

# Q3 FY24 Investor Presentation

February 2024

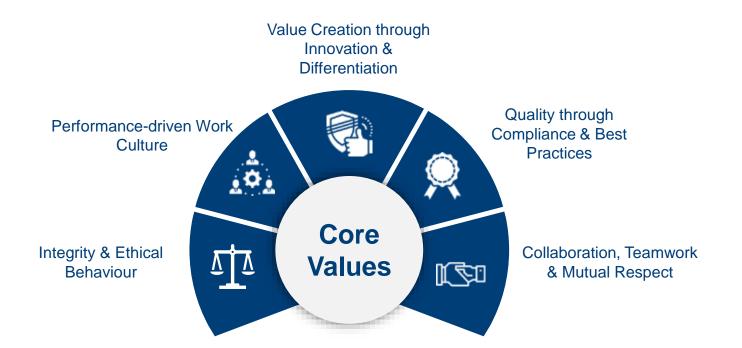


Relentless Pursuit.
Differentiated Growth.

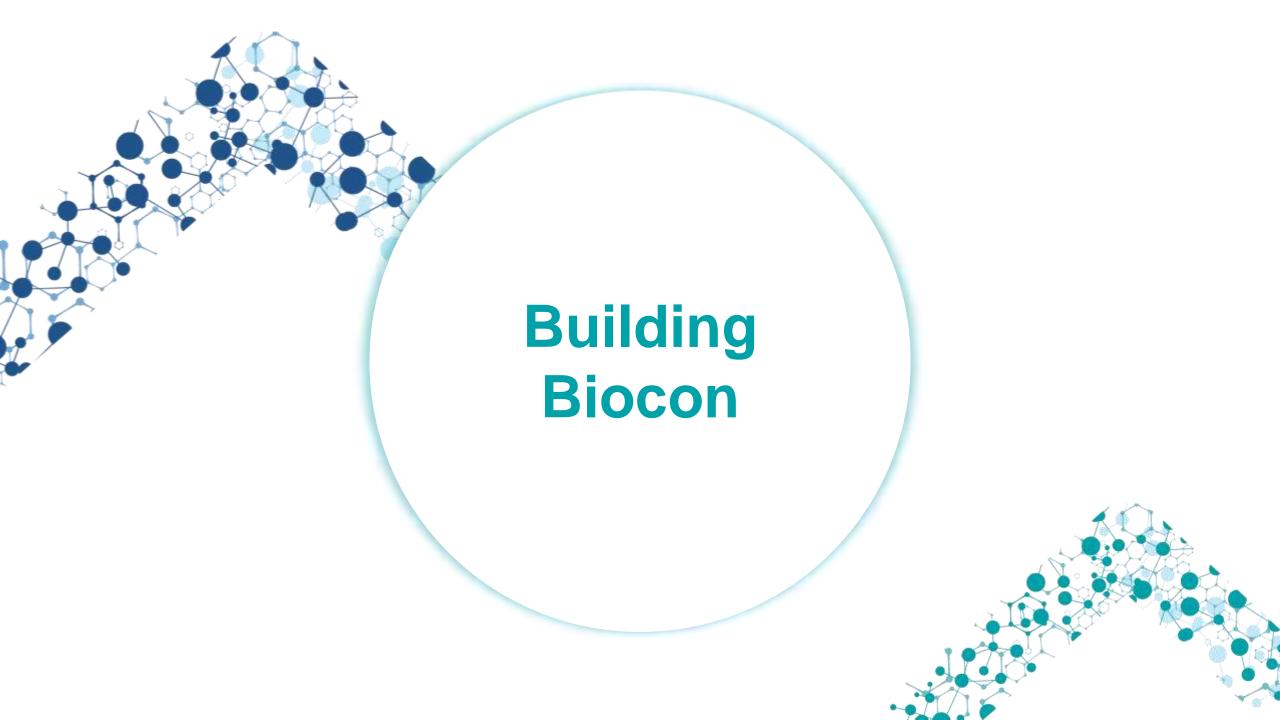




Biocon is a technology-enabled, future-ready, global biopharmaceuticals leader driven by an unwavering purpose to enhance healthcare worldwide through high-quality, affordable therapies that can lower costs, increase access and improve treatment outcomes.









## **Biocon at a Glance**





₹11,550 Cr | \$ ~1.4 bn Revenue\*



~16,500+
Total Employees\*



Rank #8

Among Top 10 Global Biotech, Pharma & Biopharma Sector\*\*



**1,500+** Patents\*



100+

cGMP approvals from International regulatory agencies



8

Manufacturing units\*



120+

Countries where our products are available\*



15 of top 20

pharma companies served by service portfolio \*



**Top 28** 

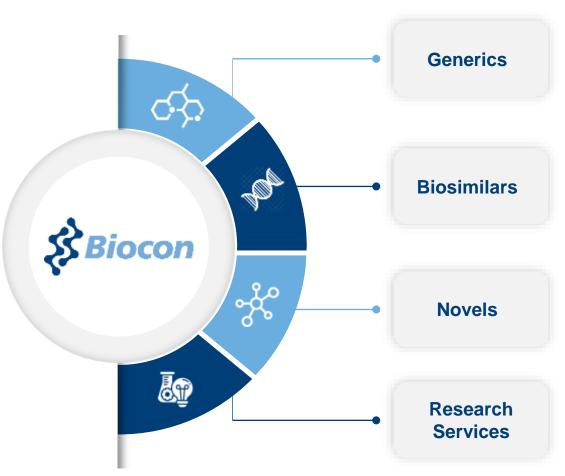
Products within portfolio\*\*\*





# 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



#### Ensuring access through quality, affordability, reliability

- Leadership in fermentation-based APIs Immunosuppressants, statins, anti-infectives
- Serving 750+ API customers with 50+ APIs from our global scale API facilities
- Expanding portfolio in peptides, high potent and synthetic APIs
- Evolving as a vertically integrated player in complex generic formulations

#### Leading vertically integrated global biosimilars company

- Invested >\$1B in the development and manufacturing of biosimilars ahead of its peers
- End-to-end capabilities spanning R&D, manufacturing and commercialization in Advanced & Emerging Markets
- Committed to enabling affordable access with global reach in 100+ countries
- Achieved several global "firsts", setting new benchmarks for the industry
- Comprehensive industry leading portfolio of 20 biosimilars targeting an attractive ~\$80B opportunity by FY28

#### Pushing scientific boundaries to deliver impactful innovations

- Differentiated pipeline in immunology with expansions into new indications
- Bicara addressing unmet need in oncology through precision immunotherapy with BCA 101

#### Syngene - partnering to deliver innovative scientific solutions

- A global CRO and CDMO offering integrated solutions across discovery research, development and manufacturing including commercial supplies for both small and large molecules
- Scientific services spanning multiple therapeutic areas, modalities and industry segments
- Working with 400+ clients and collaborated with 13 of the top 15 pharmaceutical companies
- Operating to global quality standards from 2 Mn sq. ft. R&D and manufacturing infrastructure in Bengaluru, Mangaluru, and Hyderabad



## **Generics Business at a Glance**



Presence in

100+

countries including U.S.,
Europe & large EMs



State-of-the-art manufacturing sites



90+
cGMP approvals
received from international
regulatory agencies



R&D team of 500+
Scientists & Postgraduates



750+ Global customer reach



Portfolio comprises

**50+** APIs

**75+** Generic formulations



100+

Generic formulation dossiers submitted



500+

DMFs filed in various jurisdictions



300+
patents obtained





#### **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)
- Acquisition of oral solid manufacturing facility (US)

#### **Business Development initiatives**

- · Strategic partnerships with key customers
- Local manufacturing mandate opportunities in global markets - Technology transfer/ API supply / finished dosage formulations
- API: Expansion of business in key 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 to support key strategic priorities
- Focus on ESG initiatives like use of renewable energy, promoting gender diversity (incl. women on the shop-floor)





# **Generics**: Our Key APIs and Formulations

APIs\*

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

#### FORMULATIONS

Therapeutic Area	Molecule	US	Dev. Markets: ex-US	MoW <sup>1</sup>
	Rosuvastatin Calcium		EU	
	Simvastatin			
	Atorvastatin			
Cardiovascular	Pravastatin			
	Labetalol HCI			
	Prazosin			
	Rivaroxaban		UK, EU <sup>\$</sup>	
	Everolimus		EU <sup>\$</sup>	
Oncology	Pemetrexed	TA		
Officology	Lenalidomide	TA	EU\$	
	Dasatinib	TA		
Immunosuppressants	Tacrolimus			
mmunosuppressants	Mycophenolic Sodium			
	Fingolimod			
Multiple Sclerosis	Teriflunomide			
	Dimethyl fumarate		EU\$	
	Aminocaproic acid (Antifibrinolytic)			
	Dapagliflozin (Anti Diabetic)	TA		
	Esomeprazole DR (GI)			
Others	Dorzolamide (Ophthalmic)			
	Posaconazole (Anti-Fungal)		UK, EU <sup>\$</sup>	
	Famotidine (GI)			
	Vigabatrin Oral Sol (CNS)			
	Vigabatrin Tablets (CNS)			

<sup>\*</sup> 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



Top 15
in global
biomanufacturing
capacity



85+
cGMP approvals
received from key regulatory
agencies



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



390+
patents granted



Portfolio comprises

20 biosimilars



Commercial
Products in Global
Markets

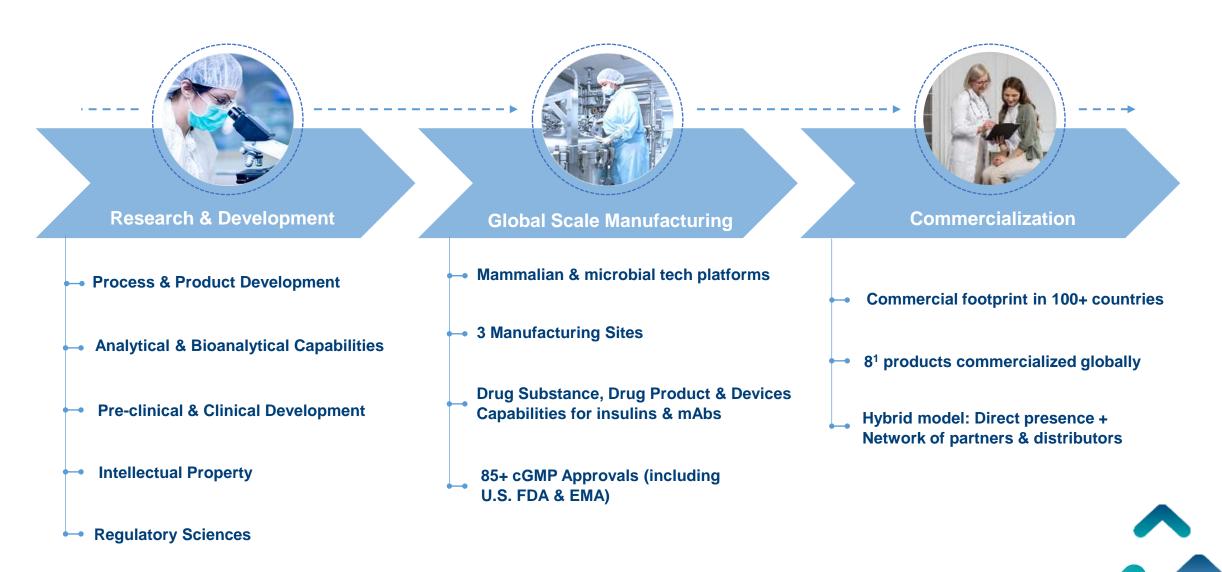


**5.5M+**Patients served





# 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 portfolioincluding 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 presence<sup>1</sup>, 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, Viatris, Serum and Edelweiss
- Biosimilars are an attractive market with FY22 addressable of \$25B<sup>2</sup>, growing to ~\$80B in FY28<sup>2</sup>

#### Committed to enabling affordable access to high quality biosimilars globally





# Biosimilars: Acquisition of Viatris' global biosimilars business

Accelerates BBL's direct entry in many markets across AMs & EMs, takes us closer to patients

Provides full
ownership
of collaboration
assets, as well as
Viatris' rights for inlicensed biosimilars

Creates a unique, fully integrated, global biosimilars enterprise



Enabling Affordable Access to Life-saving Biosimilars, Worldwide

Recognition of combined revenue and associated profits from acquired business kicks in USD 3B+ Acquisition - Amongst Largest Deals in Indian Pharma Industry

- Builds on a decade-long strategic partnership with Viatris
- Transforms Biocon Biologics into leading global player

Transformational deal to create value for all stakeholders





# Biosimilars: Comprehensive, industry leading portfolio of 20 biosimilars

Therapy Area	Oncology	Immunology	Ophthalmology	Bone Health	Diabetes	Others
Approved or Commercial	<ul><li>Pegfilgrastim</li><li>Trastuzumab</li><li>Bevacizumab</li></ul>	<ul><li>Adalimumab</li><li>Etanercept</li></ul>	Aflibercept		<ul><li>RHI</li><li>Glargine U100</li><li>Aspart</li></ul>	
Late Stage <sup>1</sup>	<ul><li>Denosumab</li><li>Pertuzumab</li></ul>	Ustekinumab		<ul> <li>Denosumab</li> </ul>		
Early Stage <sup>2</sup>	2 undisclosed assets	3 undisclosed assets			Glargine U300	2 undisclosed assets

New product launches planned almost every year through 2030





#### **Novel Molecules: Itolizumab**



#### Pushing to deliver impactful innovations in collaboration with Equillium Inc.



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 (aGVHD)

- ✓ Pivotal Phase III Study initiated in Apr '22 for use in First-Line treatment of aGVHD; enrollment ongoing
- ✓ Received US FDA Fast Track & Orphan Drug Designations
- ✓ European Commission granted Orphan Drug Designation

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 enrolment complete for the LN study
- ✓ Topline data expected early in June 2024

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

Enrolment for Phase II clinical trial in India for Ulcerative Colitis complete.



# **Novel Molecules:** Bicara Therapeutics\* - Dual Action | Dual Impact



#### 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
- ✓ BCA101 + pembrolizumab combination dose expansion study in 1L HNSCC demonstrates significant improvement over standard of care
  - ✓ In Ph 1 HNSCC trials, BCA101 demonstrated a strong clinical profile, including an ORR of 57%, CR rate of 18%, mPFS of at least 6.2mos, and a well-tolerated safety profile
- ✓ Strong scientific rationale supports BCA101's applicability beyond HNSCC, including sqNSCLC, squamous esophageal, and others

Organization

- ✓ \$165M Series C closed in December 2023 led by TPG and Braidwell. \$355M raised to date from syndicate of dedicated biotech investors. Biocon ownership is 14% as of year-end 2023.
  - ✓ Carolyn Ng, Partner of TPG life Sciences Innovation, joined the Board in conjunction with this financing.
  - ✓ All existing Series B investors participated in this Series C financing.
- ✓ Highly experienced management team, board of directors and advisory board
  - ✓ Appointed Lara Meisner as Chief Legal Officer
- Leveraging the Biocon and Syngene infrastructure to offer agility and deep experience in CMC/drug development





# Syngene's broad capabilities, spanning the value chain, facilitate integration to captures additional benefits for clients

#### **Research business**

#### **Development and Manufacturing business**

#### **Discovery Services**



Flexible Platform with capability across multiple modalities including small molecule, large molecule, peptides, oligonucleotides, antibody drug conjugates, PROTACs

**SynVent -** our proprietary platform for Integrated Drug Discovery

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

#### **Dedicated R&D Centers**



**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

#### **Development Services**



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 Services**



Manufacturing of small and large molecules for commercial supplies

cGMP-compliant facilities

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





# **Syngene: Strategic Priorities**



# Research: Discovery Services

Provide end-to-end therapeutic discovery capabilities including differentiating research technologies and platforms, across many disciplines, disease areas and therapeutic modalities



# Research: Dedicated Centers

Continue to strengthen our existing partnerships with Amgen, Bristol Myers Squibb (BMS) and Baxter through the dedicated centers which provide: a strong foundation for future planning; revenue visibility over the medium to long term; and predictable cash flows



#### **Operational Excellence**

Focus on customer delivery through operational excellence



# Development and Manufacturing Services – Small Molecules

Leverage existing capabilities to offer integrated Chemistry, Manufacturing, and Controls (CMC) solutions

Secure U.S. FDA and other major global regulatory approvals for the small molecule commercial scale manufacturing facility as a platform to attract a broader scope of projects



#### Development and Manufacturing Services – Large Molecules

Drive an integrated approach for biologics development and manufacturing to provide a one-stopshop capability from drug discovery to commercial manufacturing for biologics

Accelerate capacity build-up



#### **People**

Develop strong leaders and managers while offering all employees career- long learning opportunities



# Environmental, Social and Governance (ESG)

Committed to operating in a responsible and sustainable manner.







# **Financial Highlights: Q3 FY24**

Consolidated (in ₹ Cr.)	Q3 FY24	Q3 FY23	YoY %	
Total Revenue <sup>1</sup>	4,519	3,020	50	Biosimilars +65%   Research +9%   Generics -7%
Core EBITDA <sup>2</sup>	983	1,069	(8)	
% Margin	27%	36%		
EBITDA	1,492	723	106	Net R&D spend at ₹329 Cr, representing 11% of revenues ex-Syngene
% Margin	33%	24%		
Profit Before Tax (Before exceptional items)	787	246	220	Increase in depreciation, amortization and interest expense by ₹ 260 Cr, primarily related to acquisition of Viatris' biosimilar business
% Margin	17%	8%		
Net Profit (Before exceptional items)	644	140	360	Increase in minority interest due to dilution of shareholding in Syngene and Biocon Biologics on account of the Viatris deal
Net Profit Margin %	14%	5%		

<sup>&</sup>lt;sup>1</sup> Includes income from divesture of two non-core Branded Formulations India business units in Biocon Biologics of 350 crores and gain from Biocon's stake dilution in Bicara Therapeutics of 456 crores <sup>2</sup> Core EBITDA defined as EBITDA before forex, dilution gain in Bicara, R&D, licensing income and mark to market movement on investments.



# **Financial Highlights: Q3 FY24**

Consolidated (in ₹ Cr.)	Q3 FY24	Q3 FY23	YoY %	
Net Profit (Before exceptional items)	644	140	360	Exceptional items:
Exceptional Items (Net of tax and minority interest)	16	(182)		<ul> <li>Q3 FY24</li> <li>Gain on carrying value of existing contractual receivable arrangement; offset by</li> <li>Impairment of intangibles associated with a product in certain territories &amp; inventory provision</li> <li>Transaction costs related to Viatris transaction &amp; the Stelis facility acquisition</li> <li>Q3 FY23</li> <li>Deal related expenses of the Viatris transaction</li> </ul>
Net Profit (Reported)	660	(42)		





# **Biocon Generics: Q3 FY24 Highlights**

- Consistent steady/ growth in Generic Formulations business
- Received first Generic Formulation approval in China, for Mycophenolate Sodium
  - Vizag receives CEP from EDQM, the European regulator
  - Peptides facility in Bengaluru successfully completes validation activities
  - Process validation begins in Hyderabad for synthetic APIs

In INR Cr	Q3 FY24	Q3 FY23	Q2 FY24	YoY %	QoQ %
Segment Revenue	703	760	676	(7)	4
Core EBITDA	154	168	158	(8)	2
% of revenue	22%	21%	23%		
PBT	50	72	66	(30)	(24)
% of revenue	7%	10%	10%		





# Biocon Biologics: Biosimilars – Q3 FY24 Business Update

- Finished operational integration of acquired business from Viatris in about 120 countries, one year ahead of schedule
- Uptick in the sales of unbranded Glargine in US through a closed-door pharmacy network, not reflected in the reported market shares
- Secured several new contracts in the US for bPegfilgrastim, bTrastuzumab and bAdalimumab
- Launched bBevacizumab in Brazil with \$175m of annual originator sales

#### **Key Products' Market Share**<sup>1</sup>

United States							
Nov-23 Aug-23 Nov-22							
Fulphila (bPegfilgrastim)	18%	20%	11%				
Ogivri (bTrastuzumab)	12%	11%	10%				
Semglee (bGlargine) <sup>2</sup>	12%	12%	10%				
Hulio (bAdalimumab) <sup>3</sup>	0.1%	0.0%					

#### **Europe**

	Q3 CY'23	Q2 CY'23	Q3 CY'22
Fulphila (bPegfilgrastim)	8%	7%	5%
Ogivri (bTrastuzumab)	6%	6%	6%
Abvemy (bBevacizumab)	6%	6%	1%
Semglee (bGlargine)	4%	3%	2%
Hulio (bAdalimumab)	6%	6%	6%
Nepexto (bEtanercept)	2%	2%	1%





# Biocon Biologics: Biosimilars – Q3 FY24 Financial Update

- Excluding licensing revenues from the non-core BFI divesture, sequential growth of 8%
- Core EBITDA margin impacted on account of series of transition related expenses and one-off costs
- Received \$220m from an existing contractual receivable arrangement, ~\$200m used to pare down debt
- BBL net debt at \$1.2 billion<sup>2</sup>

In INR Cr	Q3 FY24	Q3 FY23	Q2 FY24	YoY %	QoQ %
Segment Revenue	2,483	1,507	1,969	65	26
Core EBITDA <sup>1</sup>	587	663	660	(11)	(11)
% of revenue	28%	44%	34%		
EBITDA	714	361	453	98	58
% of Revenue	29%	24%	23%		
PBT (before exceptional items)	196	102	(15)	92	
% of Revenue	8%	7%	(1)%		





# Biocon Biologics: Biosimilars – Q3 FY24 Other Business Updates

Initiated Phase 3 studies for bPertuzumab

Progressive discussion with the US FDA; Awaiting site-inspection for bAspart and bBevacizumab BLA in US

#### **Key Catalysts**

Opening up of bAdalimumab market along with regulatory approvals for bAspart and bBevacizumab in US

Debt reduction and strengthening of balance sheet remains key focus





# Novels: Q3 FY24 Update

Itolizumab (partnered with Equillium)

- 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) fully enrolled. Topline data expected in June 2024.

\*Acute Graft-Versus-Host Disease

#### BCA101 (Bicara<sup>\$</sup>)

US\$165 million Series C Financing from dedicated biotech investors closed in Dec'23. Biocon recorded a dilution & fair value gain of ₹456 crores in the consolidated P&L statement during the quarter.

As of December 2023, Biocon's shareholding in Bicara at 14%.







# Syngene: Q3 FY24 Update

- Positive performance in Development and Manufacturing Services as well as in the Dedicated Centers. Performance in Discovery Services was impacted by the slowdown in biotech funding
- In Manufacturing Services, Syngene continued to make good progress on the long-term biologics manufacturing partnership with Zoetis
- Concluded the acquisition of biologics manufacturing facility from Stelis Biopharma Ltd. The facility is expected to be operational in the second half of FY25, subject to regulatory approvals

In INR Cr	Q3 FY24	Q3 FY23	YoY %
Segment Revenue	854	786	9
EBITDA	261	248	5
% of Revenue	30%	31%	
PBT	142	140	1
% of revenue	17%	18%	







## **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

#### **Disclosures and** Recognitions



Published 1st GRI aligned Integrated Report & 2nd **BRSR Report for FY23** 



Improved ESG score of 63, part of Emerging Markets Index & 2024 Sustainability Yearbook



Score of 'B' for Climate CDP Change and 'C' for Water Security in 2023

ecovadis Secured 'Silver' place and improved score to 66 in 2022.





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



**Won ET Edge Employee Excellence Award, 2023** 





# **Progressed to Integrated Reporting**

Continuously improving disclosures towards better transparency



1<sup>st</sup> GRI aligned Integrated Report for FY23 with many maiden disclosures

Outcome of Gender Pay Gap Analysis

Alignment with TCFD

**Outcome of Water Risk Assessment** 

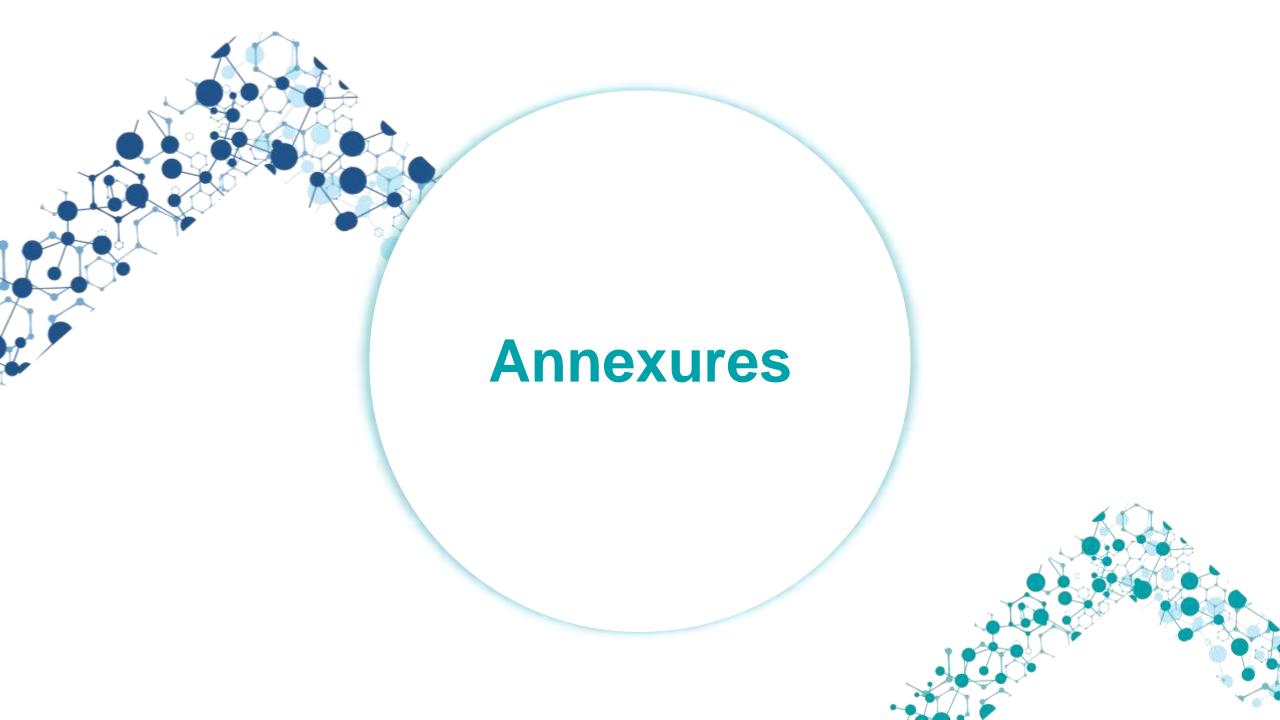
**Outcome of Biodiversity Impact Assessment** 

Third Party Assurance of EHS data

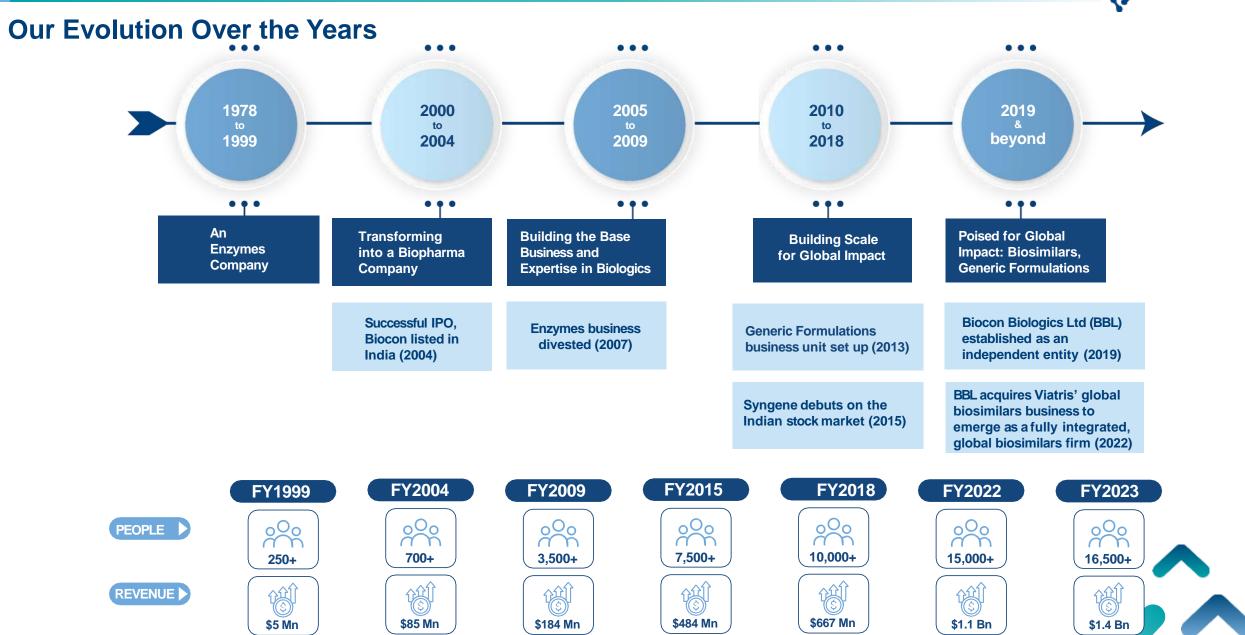
Alignment with UNGC Principles

BRSR (voluntarily adopted in FY22)



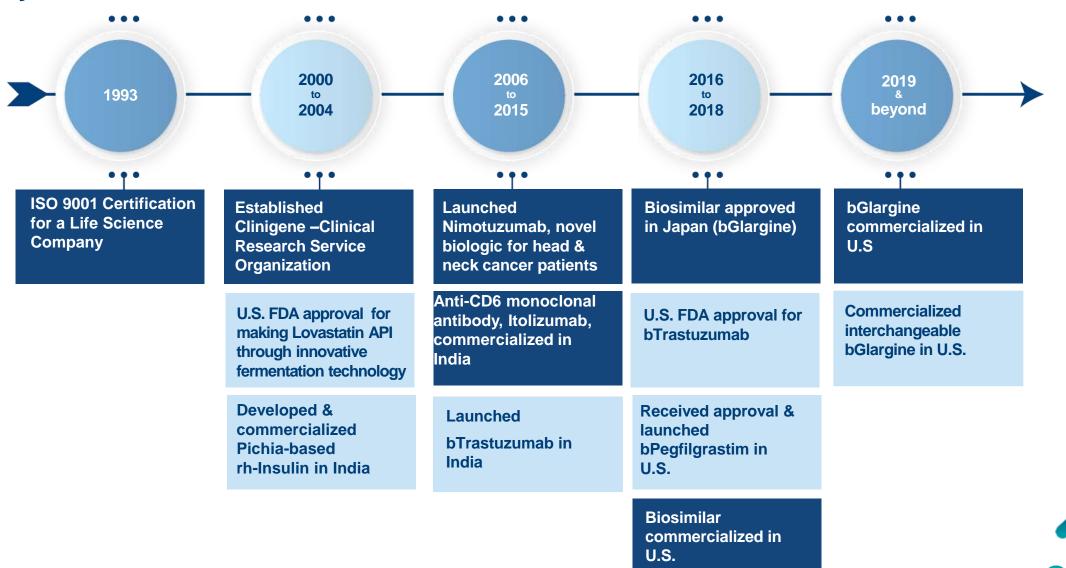








## With many firsts, Biocon is ahead of the curve





## **Safe Harbor Statement**

This release may include statements of future expectations and other forward-looking statements based on management's current expectations and beliefs concerning future developments and their potential effects upon Biocon and its subsidiaries/ associates. These forward-looking statements involve known or unknown risks and uncertainties that could cause actual results, performance, or events to differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from our expectations include, amongst other: general economic and business conditions in India and overseas, 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 currency changes, 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 and global biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither Biocon, nor our directors, or any of our subsidiaries/associates assume any obligation to update any particular forward-looking statement contained in this release.



# **Thank You**



Relentless Pursuit.
Differentiated Growth.

