

Biocon Limited 20th KM, Hosur Road Electronic City Bangalore 560 100, India T 91 80 2808 2808 F 91 80 2852 3423

CIN: L24234KA1978PLC003417

www.biocon.com

May 24, 2023

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

Dear Sir/Madam,

Subject: Investor Presentation – Q4 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 <u>www.biocon.com</u>.

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



Q4 FY23 Investor Presentation

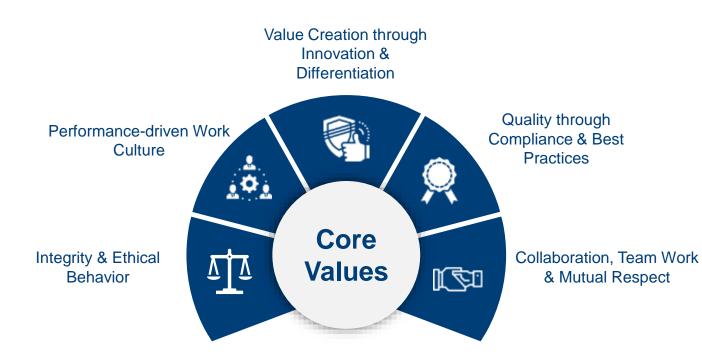
May 2023

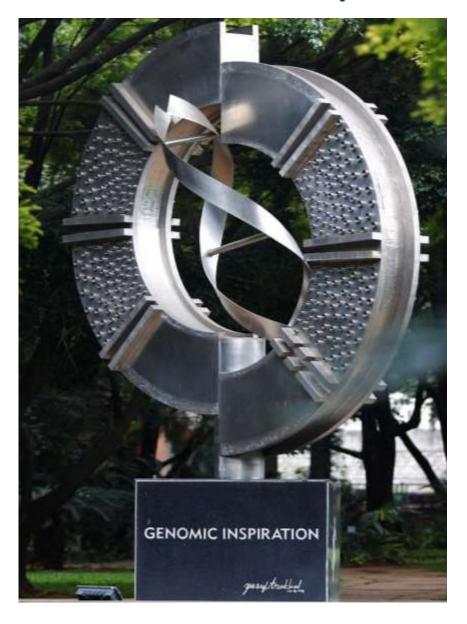


Biocon 5.0



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







Biocon at a Glance





* Revenue numbers for FY23, others numbers as of FY22, ** 2022 Ranking by Science Magazine, *** As per IQVIA MIDAS Oct'22 MAT, top 50 molecules by revenue

Building Biocon

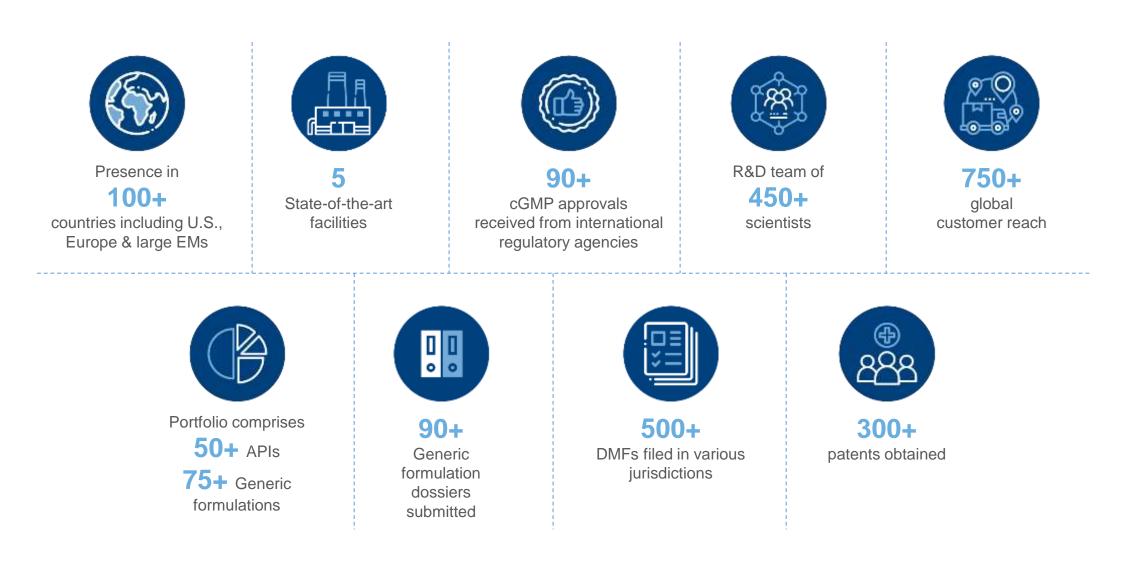
Biocon: One Company, with multiple value propositions across its verticals



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







Generics : API & Formulations - Growth Levers



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, modifiedrelease 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)



MoW¹

Generics : Our Key APIs and Formulations

APIs*

Therapeutic Area	Molecule	Therapeutic Area	Molecule
	Apixaban		Tacrolimus
	Atorvastatin		Mycophenolate Mofetil
	Dabigatran	_	Mycophenolate
	Fluvastatin	Immunosuppressants	Sodium
	Ivabradine		Everolimus
ardiovascular	Pravastatin		Tacrolimus
Rivaroxab Rosuvasta Simvastat Lovastatin	Piyaroyahan		Pimecrolimus
			Dasatinib
	Rosuvastatin	Oncology	Everolimus
	Simvastatin		Lenalidomide
	Lovastatin		Temsirolimus
	Sacubitril Sodium		Micafungin
	Liraglutide	Anti-fungal	Anidulafungin
	Dapagliflozin		Posaconazole
	Empagliflozin	Multiple Sclerosis	Fingolimod
	Linagliptin		Teriflunomide
nti-Diabetics	Repaglinide		Orlistat
	Sitagliptin	-	Deferasirox
	Vildagliptin	- Others	Brinzolamide
	Pioglitazone		Mirabegron

FORMULATIONS US Molecule Dev. Markets: ex-US

Therapeutic Area

merapeutic Area	Wolecule	03	Dev. Markets: ex-05	INIO AA .
	Rosuvastatin Calcium		EU	
	Simvastatin			
Cardiovascular	Atorvastatin			
Cardiovascular	Pravastatin			
	Labetalol HCI			
	Prazosin			
	Everolimus		EU\$	
Oncology	Pemetrexed	ТА		
	Lenalidomide	ТА	EU\$	
Immunocupproceante	Tacrolimus			
Immunosuppressants	Mycophenolic Sodium			
Multiple Sclerosis	Fingolimod			
	Teriflunomide			
	Aminocaproic acid (Antifibrinolytic)			
	Dapagliflozin (Anti Diabetic)	ТА		
	Esomeprazole DR (Gastrointestinal)			
Others	Dorzolamide (Ophthalmic)			
	Posaconazole (Anti-Fungal)		UK, EU ^{\$}	
	Vigabatrin Oral Solution (CNS)			
	Vigabatrin Tablets (CNS)			
Launched	Approved			

Biosimilars Business at a Glance





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



Top 15 in global biomanufacturing capacity



25+ cGMP approvals received from key regulatory agencies



Diverse global talent pool of **5,500+** people



965+ patents granted



Portfolio comprises 20 biosimilars



8 Commercial Products in Global Markets

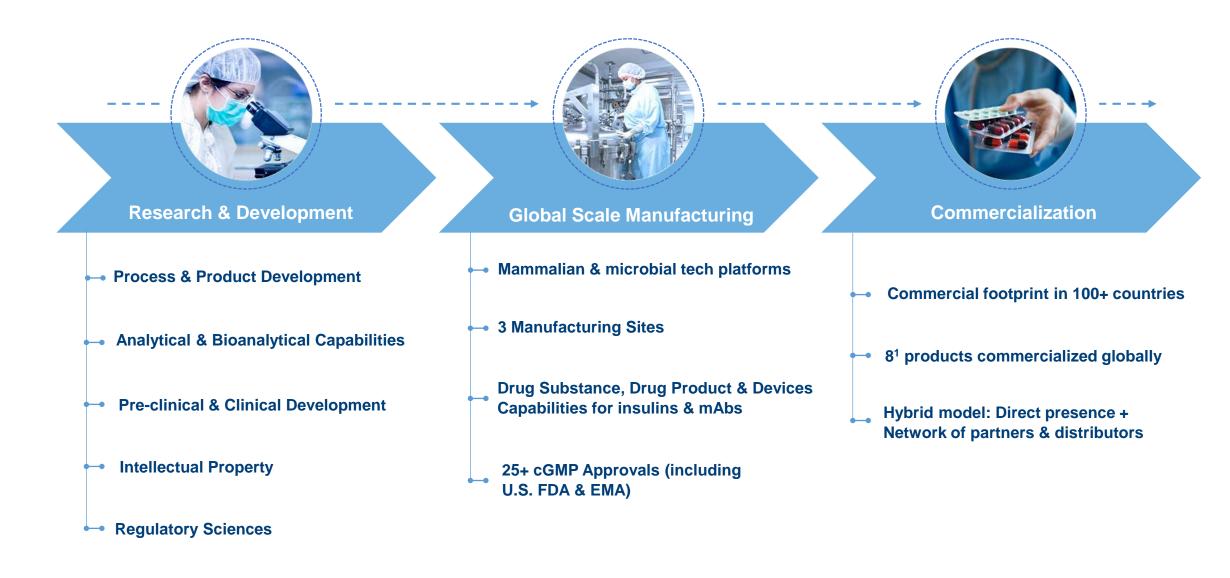


>5M Patients served

Unique, fully integrated leading global biosimilars player

Biosimilars: Unique, fully integrated capabilities from lab to market





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

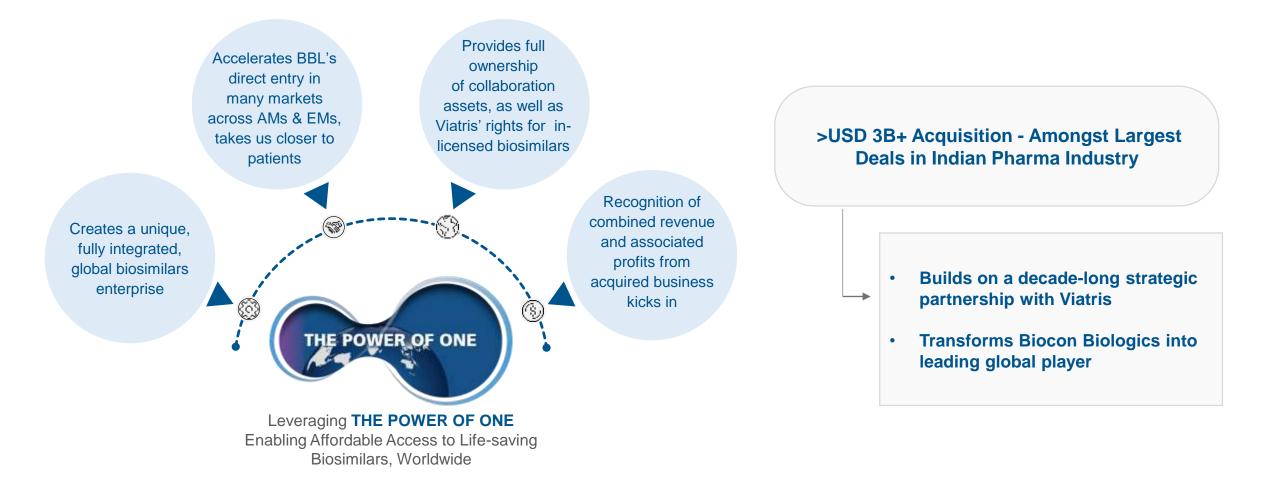
...with a strong track record in an attractive market

- 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 \$25B², growing to \$78B in FY28²

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

Biosimilars: Comprehensive, industry leading portfolio of 20 biosimilars



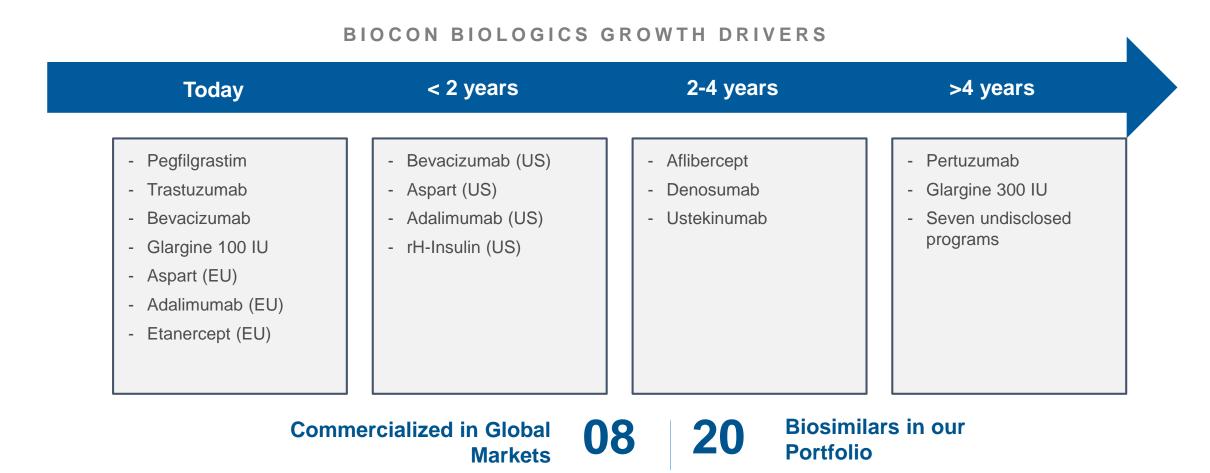
Therapy Area	Oncology X	Immunology	Ophthalmology	Bone Health	Diabetes	Others	Vaccines
	Pegfilgrastim	Adalimumab			• RHI		
Approved or Commercial	Trastuzumab	Etanercept			Glargine U100		
	Bevacizumab				Aspart		
	Denosumab	Ustekinumab	Aflibercept	Denosumab			Several Infectious
Late Stage ¹	Pertuzumab						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' portfolio targets a ~US\$ 78 Billion addressable market by FY28

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

Novel Molecules : Itolizumab





Pushing to deliver impactful innovations in collaboration with Equillium Inc.

World's first novel humanized anti-CD6 monoclonal antibody	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
<i>that selectively targets the CD6-</i> <i>ALCAM pathway</i> Biocon's second global 'lab to market' novel biologic after Nimotuzumab Launched in India in 2013 to treat	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 ✓ Topline data expected in the first half of 2024
chronic plaque psoriasis under the brand ALZUMAb [™] Licensed out rights to develop & commercialize in the U.S., Canada, Australia and New Zealand to U.Sbased biotechnology company, Equillium Inc. in 2017	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
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	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 targete	d therapies	The powe	r of tumor r	nodulators
		or targoto	a thorapioo			ino a anacor o

ళో స్ స్పోర్ BCA101	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
(Formerly FmAb2) Lead candidate First-in-class EGFR / TGFβ-trap bifunctional antibody	Organization	 Highly experienced management team, board of directors and advisory board \$82M raised in Seed/Series A from syndicate of dedicated biotech investors \$105M raised in Series B funding. Biocon ownership at 38%, to reduce to ~23% in FY24. 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:





SARchitect- Syngene's proprietary platform for data visualization and analysis, including features specifically designed to foster collaboration between scientific experts across geographies

Ring-fenced infrastructure for exclusive

Access to entire Syngene ecosystem for operations



Development Services

Pre-clinical to clinical trials

Drug substance and drug product development for both large and small molecules

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 Services

Development and Manufacturing business



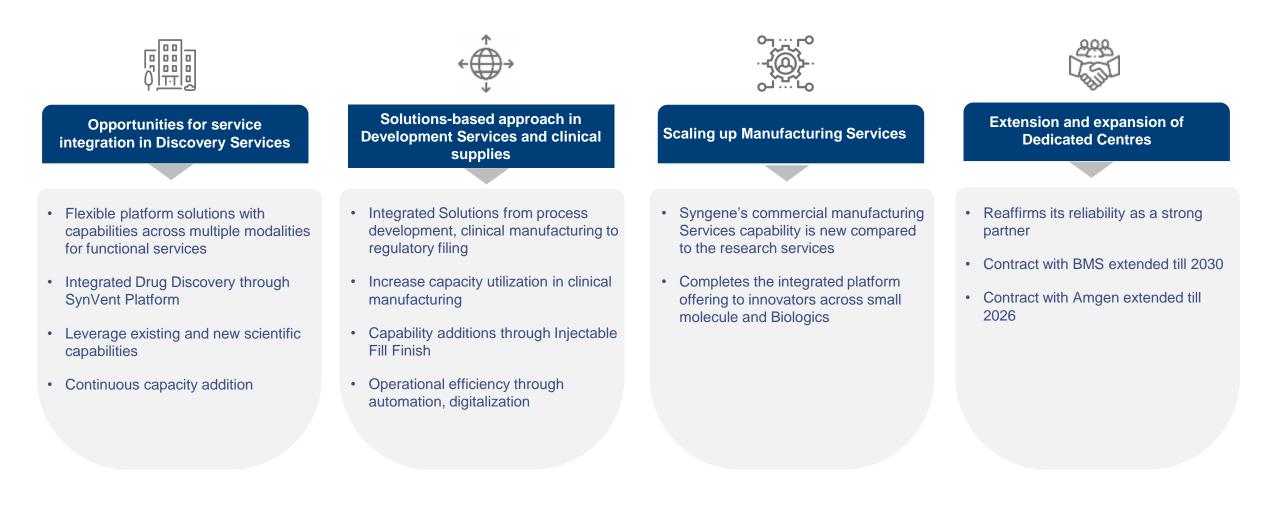
Manufacturing of small and large molecules for commercial supplies

cGMP-compliant facilities

State-of-the-art API manufacturing and biologics manufacturing facilities

Research Services (Syngene) : Key Growth Levers





Q4 & Full Year FY23 Highlights

Financial Highlights: Q4 FY23



Consolidated (in ₹ Cr.)	Q4 FY23	Q4 FY22	YoY %	
Total Revenue	3,929	2,476	59	Biosimilars +114% Research +31% Generics - Includes ₹109 Cr from Bicara stake dilution gain
Core EBITDA ¹	1,260	809	56	Growth driven by Biosimilars & Research services
% Margin	35%	33%		
EBITDA	1,152	659	75	Net R&D spend at ₹342 Cr, up ₹152 Cr vs Q4 FY22, representing 12% of revenues ex-Syngene
% Margin	29%	27%		
Profit Before Tax (Before exceptional charge)	500	384	30	Increase in depreciation, amortization and interest expense primarily related to acquisition of Viatris' biosimilar business
% Margin	13%	15%		
Net Profit (Before exceptional charge)	335	262	28	Increase in minority interest due to dilution of shareholding in Syngene and Biocon Biologics on account of the Viatris deal
Net Profit Margin %	9%	11%		

¹ Core EBITDA defined as EBITDA before forex, dilution gain in Bicara, R&D, licensing income and mark-to-market movement on financial instruments

Financial Highlights: FY23 (1/2)



Consolidated (in ₹ Cr.)	FY23	FY22	YoY %	
Total Revenue	11,550	8,397	38	Biosimilars +61% Research +23% Generics +13% Includes ₹217 Cr from Bicara stake dilution gain
Core EBITDA ¹	3,807	2,669	43	Growth driven by Biosimilars & Research services
% Margin	34%	32%		
EBITDA	2,888	2,183	32	Net R&D spend at ₹1,119 Cr, up ₹524 Cr vs FY22, representing 14% of revenues ex-Syngene Forex Loss of ₹160 Cr vs. gain of ₹58 Cr last year.
% Margin	25%	26%		
Profit Before Tax (Before exceptional charge)	1,189	1,094	9	Increase in depreciation, amortization and interest expense primarily related to acquisition of Viatris' biosimilar business
% Margin	10%	13%		
Net Profit (Before exceptional charge)	787	722	9	Increase in minority interest due to dilution of shareholding in Syngene and Biocon Biologics on account of the Viatris deal
Net Profit Margin %	7%	9%		

¹ Core EBITDA defined as EBITDA before forex, dilution gain in Bicara, R&D, licensing income and mark-to-market movement on financial instruments

Financial Highlights: FY23 (2/2)



Consolidated (in ₹ Cr.)	FY23	FY22	YoY %	
Net Profit (before exceptional charge)	787	722	9	Exceptional items during FY23:
Exceptional Items (net of tax and minority interest)	(324)	74		 Deal related expenses of the Viatris transaction MAT credit balance charge on adoption of new tax regime of 25%
Net Profit / (loss) (Reported)	463	648		

Generics: Q4 & full year FY23 Update

KEY HIGHLIGHTS



Revenue growth for the quarter muted mainly due to product mix, margins lower due to price erosion in base business products

Delivered revenue in-line with guidance of for the full year driven by API sales, namely from immunosuppressants and specialty APIs and higher volume market share of recently launched generic formulation products in the U.S.

Validation of the immunosuppressant API facility in Visakhapatnam and peptide facility in Bengaluru expected to be completed by H1 FY24.

Made 32 filings and received 19 approvals for our generic formulation products across U.S., EU, UK, and emerging markets

Continued focus on enhancement of our manufacturing capacities and capabilities - investing in a new injectables facility, expanding our larger scale peptide, synthetic and non-immunosuppressant API manufacturing capacities

In February, our API manufacturing facility in Bengaluru underwent an EU GMP inspection with no critical or major observations. US FDA preapproval inspection in Hyderabad concluded on 19-May-23 with no observations

In INR Cr	Q4 FY23	Q4 FY22	YoY %
Segment Revenue	717	717	0
PBT	75	116	(35)
% of revenue	10%	16%	
In INR Cr	FY23	FY22	YoY %
In INR Cr Segment Revenue	-	FY22 2,341	YoY % 13
	-		



Biosimilars: Q4 and full year FY23 Update

KEY HIGHLIGHTS



R&D investments increased to ₹889 Crores; bDenosumab, bUstekinumab and bPertuzumab undergoing clinical trials

Restructured vaccines alliance with Serum, withdrawing the issuance of 15% stake in BBL

35+ new launches in FY23, increasing reach of BBL products

Market share for Fulphila and Semglee in US at 14% and 12%, respectively

Malaysia site inspection by US FDA in Q2 FY24

In INR Cr	Q4 FY23	Q4 FY22	YoY %
Revenue	2,102	982	114
Core EBITDA	742	382	95
% of revenue	39%	39%	
EBITDA	573	257	123
PBT (before exceptions)	152	144	5
% of revenue	7%	15%	
In INR Cr	FY23	FY22	YoY %

In INR Cr	FY23	FY22	YoY %
Revenue	5,584	3,464	61
Core EBITDA	2,216	1,320	68
% of revenue	41%	39%	
EBITDA	1,338	1,013	32
PBT (before exceptions)	403	543	(26)
% of revenue	7%	16%	

Novels : Q4 FY23 update

KEY HIGHLIGHTS



Patient enrolment ramped up in the pivotal Phase III clinical study of itolizumab in patients with aGVHD* (EQUATOR study)

Pivotal Phase 1b clinical study of itolizumab for Lupus Nephritis (EQUALISE study) remains on track, top line data expected in 1H2024

BCA101 is currently in Phase1/1b clinical development in head and neck cancer

Bicara completed USD 108 million series B financing – fund raise to help advance its lead program BCA101



Biocon

Research Services: Q4 & full year FY23 update

KEY HIGHLIGHTS

Biggest quarter ever. Strong growth with positive performances across all four divisions

The growth of Discovery Services and Dedicated Centers remained steady. The Discovery Services research facility in Hyderabad continued to expand and now houses approximately 900 scientists

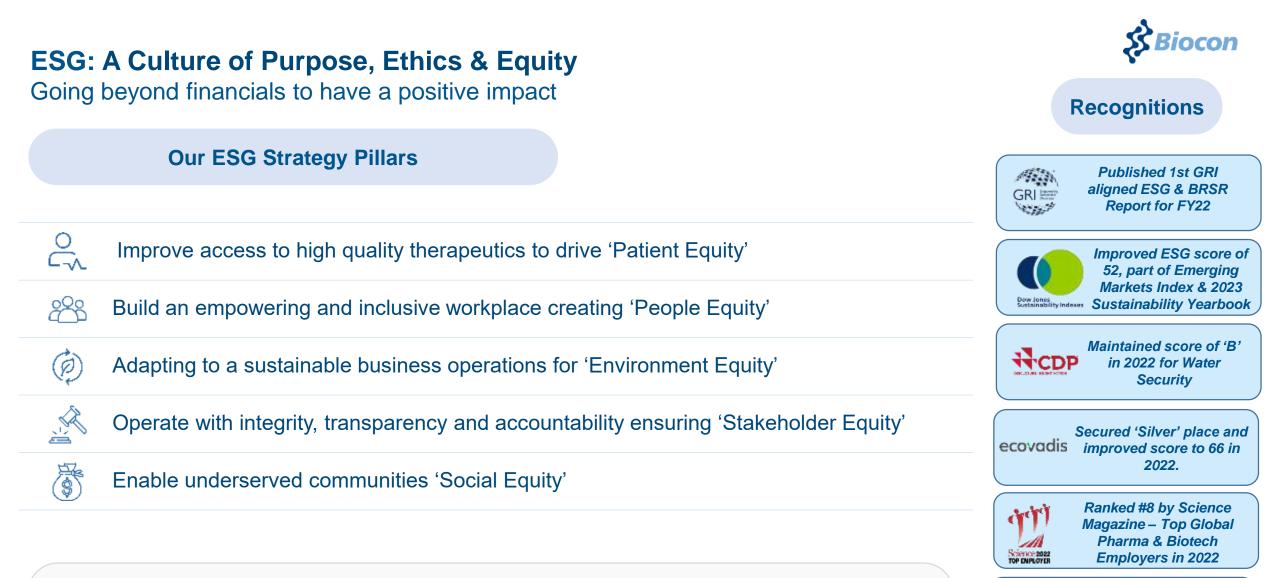
Growth in Development Services was driven predominantly by further orders from existing clients

Manufacturing Services continued to support the long-term partnership with Zoetis, following the successful regulatory inspections by the U.S, European and U.K. regulatory authorities

In INR Cr	Q4 FY23	Q4 FY22	YoY %
Segment Revenue	994	758	31
PBT	231	179	29%
% of revenue	23%	24%	
In INR Cr	FY23	FY22	YoY %
In INR Cr Segment Revenue		FY22 2,604	YoY % 23

- Delivered full-year results ahead of upgraded guidance,
- FY23 delivered the highest absolute year-on-year increase in revenue and EBITDA in the last 5 years

Environment, Social, Governance



Monitor Performance \rightarrow Improve Through Initiatives \rightarrow Report Outcomes



Great

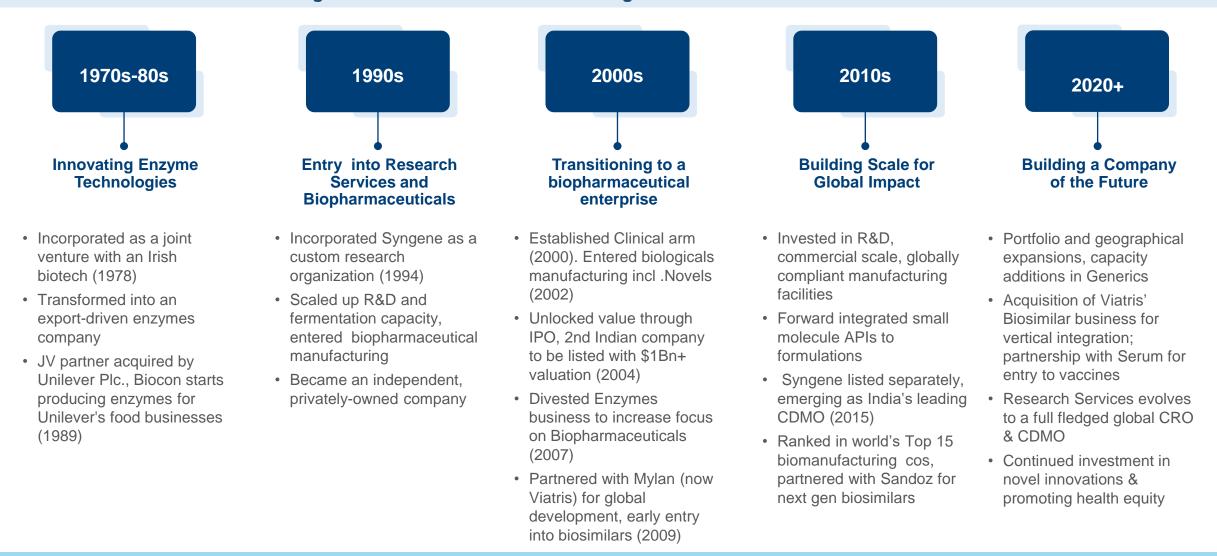
To Work,

Certified

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





With many firsts, Biocon is ahead of the curve

• 1 st Indian Life Sciences Company to get ISO 9001 Certification	1 st Clinical Research Service Organization in India established - Clinigene	• 1 st company globally to get U.S. FDA approval for making Lovastatin API through innovative fermentation technology.	 1st company in the world to develop & commercialize Pichia -based rh-Insulin 	 1st Indian Company to launch a novel biologic, Nimotuzumab for head and neck cancer patients 	• 1 st anti-CD6 monoclonal antibody in the world, Itolizumab, commercialised in India
1993	2000	2001	2004	2006	2013
• 1 st company to introduce biosimilar Trastuzumab in the world	 1st company from India to have a biosimilar approved in Japan 	 1st company globally to receive U.S. FDA approval for biosimilar Trastuzumab 	 1st company to launch Fulphila[™], biosimilar Pegfilgrastim in U.S. 	 1st company from India to have a biosimilar commercialized in the US 	• 1 st company to receive interchangeability designation for a biosimilar (insulin glargine) in the US
2014	2016	2017	2018	2018	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.

