

Q2 FY24 Investor Presentation

November 2023

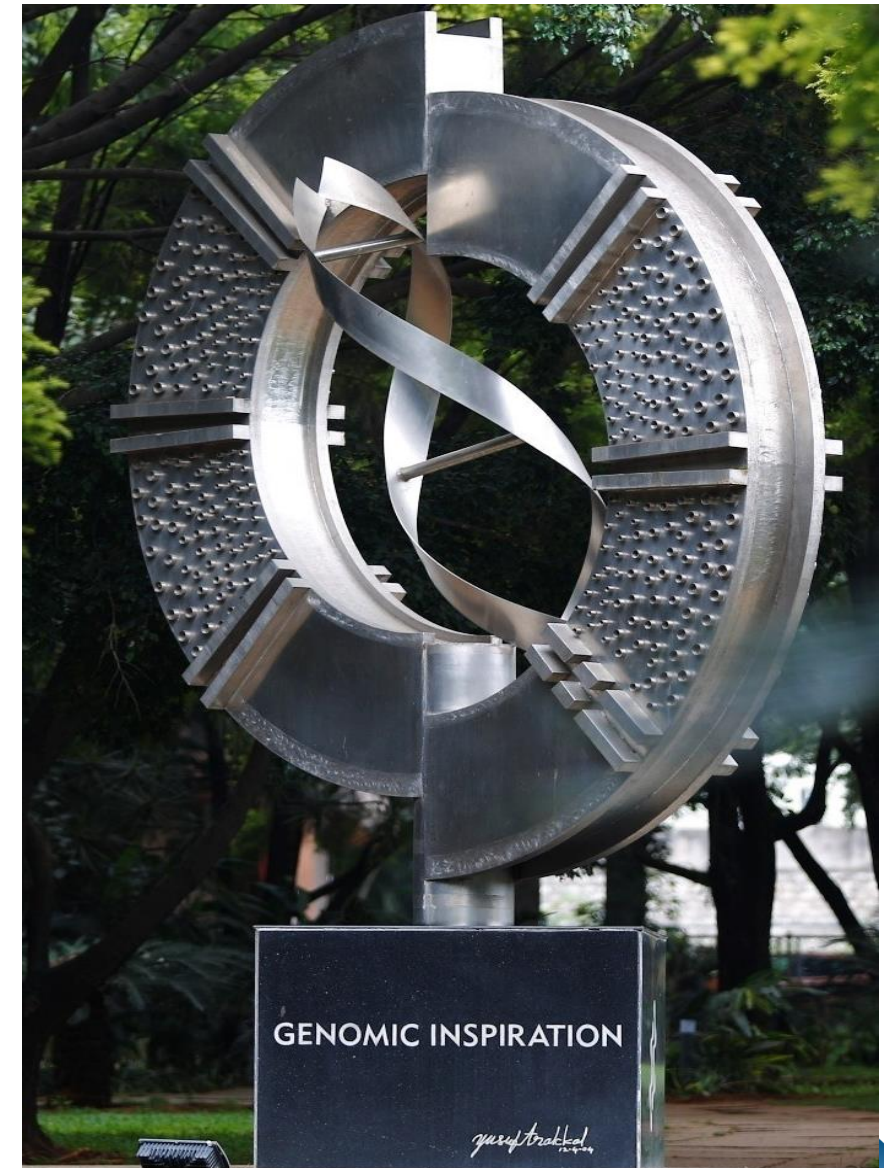
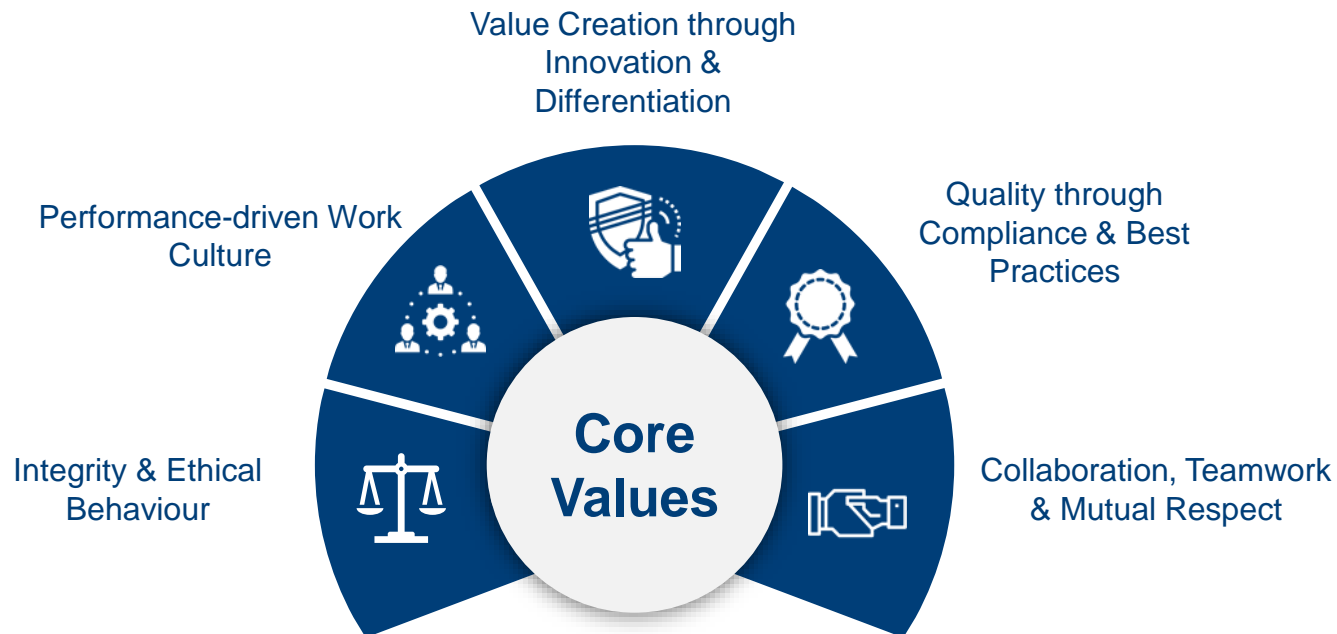


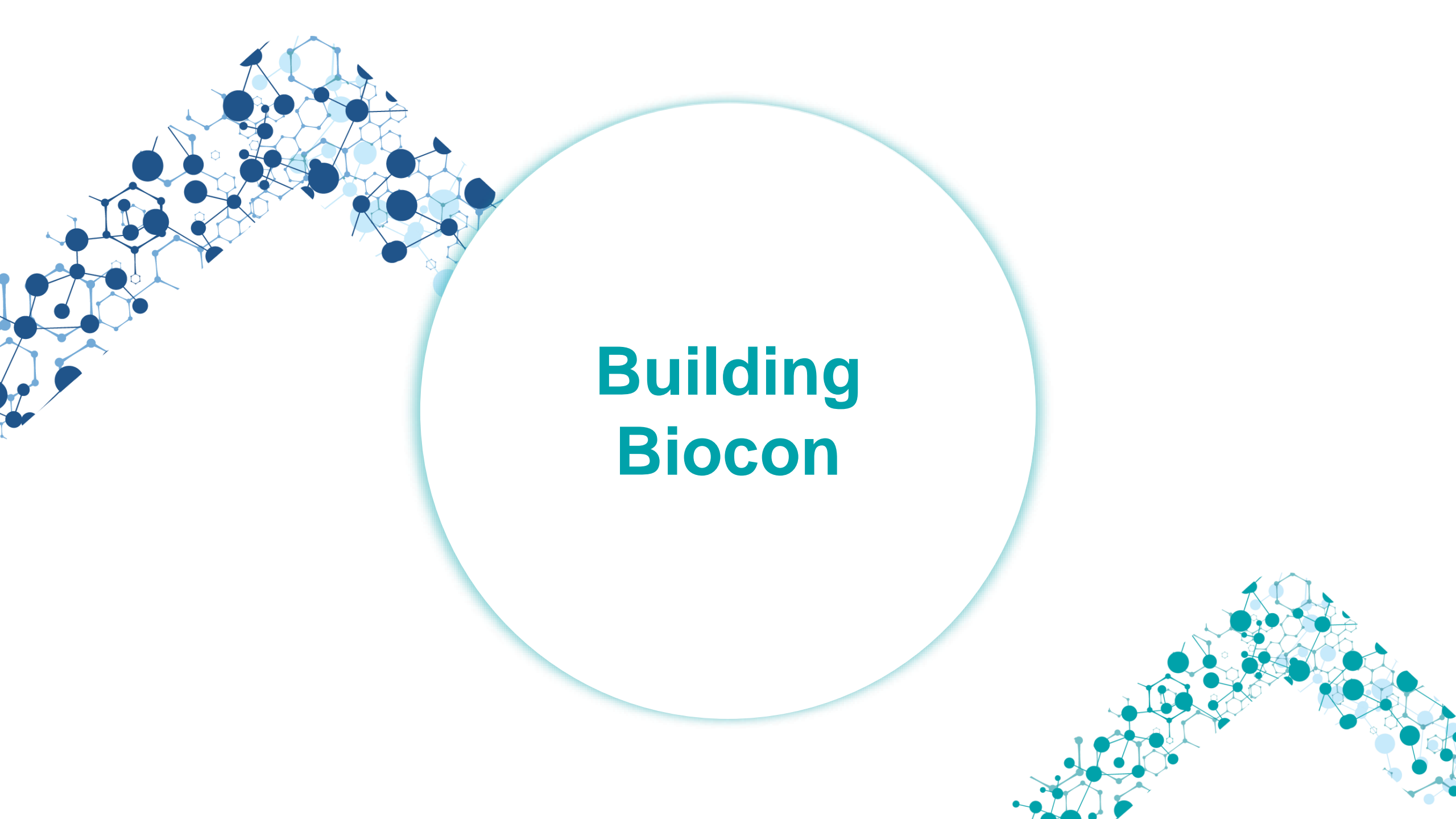
**Relentless Pursuit.
Differentiated Growth.**

Integrated Annual Report FY 2023



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.





Building Biocon

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 *

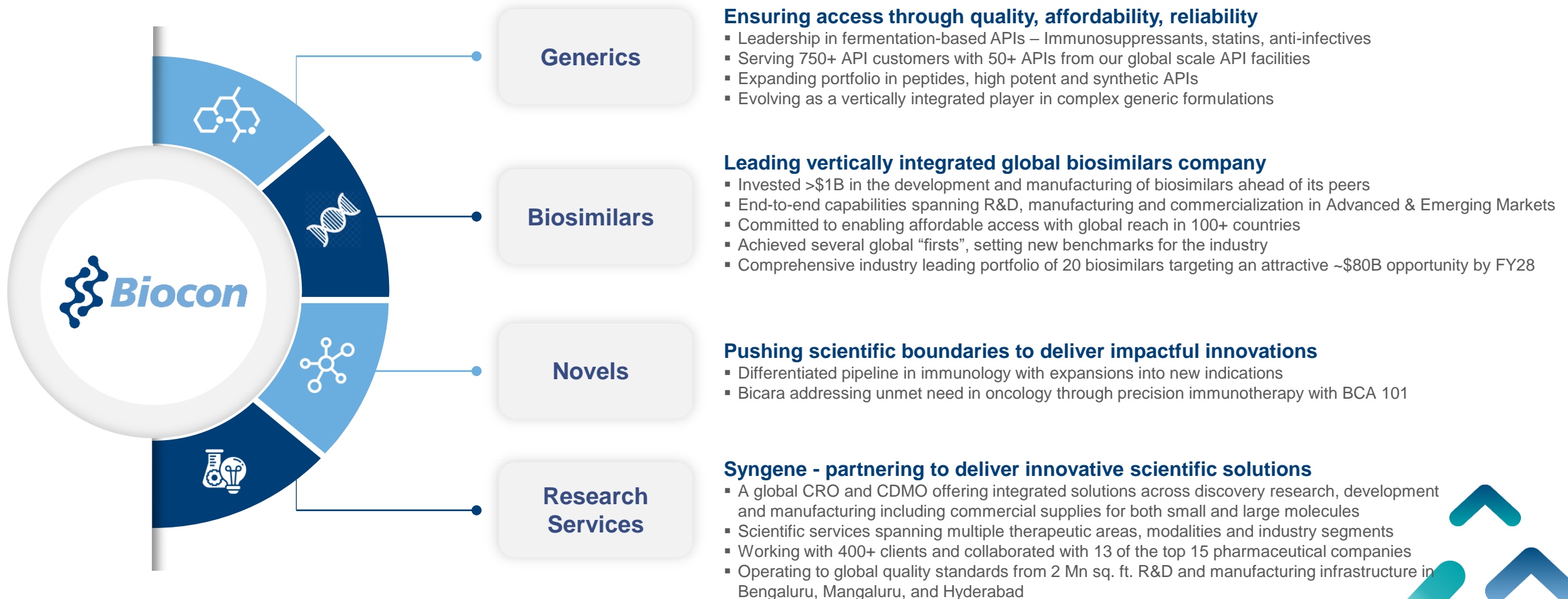


Top 28
Products within
portfolio***



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



Generics Business at a Glance



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



7
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, 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)
- 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
Cardiovascular	Apixaban	Immunosuppressants	Tacrolimus
	Atorvastatin		Mycophenolate Mofetil
	Dabigatran		Mycophenolate Sodium
	Fluvastatin		Everolimus
	Ivabradine		Sirolimus
	Pravastatin		Pimecrolimus
	Rivaroxaban	Oncology	Dasatinib
	Rosuvastatin		Everolimus
	Simvastatin		Lenalidomide
	Lovastatin		Temsirolimus
Anti-Diabetics	Sacubitril	Anti-fungal	Cabozantinib
	Liraglutide		Micafungin
	Dapagliflozin		Anidulafungin
	Empagliflozin	Multiple Sclerosis	Posaconazole
	Linagliptin		Fingolimod
	Repaglinide	Others	Teriflunomide
	Sitagliptin		Orlistat
	Vildagliptin		Deferasirox
	Pioglitazone		Brinzolamide
			Mirabegron
			Fidaxomicin

FORMULATIONS

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

* 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



8
Commercial
Products in Global
Markets

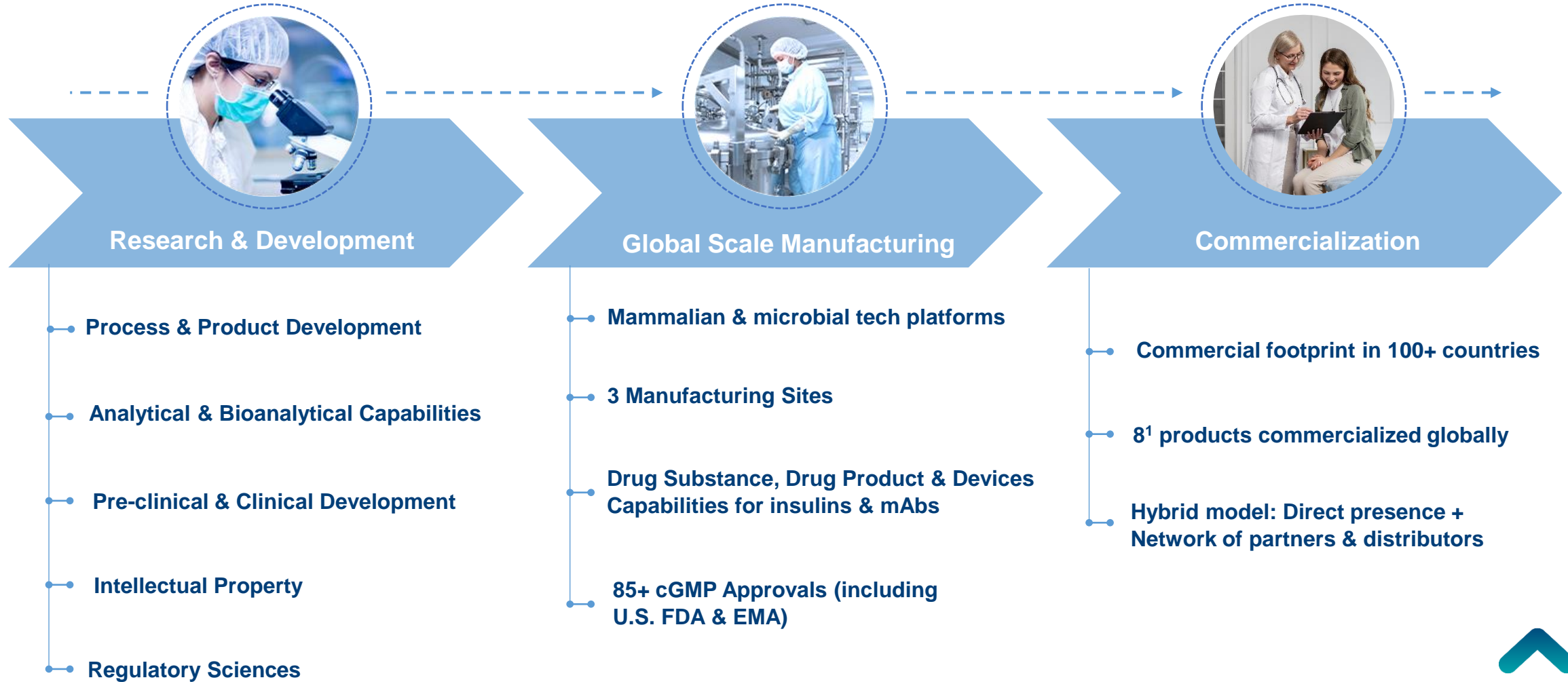


5.5M+
Patients served

Unique, fully integrated leading global biosimilars player



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

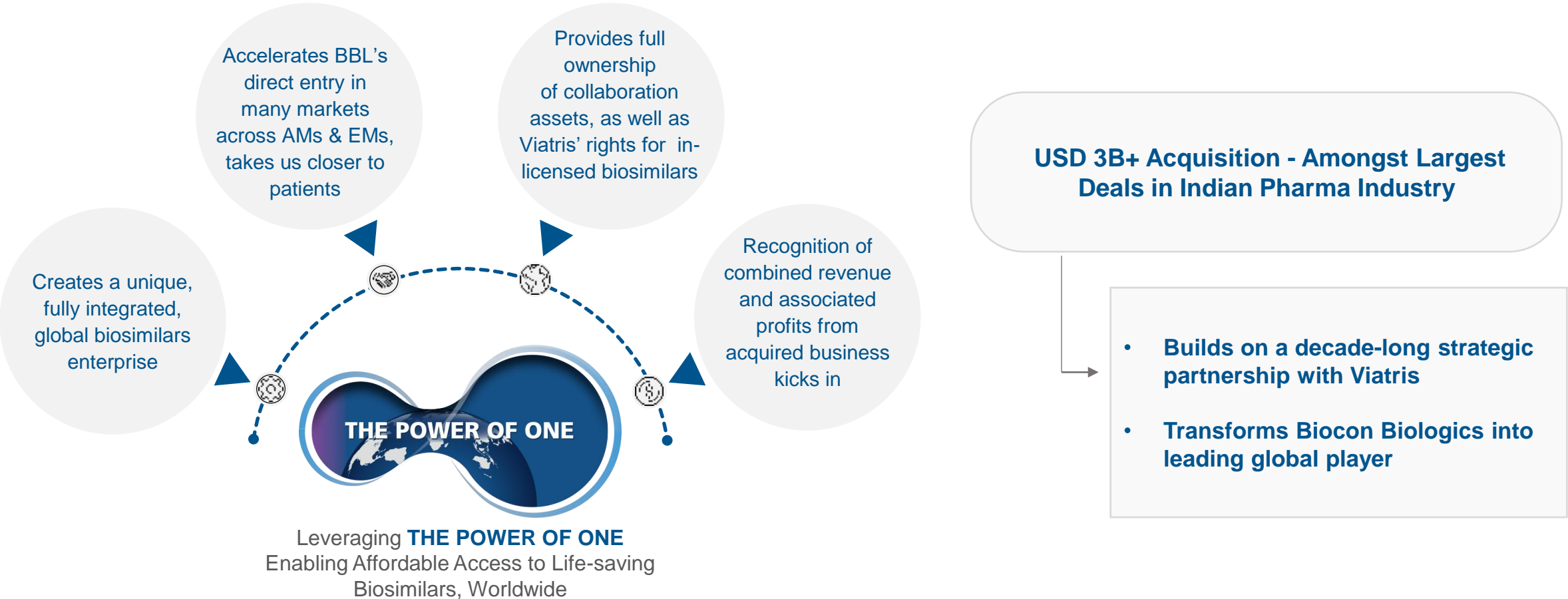
- **Invested >\$1B in biosimilars ahead of its peers** to build expertise across multiple platforms and a differentiated portfolio - including insulins, mAbs and fusion proteins
- **In-house R&D, clinical and regulatory capabilities** to develop high precision biosimilars for global markets
- **Expertise 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, Viatriis, Serum and Edelweiss
- Biosimilars are an **attractive market** with FY22 addressable of \$25B², growing to **~\$80B in FY28²**

Committed to enabling affordable access to high quality biosimilars globally







Biosimilars: Acquisition of Viatri's global biosimilars business



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 style="list-style-type: none"> • Pegfilgrastim • Trastuzumab • Bevacizumab 	<ul style="list-style-type: none"> • Adalimumab • Etanercept 	<ul style="list-style-type: none"> • Aflibercept 		<ul style="list-style-type: none"> • RHI • Glargine U100 • Aspart 	
Late Stage¹	<ul style="list-style-type: none"> • Denosumab • Pertuzumab 	<ul style="list-style-type: none"> • Ustekinumab 		<ul style="list-style-type: none"> • Denosumab 		
Early Stage²	2 undisclosed assets	3 undisclosed assets			<ul style="list-style-type: none"> • 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.



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 (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 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

- ✓ Initiated Phase 2 clinical study of Itolizumab in patients with Ulcerative Colitis in Dec '22

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

- ✓ Highly experienced management team, board of directors and advisory board
 - ✓ Expanded Board with recent additions of Kate Haviland, CEO Blueprint Medicines and Scott Robertson, CFO Dice Therapeutics
- ✓ \$190M raised to date from syndicate of dedicated biotech investors. 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

*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.

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

Research 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 and Manufacturing business

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-stop-shop 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.



Q2 FY24 Highlights

Financial Highlights: Q2 FY24

Consolidated (in ₹ Cr.)	Q2 FY24	Q2 FY23	YoY %	
Total Revenue	3,620	2,384	52	Biosimilars +97% Research +18% Generics +4%
Core EBITDA ¹	1,100	815	35	Growth across Generics, Biosimilars & Research Services
% Margin	32%	35%		
EBITDA	900	535	68	Net R&D spend at ₹264 Cr, up ₹22 Cr vs Q2 FY23, representing 10% of revenues ex-Syngene
% Margin	25%	22%		
Profit Before Tax (Before exceptional charge)	238	246	(3)	Increase in depreciation, amortization and interest expense by ₹376 Cr, primarily related to acquisition of Viatris' biosimilar business
% Margin	7%	10%		
Net Profit (Before exceptional charge)	142	168	(16)	Increase in minority interest due to dilution of shareholding in Syngene and Biocon Biologics on account of the Viatris deal
Net Profit Margin %	4%	7%		

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



Financial Highlights: Q2 FY24

Consolidated (in ₹ Cr.)	Q2 FY24	Q2 FY23	YoY %	
Net Profit <i>(before exceptional charge)</i>	142	168	(16)	Exceptional items: <ul style="list-style-type: none"> Q2 FY24 <ul style="list-style-type: none"> PLI accrual reversal for last year Stelis acquisition related expenses Q2 FY23 <ul style="list-style-type: none"> Deal related expenses of the Viatris transaction MAT credit balance charge on adoption of new tax regime of 25%
Exceptional Items <i>(net of tax and minority interest)</i>	(16)	(122)		
Net Profit <i>(Reported)</i>	126	47	168	



Biocon Generics: Q2 FY24 Highlights

- Performance driven by continued traction in our US generic formulations business and expansion in MoW markets. API business performance muted.
- Announced a partnership agreement with Juno Pharmaceuticals for the commercialization of Liraglutide in Canada
- Acquired U.S. FDA approved oral solid dosage facility of Eywa Pharma Inc.
- Received seven generic formulations approvals across markets. Two API approvals each, received in the U.S. and EU
- Process validation at the Company's greenfield immunosuppressant API facility in Visakhapatnam successfully completed
- Expect sustained performance from the generic formulations and some recovery in API business performance

In ₹ Cr	Q2 FY24	Q2 FY23	YoY %
Segment Revenue	676	652	4
PBT	66	54	22
% of revenue	10	8	



Biocon Biologics: Biosimilars – Q2 FY24 Business Update

- Integrated North America business – seamless commercial operations from 1st September; remain on track to transition Europe, JANZ and the remaining Emerging Markets later during the year
- Good momentum across oncology and insulins; Addition of new customers enables volume growth, accommodating for price erosion
- bAdalimumab (US): adoption of biosimilars slower than anticipated across the market
- Potential to improve EU performance with the completion of transition
- Divesting non-core Dermatology and Nephrology business in India, sharpening focus and aligning it with our global portfolio and strategy

Key Products' Market Share¹

United States

	Sep-23	Jun-23	Sep-22
Fulphila (bPegfilgrastim)	19%	16%	11%
Ogivri (bTrastuzumab)	12%	11%	10%
Semglee (bGlargine)²	11%	12%	9%

Europe

	Jul-23	May-23	Jul-22
Fulphila (bPegfilgrastim)	8%	7%	5%
Ogivri (bTrastuzumab)	4%	5%	5%
Abvemy (bBevacizumab)	7%	5%	1%
Semglee (bGlargine)	2%	2%	1%
Hulio (bAdalimumab)	6%	6%	6%
Nepexto (bEtanercept)	2%	1%	1%

1. Market shares based on IQVIA volumes, Eq.SU | 2. Includes both Semglee and unbranded Glargine

Biocon Biologics: Biosimilars – Q2 FY24 Financial Update

➤ Revenues marginally down despite significantly lower licensing revenues versus last quarter

➤ Excluding licensing revenues, sequential growth at 6%, reflecting underlying positive performance of commercial products

➤ Core EBITDA¹ margin in line with guidance of mid-30s; R&D at 11% of revenue

➤ Sequential increase of ₹35 Cr in D&A and interest expense

In ₹ Cr	Q2 FY24	Q1 FY24	QoQ %
Revenue	1,969	2,015	(2)
Core EBITDA ¹	660	513	29
% of revenue	34	28	
EBITDA	453	457	(1)
% of Revenue	23	23	
PBT	(15)	24	(164)
% of Revenue	(1)	1	

1. EBITDA before R&D, licensing income, forex and mark-to-market movement on investments



Biocon Biologics: Biosimilars – Q2 FY24 Other Business Updates

➤ European Commission granted MA for Yesafili (bAflibercept): EU brand sales of ~\$1.8 billion annually

➤ US FDA has issued a CRL for the BLA of our Insulin Aspart

Key Catalysts

➤ Activation of near-term catalysts: bAdalimumab, bAspart and bBevacizumab

➤ Future growth catalysts: bAflibercept, bUstekinumab, bDenosumab (total originator sales of \$25 billion)



Novels : Q2 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 early in 2024.

*Acute Graft-Versus-Host Disease

BCA101 (*Bicara^{\$}*)

- Bicara recently presented updated, positive interim data from its ongoing, open-label Phase 1/1b dose expansion study of BCA101 in European Society for Medical Oncology (ESMO) Congress; strong investigator interest to enroll patients in future studies
- \$108 million Series B Financing from dedicated biotech investors is being realized in a staggered manner; Biocon recorded a step-up gain of ₹75 crores in the consolidated P&L statement during the quarter



^{\$}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.



Syngene: Q2 FY24 Update

➤ Strong performance led by Development and Manufacturing Services; supported by sustained momentum in Dedicated Centers

➤ In Manufacturing Services, Syngene continued to make good progress on the long-term biologics manufacturing partnership with Zoetis

In ₹ Cr	Q2 FY24	Q2 FY23	YoY %
Revenue	910	768	18
EBITDA	276	232	19
% of Revenue	30	30	
PBT	158	130	22
% of revenue	17%	17%	










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

Disclosures and Recognitions



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



*Improved ESG score of
52, part of Emerging
Markets Index & 2023
Sustainability Yearbook*



*Maintained score of 'B'
in 2022 for Water Security*



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



*Ranked #8 by Science
Magazine – Top Global Pharma
& Biotech Employers in 2023*



*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

1st GRI aligned Integrated Report for FY23 with many maiden disclosures



**Relentless Pursuit.
Differentiated Growth.**
Integrated Annual Report 2023



Integrated Annual Report 2023 | 1

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

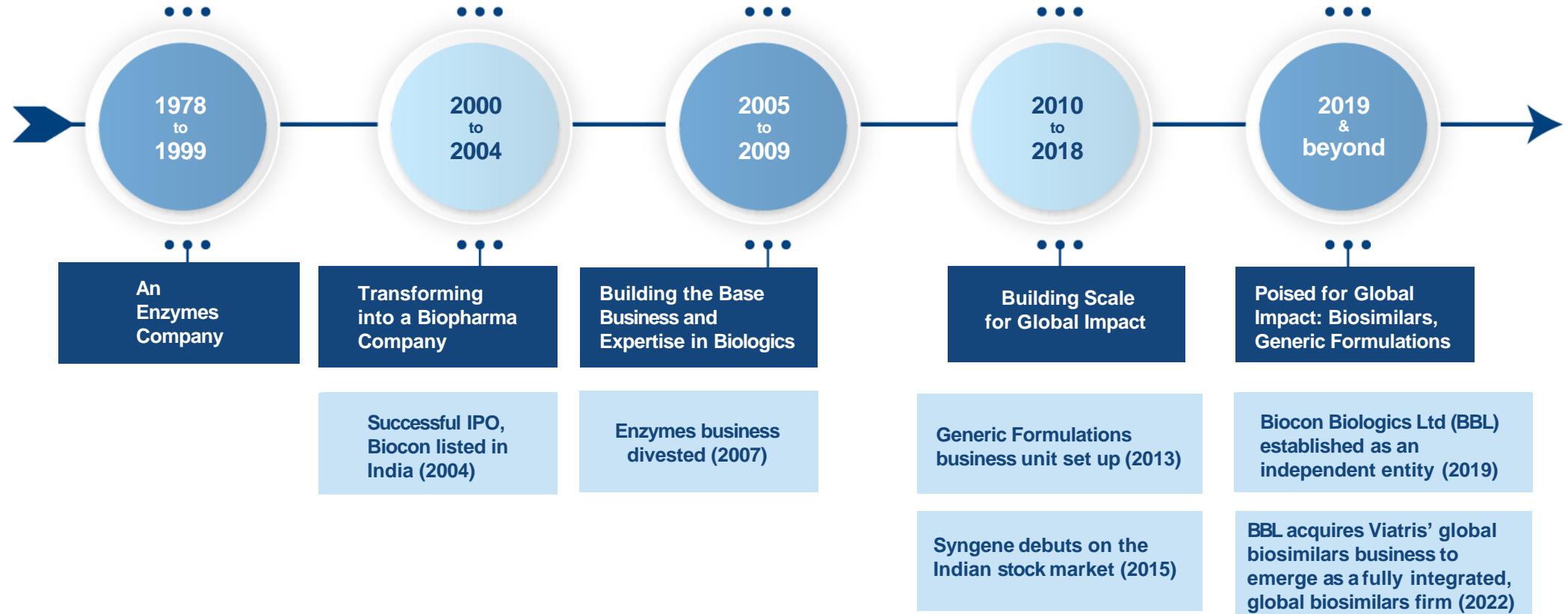
BRSR (voluntarily adopted in FY22)





Annexures

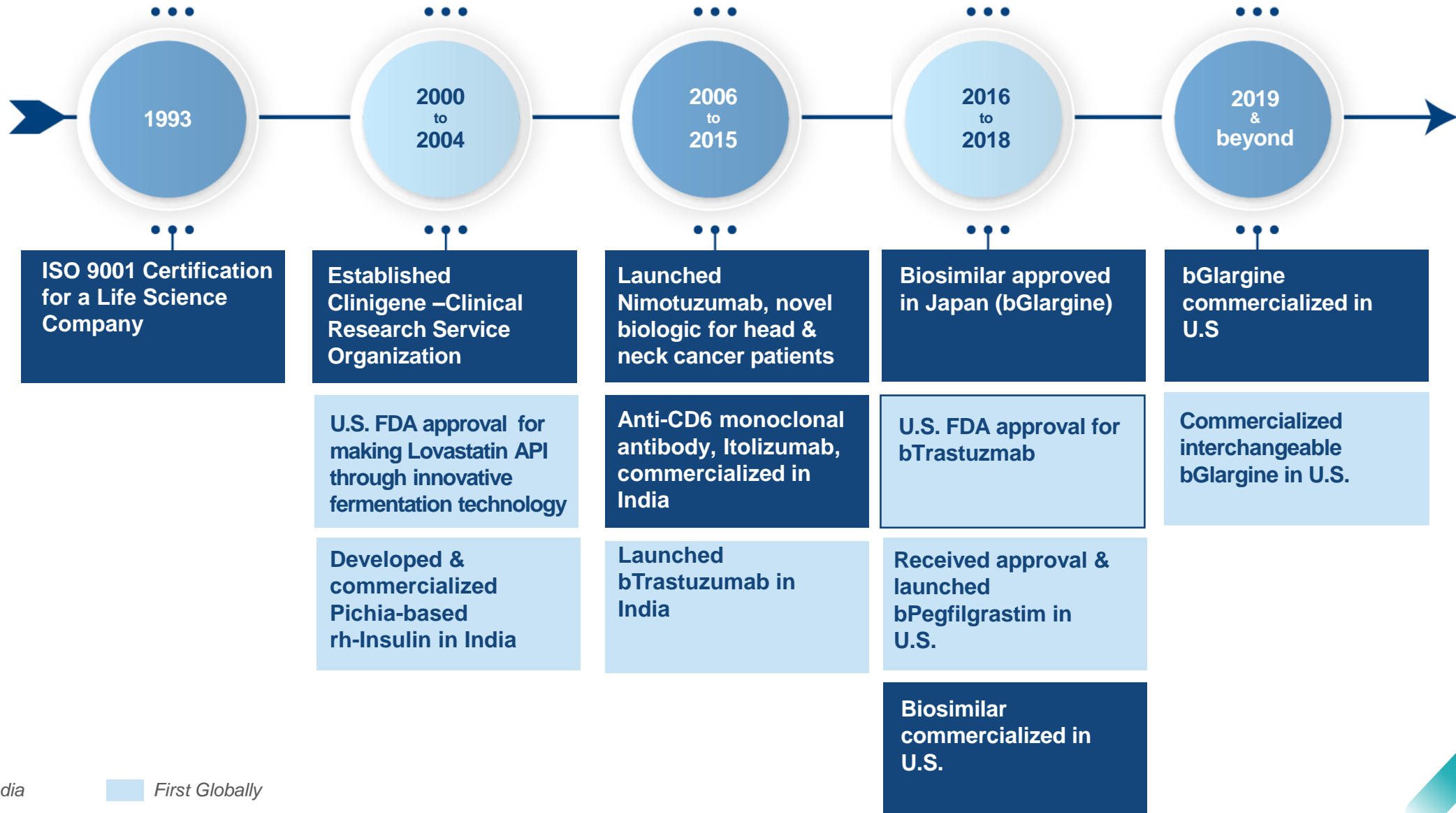
Our Evolution Over the Years



	FY1999	FY2004	FY2009	FY2015	FY2018	FY2022	FY2023
PEOPLE	250+	700+	3,500+	7,500+	10,000+	15,000+	16,500+
REVENUE	\$5 Mn	\$85 Mn	\$184 Mn	\$484 Mn	\$667 Mn	\$1.1 Bn	\$1.4 Bn

1 USD = ₹82.21 for FY23

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



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Differentiated Growth.**

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