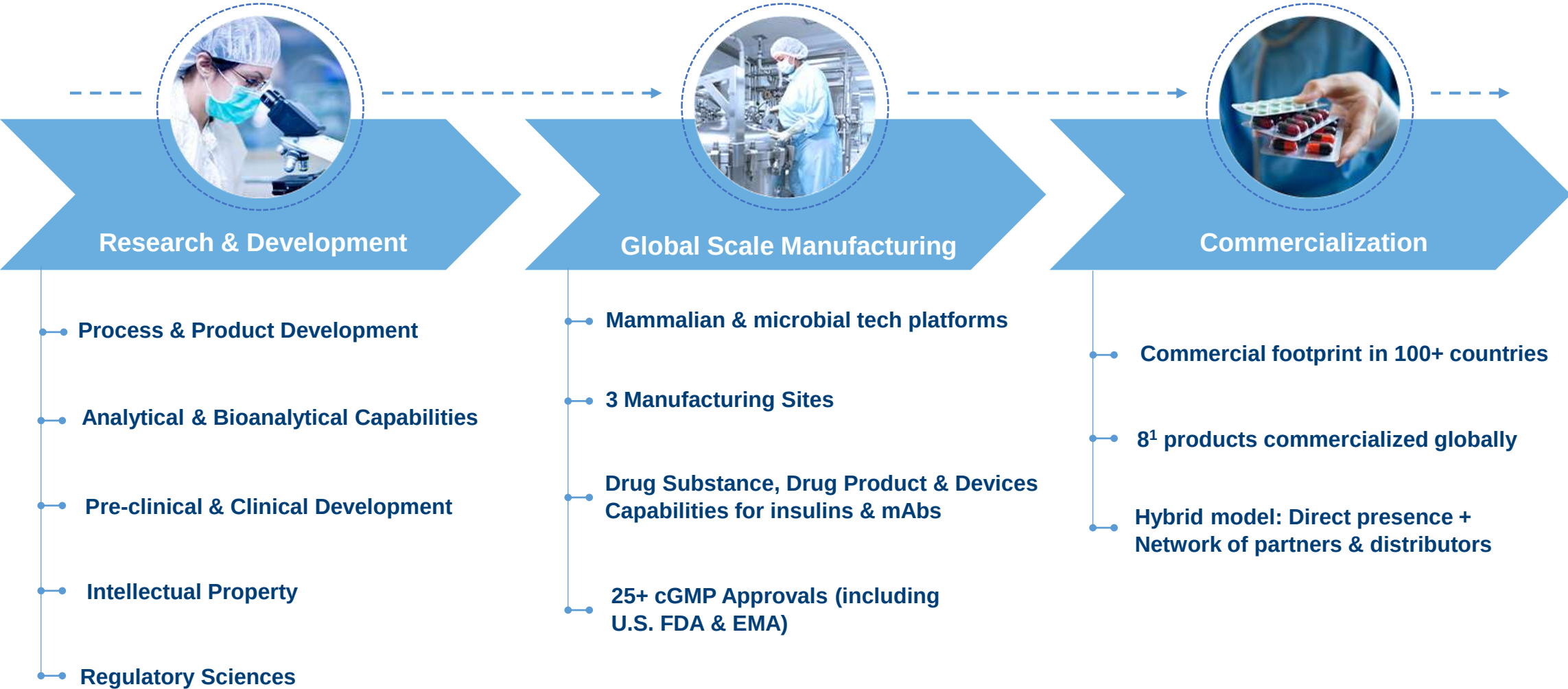


8
Commercial
Products



>5M
Patients served

Biosimilars: Unique, fully integrated capabilities from lab to market



¹Two products are in-licensed i.e. Adalimumab & Etanercept

Biosimilars: Leading global player with a strong track record of success



Built on a 40+ year legacy of cutting-edge science

- **Invested >\$1B in biosimilars ahead of its peers** to build expertise across multiple platforms and a differentiated portfolio - including insulins, mAbs and fusion proteins
- **In-house R&D, clinical and regulatory capabilities** to develop high precision biosimilars for global markets
- **Expertise in large scale manufacturing**, across Drug Substance, Drug Product and Devices and among the **Top 15 globally** in biomanufacturing **capacity**
- **Commercial reach in 100+ markets** through a combination of direct presence¹, strategic partnerships and distributors

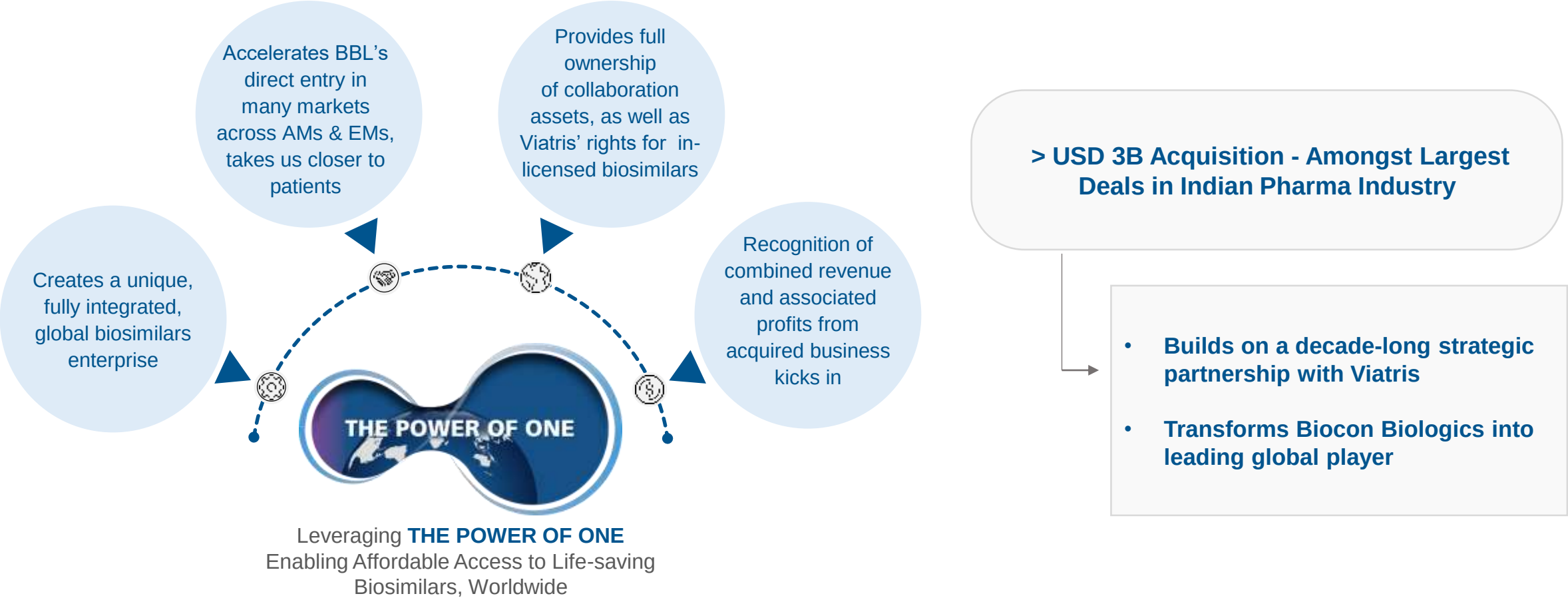
...with a strong track record in an attractive market

- **Achieved many 'firsts' in the industry** - first to receive bTrastuzumab, bPegfilgrastim and interchangeable bGlargine approval in the US
- **Commercialized products in key Advanced Markets**, such as the US, EU, Japan and **several Emerging Markets** (e.g., India, Brazil, UAE, etc.)
- **Backed by marquee investors** including Tata Capital, True North, Goldman Sachs, ADQ and Viatris
- Biosimilars are an **attractive market** with FY22 addressable of \$21B², growing to **\$70B in FY27²**

Committed to enabling affordable access to high quality biosimilars globally

¹ Through the acquisition of Viatris' biosimilars business | ² Only includes products where there has been company reported sales; Biosimilar sales only included for companies that report the numbers

Biosimilars: Acquisition of Viatris' global biosimilars business



Transformational deal to create value for all stakeholders

AMs: Advanced Markets | EMs: Emerging Markets

Biosimilars: Comprehensive, industry leading portfolio of 20 biosimilars



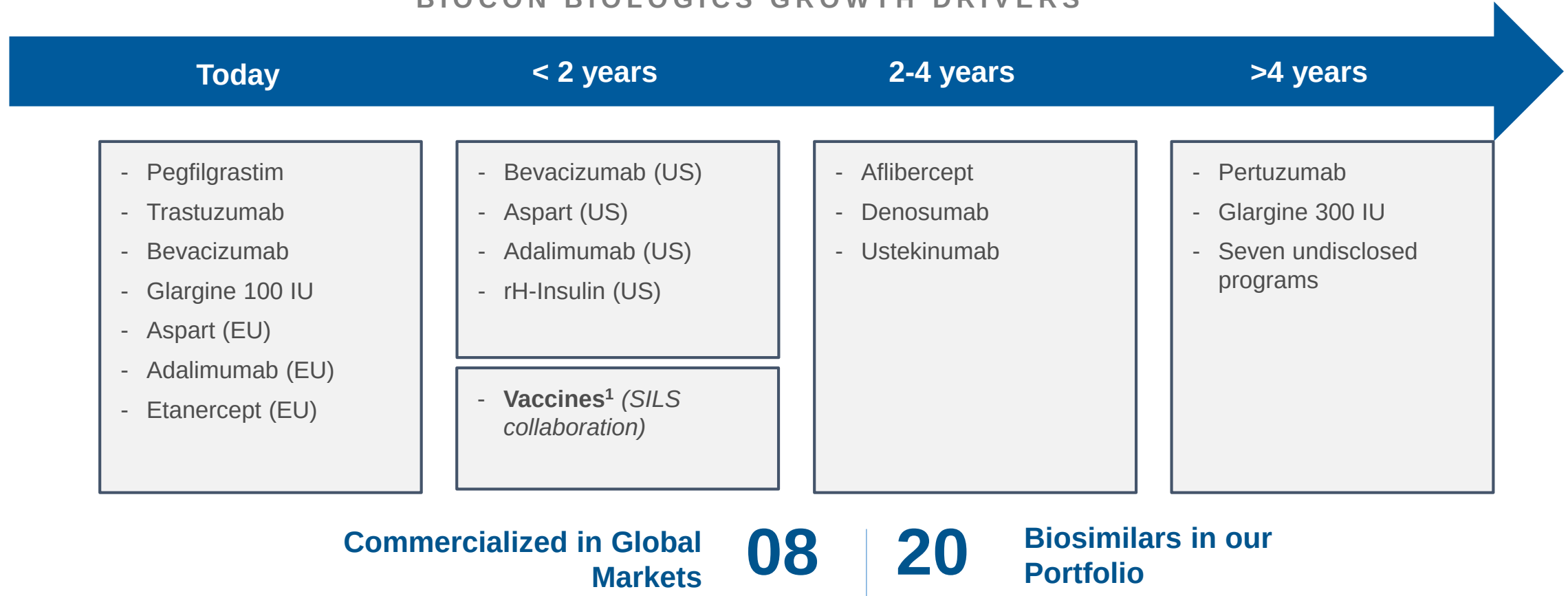
Therapy Area	Oncology 	Immunology 	Ophthalmology 	Bone Health 	Diabetes 	Others 	Vaccines 
Approved or Commercial	• Pegfilgrastim • Trastuzumab • Bevacizumab	• Adalimumab • Etanercept			• RHI • Glargine U100 • Aspart		
Late Stage ¹	• Denosumab • Pertuzumab	• Ustekinumab	• Aflibercept	• Denosumab			Several Infectious Disease Vaccines e.g. Malaria
Early Stage ²	2 undisclosed assets	3 undisclosed assets			• Glargine U300	2 undisclosed assets	

New product launches planned almost every year through 2030

1. Clinical to BLA Review; 2. Pre-Clinical

Biosimilars: Portfolio offers multiple shots on goal to drive sustainable growth

BIOCON BIOLOGICS GROWTH DRIVERS



Biocon Biologics' portfolio targets a ~US\$ 70 Billion addressable market by FY27

Note: Market size only includes products where there has been company reported sales; Biosimilar sales only included for companies that report the numbers

Pushing to deliver impactful innovations in collaboration with Equillium Inc.



Itolizumab

World's first novel humanized anti-CD6 monoclonal antibody that selectively targets the CD6-ALCAM pathway

Biocon's second global 'lab to market' novel biologic after Nimotuzumab

Launched in India in 2013 to treat chronic plaque psoriasis under the brand ALZUMAb™

Licensed out rights to develop & commercialize in the U.S., Canada, Australia and New Zealand to U.S.-based biotechnology company, Equillium Inc. in 2017

Option and Purchase Agreement entered between Equillium and Ono Pharmaceutical Co., Ltd, Japan, where Equillium has granted Ono the exclusive right to acquire its rights to itolizumab

Acute Graft-Versus-Host Disease (GVHD)

- ✓ Pivotal Phase III Study initiated in Mar '22 for use in First-Line treatment of Acute GVHD; patient dosing initiated
- ✓ European Commission granted Orphan Drug Designation for treatment of aGVHD in Jul '21
- ✓ Received Fast Track designation from the US FDA

Systemic Lupus Erythematosus/ Lupus Nephritis (SLE/LN)

- ✓ Received Fast Track designation from the US FDA
- ✓ Given positive trends in Part A, expanded Part B portion of Phase 1b EQUALISE study to clinical centers in India
- ✓ Patient recruitment continues

Cytokine Release Syndrome treatment in 'Moderate to Severe' Acute Respiratory Distress Syndrome

- ✓ Repurposed for prevention & treatment of COVID-19 complications in India in 2020
- ✓ Granted 'Restricted Emergency Use' approval in Sep '20

Ulcerative Colitis

- ✓ Application for Phase 2 clinical trials in India for the treatment of ulcerative colitis using Itolizumab, approved by the DCGI
- ✓ Initiated Phase 2 clinical study of itolizumab in patients with ulcerative colitis in Dec '22

The precision of targeted therapies | The power of tumor modulators



BCA101

(Formerly FmAb2)

Lead candidate

*First-in-class EGFR / TGFβ-trap
bifunctional antibody*

BCA 101

- ✓ Lead product candidate, **BCA101** (EGFR / TGF-β-trap) demonstrates tumor target engagement and clinical activity
 - ✓ **Monotherapy activity** in difficult to treat post-pembro squamous lung cancer
 - ✓ Activity in combination with pembro in **checkpoint and cetuximab-refractory** head and neck cancer (HNSCC) and anal canal cancer
- ✓ BCA101 + pembrolizumab combination dose expansion study **currently enrolling in 1L HNSCC – achieved efficacy threshold for Stage 1 prior to completing enrollment**

Organization

- ✓ Highly experienced management team, board of directors and advisory board
- ✓ \$82M raised in Seed/Series A from syndicate of dedicated biotech investors (Biocon ownership at 53%)
- ✓ Leveraging the Biocon and Syngene infrastructure to offer agility and deep experience in CMC/drug development

Platform

- ✓ ToTeM™ – leverages rational combinations to unleash the full potential of targeted tumor modulators
- ✓ Pragmatic antibody engineering and manufacturable IgG-like biologics
- ✓ Delivering 2 additional INDs in 2023-2024

*a US based clinical-stage biotechnology company. In Q4FY21, Biocon ceded control over the Board of Directors and Operations of Bicara to enable it to operate independently under a US based leadership team and raise funds to advance its development programs. As a result of this change, Bicara was classified as an Associate from a Subsidiary under IND-AS.

Research Services :

Syngene has capabilities spanning the value chain, facilitating integration



Research business		Development and Manufacturing business	
Discovery Services	Dedicated R&D Centres	Development Services	Manufacturing Services
			
Flexible Platform with capability across multiple modalities, including small molecule, large molecule, peptides, oligonucleotides, antibody drug conjugates, PROTACs SynVent Syngene's proprietary platform for Integrated Drug Discovery	Ring-fenced infrastructure for exclusive operations for an individual client Dedicated, multi-disciplinary team of scientists Access to entire Syngene ecosystem for specialist research and development operations	Pre-clinical to clinical trials Drug substance and drug product development Associated services to demonstrate the safety, tolerability and efficacy of the selected drug candidate cGMP-compliant manufacturing of clinical supplies, and registration batches for small molecules	Manufacturing of small and large molecules for commercial supplies cGMP-compliant facilities State-of-the-art API manufacturing and biologics manufacturing facilities

Research Services (Syngene) : Key Growth Levers



Platform Play in Discovery Services

- Flexible platform solutions with capabilities across multiple modalities for functional services
- Integrated Drug Discovery through SynVent Platform
- Leverage existing and new scientific capabilities
- Continuous in capacity addition



Integrated Solutions in Development Services and clinical supplies

- Integrated Solutions from process development, clinical manufacturing to regulatory filing
- Increase capacity utilization in clinical manufacturing
- Capability additions through Injectable Fill Finish
- Operational efficiency through automation, digitalization



Scaling up Manufacturing Services

- Syngene's commercial manufacturing Services capability is new compared to the research services
- Completes the integrated platform offering to innovators across small molecule and Biologics



Extension and expansion of Dedicated Centres

- Reaffirms its reliability as a strong partner
- Contract with BMS extended till 2030
- Contract with Amgen extended till 2026

Quarterly Highlights



Financial Highlights: Q3 FY23 (1/2)

Consolidated (in INR Cr.)	Q3 FY23	Q3 FY22	YoY %	
Total Revenue	3,020	2,223	36	Biosimilars +54% Research +23% Generics +18%
Core EBITDA¹	1,069	715	49	
<i>% Margin</i>	36%	33%		
EBITDA	723	537	35	Net R&D spend at ₹337Cr, up ₹199 Cr vs Q3 FY22 Forex Loss of ₹44Cr vs gain of ₹19 Cr in Q3 FY22
<i>% Margin</i>	24%	24%		
Profit Before Tax <i>(Before exceptional charge)</i>	246	269	(9)	Increase in amortisation and interest expense related to the acquisition of Viatris' biosimilar business
<i>% Margin</i>	8%	12%		
Net Profit <i>(Before exceptional charge)</i>	140	187	(25)	Increase in minority interest due to dilution of shareholding in Biocon Biologics and Syngene
Net Profit Margin %	5%	8%		

¹ Core EBITDA defined as EBITDA before forex, dilution gain in Bicara, R&D, licensing income and mark to market movement investments.

Financial Highlights: Q3 FY23 (2/2)

Consolidated (in INR Cr.)	Q3 FY23	Q3 FY22	YoY %	
Net Profit <i>(before exceptional charge)</i>	140	187	(25)	Exceptional items during Q3 FY23: Primarily pertain to deal related expenses of the Viatris transaction. .
Exceptional Items <i>(net of tax and minority interest)</i>	(182)	-		
Net Profit /(loss) <i>(Reported)</i>	(42)	187		

Generics: Q3 FY23 Update

KEY HIGHLIGHTS

- Revenue growth led by increased demand for Immunosuppressant APIs as well as Generic Formulations
- Margins, compared to the previous year were muted due to continued pricing pressure in the US market
- Signed a partnership agreement with Zentiva for commercialising Liraglutide in 30 European countries
- Signed a long term strategic partnership in Brazil for the supply and tech-transfer of a finished dose formulation immunosuppressant product
- Issued a GMP Certificate of Compliance by the European Directorate for the Quality of Medicines & HealthCare (EDQM), for our API manufacturing facility in Bengaluru, following a GMP inspection of the site conducted in September 2022.
- Validation of the immunosuppressant API facility in Visakhapatnam and peptide facility in Bengaluru expected to be completed by H1 FY24

In INR Cr	Q3 FY23	Q3 FY22	YoY %
Revenue from operations	718	607	18
PBT	72	67	8
% of revenue	10%	11%	

Biosimilars: Q3 FY23 Update

KEY HIGHLIGHTS

- Revenue growth of 54% driven by Viatris deal closure and steady growth in BBL-led business
- R&D investments increased to ₹280 Crores; completed recruitment for bDenosumab and bUstekinumab clinical trials
- bPertuzumab entered Phase 1 trials, initiated interchangeability study for bAdalimumab
- All products surpass 10% market share in US; bAdalimumab garners 18% and 10% market share in Germany and France, respectively
- Eight new launches in Emerging Markets
- CAPA plan submitted for bAspart and bBevacizumab; committed to closure of actions within stipulated timeline

In INR Cr	Q3 FY23	Q3 FY22	YoY %
Revenue from operations	1,507	981	54
Core EBITDA	663	363	83
% of revenue	44%	38%	
PBT <i>(before exceptions)</i>	102	124	(17)
% of revenue	7%	13%	

*Core EBITDA defined as EBITDA excluding R&D, forex, licensing income and mark-to-market movement on investments

Novels : Q3 FY23 Update

KEY HIGHLIGHTS

- Enrolment continues to ramp up in the pivotal Phase III clinical study of Itolizumab in patients with aGVHD* (EQUATOR study)
- Patient enrolment also continues for the pivotal Phase 1b clinical study of Itolizumab for Lupus Nephritis (equalise study)
- The Phase II trial underway in India for the clinical study of Itolizumab in patients with Ulcerative Colitis, patient dosing (Randomization) began in December, 2022
- Equillum has recently entered into an Option and Purchase Agreement with Ono Pharmaceutical Co., Ltd, Japan, where Equillum has granted Ono the exclusive right to acquire its rights to Itolizumab



*Acute Graft-Versus-Host Disease

Research Services: Q3 FY23 Update

KEY HIGHLIGHTS

- Delivered positive performances in all divisions. Sustained growth in Research divisions - Discovery Services and the Dedicated Centers
- Development Services growth primarily driven by repeat orders from existing clients and a growing number of collaborations with emerging biopharma companies
- Syngene successfully completed the US Food and Drug Administration (US FDA), European Medicines Agency (EMA) and Medicines and Healthcare products Regulatory Agency (MHRA) regulatory audits for its biologics manufacturing facility
- With the Good Manufacturing Practice (cGMP) certifications from the regulatory agencies in place, the Company is on track to execute manufacturing of drug substance at a commercial scale and progress its Biologics manufacturing services growth strategy

In INR Cr	Q3 FY23	Q3 FY22	YoY %
Revenue from operations	786	641	23%
PBT	140	128	9%
% of revenue	18%	20%	



Environment, Social, Governance



ESG: A Culture of Purpose, Ethics & Equity

Going beyond financials to have a positive impact

Our ESG Strategy Pillars



Improve access to high quality therapeutics to drive 'Patient Equity'



Build an empowering and inclusive workplace creating 'People Equity'



Adapting to a sustainable business operations for 'Environment Equity'



Operate with integrity, transparency and accountability ensuring 'Stakeholder Equity'



Enable underserved communities 'Social Equity'

Monitor Performance → Improve Through Initiatives → Report Outcomes

Recognitions



Published 1st GRI aligned ESG & BRSR Report for FY22



Improved ESG score over 2021 from 45 to 52



Maintained score of 'B' in 2022 for Water Security



Top 10 - India's Best Workplaces in Diversity, Equity and Inclusion, 2021



Secured 'Bronze' place and improved score to 52 in 2021.

Annexures



Biocon's Evolution: Our journey over the last 5 decades

Metamorphosis from manufacturer of enzymes to a vertically integrated bio-pharmaceutical player and global CRO & CDMO of global standing.
Created tangible differentiators for sustainable growth with focus on research and innovation

1970s-80s

Innovating Enzyme Technologies

- Incorporated as a joint venture with an Irish biotech (1978)
- Transformed into an export-driven enzymes company
- JV partner acquired by Unilever Plc., Biocon starts producing enzymes for Unilever's food businesses (1989)

1990s

Entry into Research Services and Biopharmaceuticals

- Incorporated Syngene as a custom research organization (1994)
- Scaled up R&D and fermentation capacity, entered biopharmaceutical manufacturing
- Became an independent, privately-owned company

2000s

Transitioning to a biopharmaceutical enterprise

- Established Clinical arm (2000). Entered biologicals manufacturing incl .Novels (2002)
- Unlocked value through IPO, 2nd Indian company to be listed with \$1Bn+ valuation (2004)
- Divested Enzymes business to increase focus on Biopharmaceuticals (2007)
- Partnered with Mylan (now Viatris) for global development, early entry into biosimilars (2009)

2010s

Building Scale for Global Impact

- Invested in R&D, commercial scale, globally compliant manufacturing facilities
- Forward integrated small molecule APIs to formulations
- Syngene listed separately, emerging as India's leading CDMO (2015)
- Ranked in world's Top 15 biomanufacturing cos, partnered with Sandoz for next gen biosimilars

2020+

Building a Company of the Future

- Portfolio and geographical expansions, capacity additions in Generics
- Acquisition of Viatris' Biosimilar business for vertical integration; partnership with Serum for entry to vaccines
- Research Services evolves to a full fledged global CRO & CDMO
- Continued investment in novel innovations & promoting health equity

With many firsts, Biocon is ahead of the curve

- 1st Indian Life Sciences Company to get ISO 9001 Certification

1993

- 1st Clinical Research Service Organization in India established - Clinigene

2000

- 1st company globally to get U.S. FDA approval for making Lovastatin API through innovative fermentation technology.

2001

- 1st company in the world to develop & commercialize Pichia-based rh-Insulin

2004

- 1st Indian Company to launch a novel biologic, Nimotuzumab for head and neck cancer patients

2006

- 1st anti-CD6 monoclonal antibody in the world, Itolizumab, commercialised in India

2013

- 1st company to introduce biosimilar Trastuzumab in the world

2014

- 1st company from India to have a biosimilar approved in Japan

2016

- 1st company globally to receive U.S. FDA approval for biosimilar Trastuzumab

2017

- 1st company to launch Fulphila™, biosimilar Pegfilgrastim in U.S.

2018

- 1st company from India to have a biosimilar commercialized in the US

2018

- 1st company to receive interchangeability designation for a biosimilar (insulin glargine) in the US

2021

Safe Harbor Statement

Certain statements in this release concerning our future growth prospects are forward-looking statements, which are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those contemplated in such forward-looking statements. Important factors that could cause actual results to differ materially from our expectations include, amongst others general economic and business conditions in India, our ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currencies, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global biotechnology and pharmaceuticals industries, increasing competition in and the conditions of the Indian biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither the company, nor its directors and any of the affiliates have any obligation to update or otherwise revise any statements reflecting circumstances arising after this date or to reflect the occurrence of underlying events, even if the underlying assumptions do not come to fruition.

**Thank
You**

