

Q1 FY24 Investor Presentation

August 2023

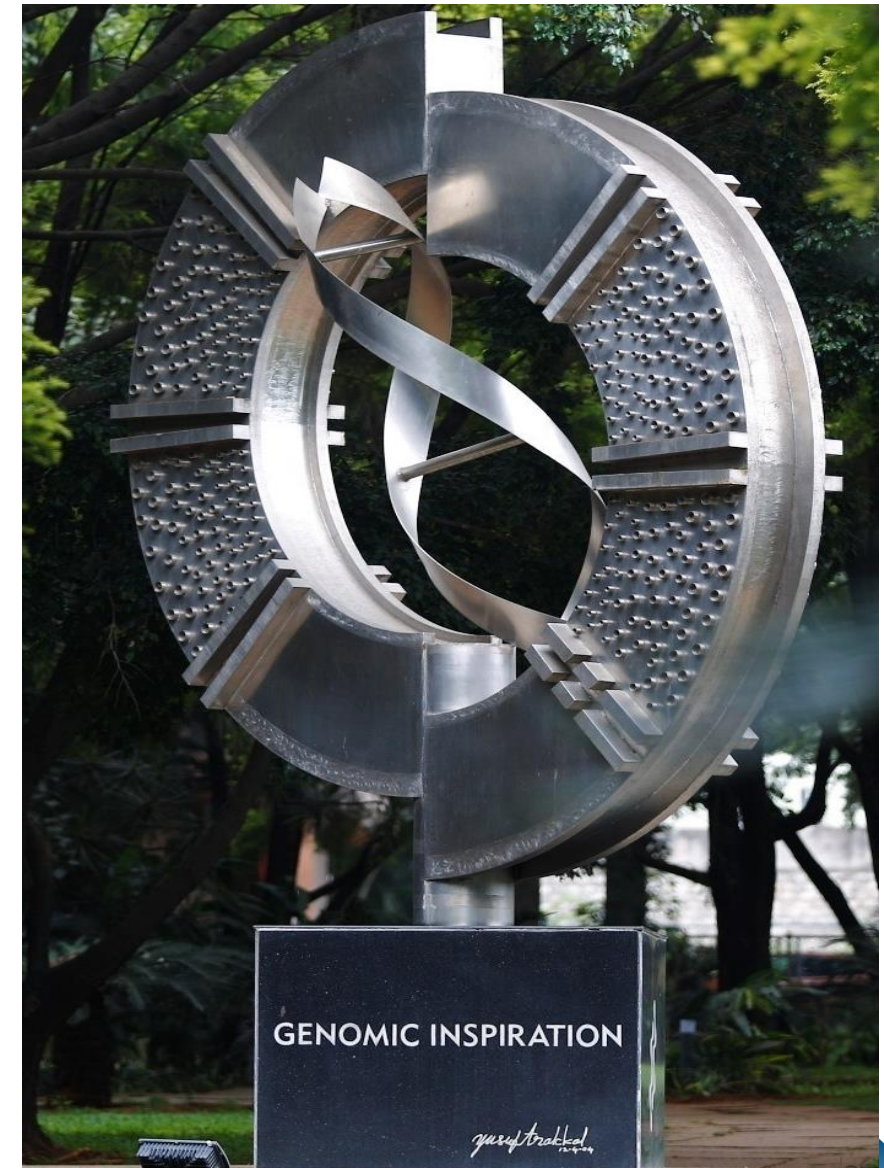
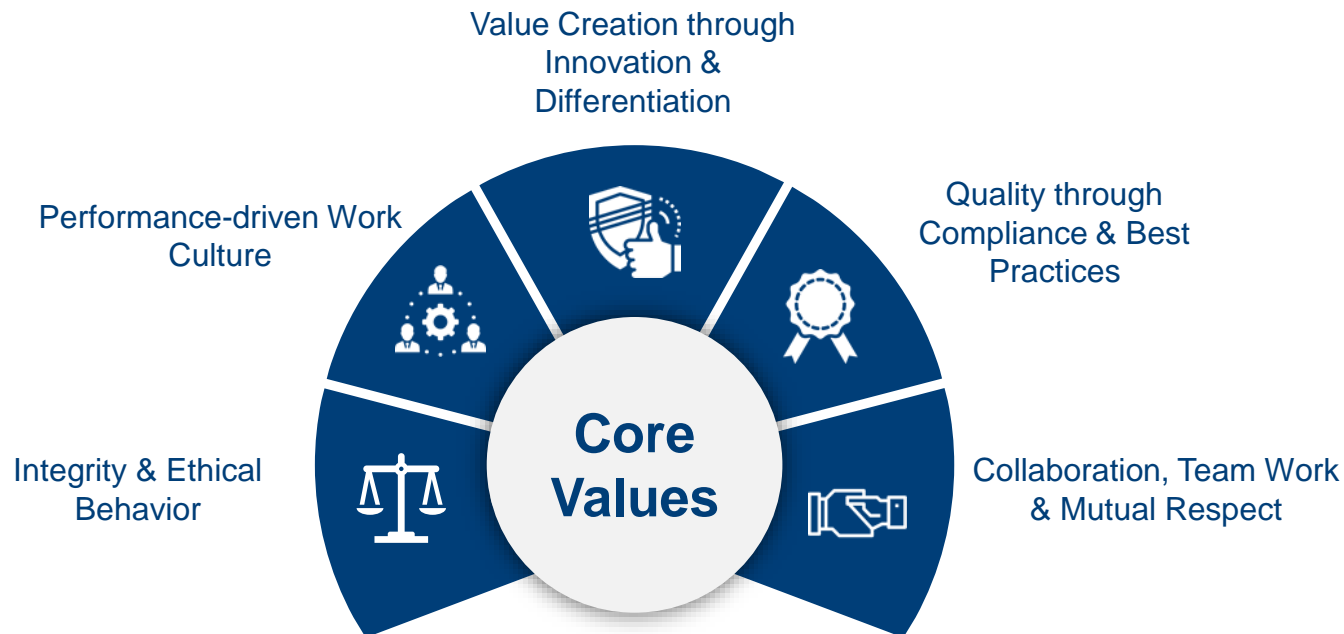


**Relentless Pursuit.
Differentiated Growth.**

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.



Biocon at a Glance



**₹ 11,550 Cr |
\$ ~1.4 bn**
Revenue*



~16,500+
Total Employees*



Rank #8
Among Top 10 Global
Biotech Employers**



1,500+
Patents*



100+
cGMP approvals from
International regulatory agencies



7
Manufacturing
units*



120+
Countries where our
products are
available*

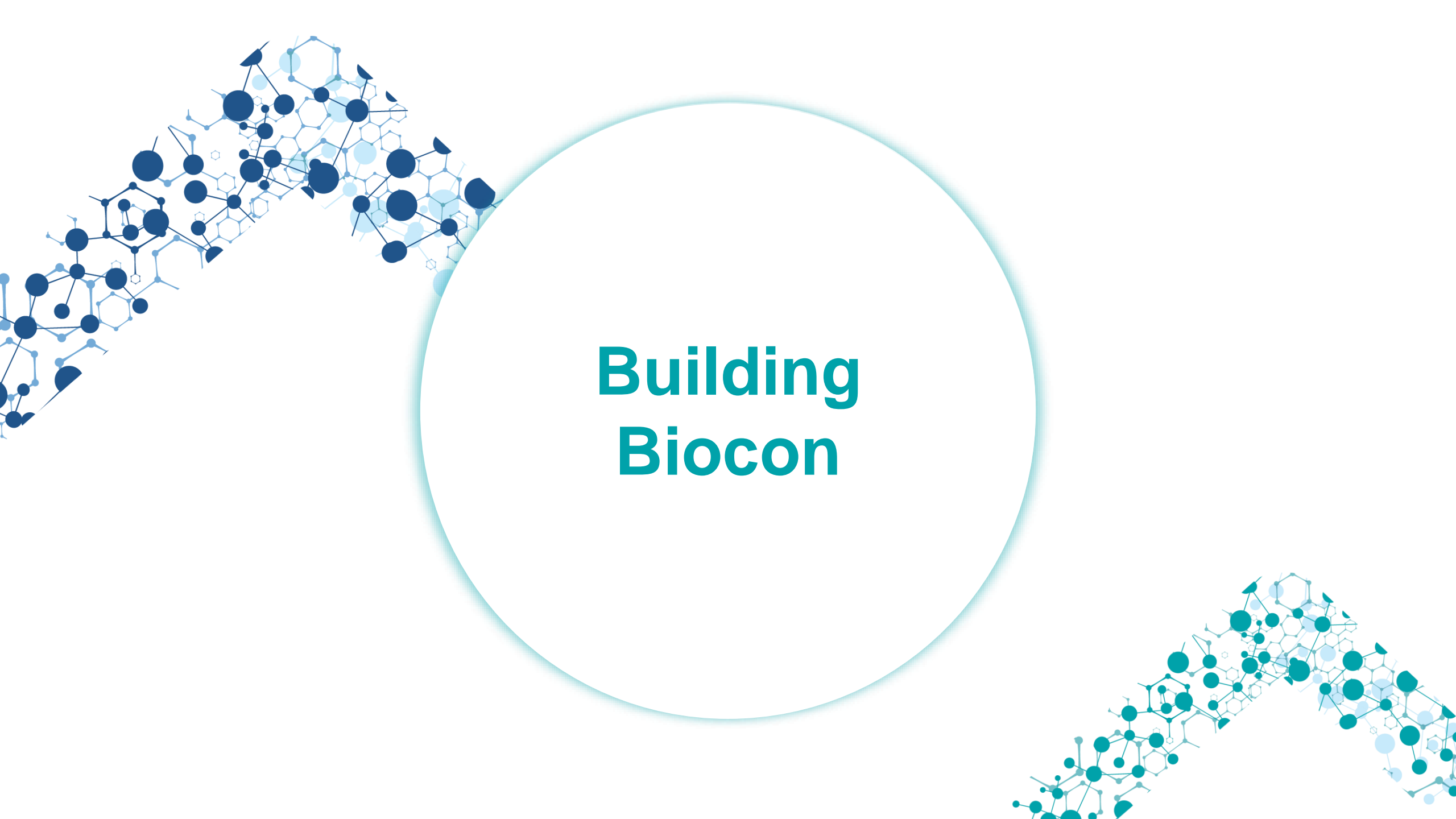


15 of top 20
pharma companies
served by service
portfolio *



Top 28
Products within
portfolio***





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 Business at a Glance



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



6
State-of-the-art
manufacturing
sites



90+
cGMP approvals
received from international
regulatory agencies



R&D team of
450+
scientists



750+
global
customer reach



Portfolio comprises
50+ APIs
75+ Generic
formulations



90+
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)

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

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

| 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\$ | Launched |
| | Pemetrexed | TA | | |
| | Lenalidomide | TA | EU\$ | |
| Immunosuppressants | Tacrolimus | Launched | | Launched |
| | Mycophenolic Sodium | Launched | | |
| Multiple Sclerosis | Fingolimod | Launched | Launched | |
| | Teriflunomide | Launched | | |
| Others | Aminocaproic acid (Antifibrinolytic) | Launched | | |
| | Dapagliflozin (Anti Diabetic) | TA | | |
| | Esomeprazole DR (Gastrointestinal) | Launched | | |
| | Dorzolamide (Ophthalmic) | Launched | | |
| | Posaconazole (Anti-Fungal) | Launched | UK, EU\$ | Launched |
| | Vigabatrin Oral Solution (CNS) | Launched | | Launched |
| | Vigabatrin Tablets (CNS) | Launched | | Launched |

Launched Approved

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

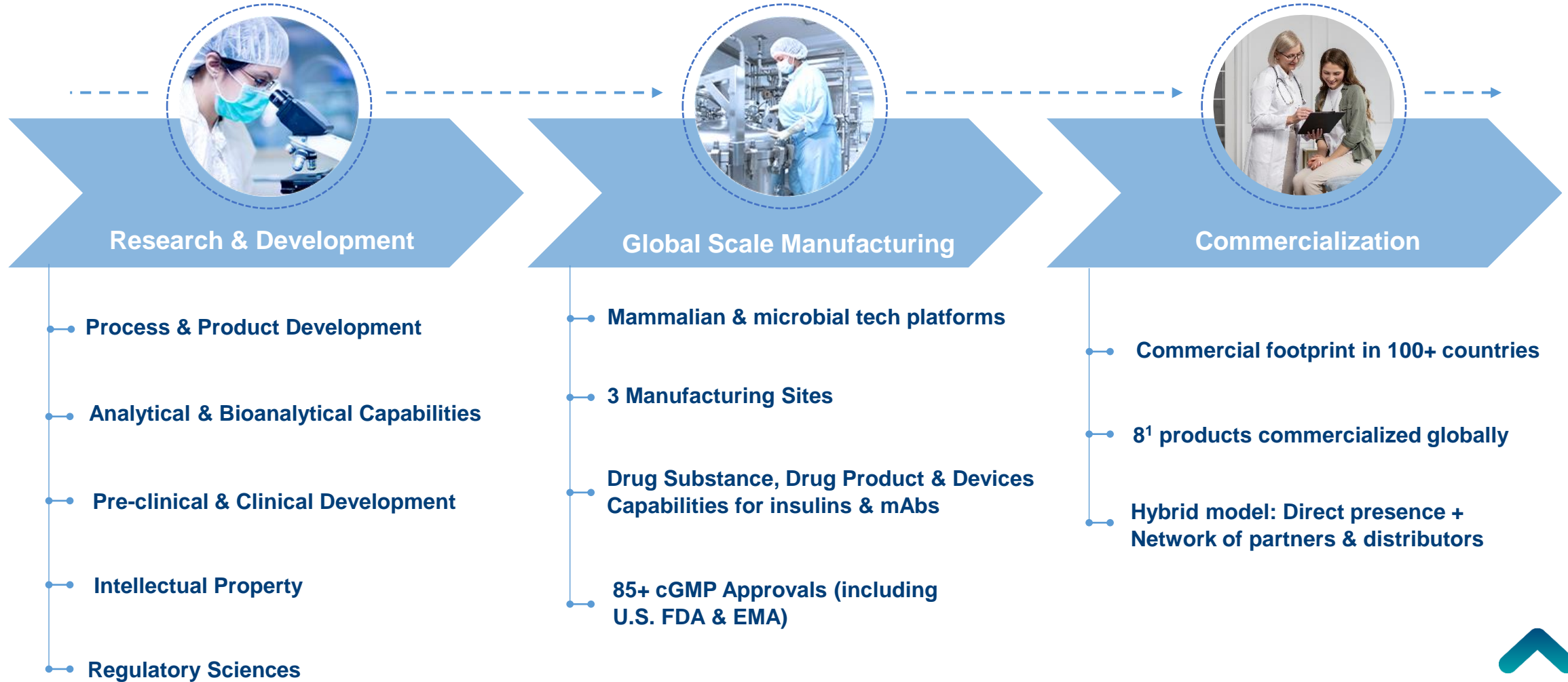


5.5M+
Patients served

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

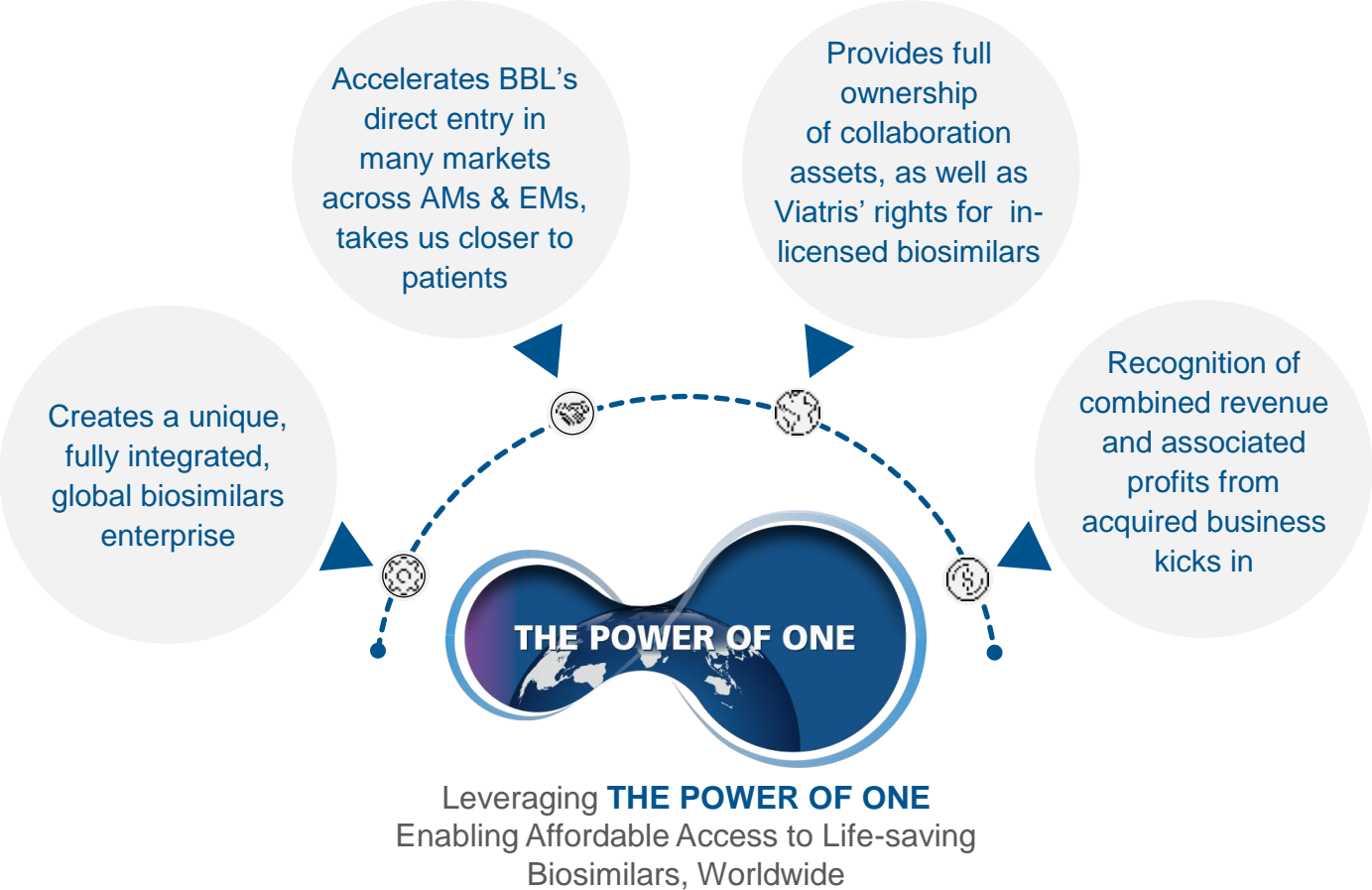
- **Invested >\$1B in biosimilars ahead of its peers** to build expertise across multiple platforms and a differentiated portfolio - including insulins, mAbs and fusion proteins
- **In-house R&D, clinical and regulatory capabilities** to develop high precision biosimilars for global markets
- **Expertise 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 Viatris' global biosimilars business









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 style="list-style-type: none"> Pegfilgrastim Trastuzumab Bevacizumab | <ul style="list-style-type: none"> Adalimumab Etanercept | | | <ul style="list-style-type: none"> RHI Glargine U100 Aspart | |
| Late Stage ¹ | <ul style="list-style-type: none"> Denosumab Pertuzumab | <ul style="list-style-type: none"> Ustekinumab | <ul style="list-style-type: none"> Aflibercept | <ul style="list-style-type: none"> Denosumab | | |
| Early Stage ² | 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 (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 enrolment complete for the LN study
- ✓ Topline data expected in the first half of 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

- ✓ 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

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
 - ✓ **Monotherapy activity** in difficult to treat post-pembro squamous lung cancer and cutaneous squamous carcinoma
 - ✓ Activity in combination with pembro in **checkpoint and cetuximab-refractory** head and neck cancer (HNSCC)
- ✓ BCA101 + pembrolizumab combination dose expansion study in **1L HNSCC demonstrates significant improvement over standard of care**

Organization

- ✓ Highly experienced management team, board of directors and advisory board
- ✓ \$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

Platform

- ✓ **ToTeM™** – leverages rational combinations to unleash the full potential of **targeted tumor modulators**
- ✓ Pragmatic antibody engineering and manufacturable IgG-like biologics

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.



Q1 FY24 Highlights

Financial Highlights: Q1 FY24

| Consolidated (in ₹ Cr.) | Q1 FY24 | Q1 FY23 | YoY % | |
|--------------------------|---------|---------|-------|---|
| Total Revenue | 3,516 | 2,217 | 59 | Biosimilars +106% Research +25% Generics 15% |
| Core EBITDA ¹ | 936 | 661 | 42 | Growth across Generics, Biosimilars & Research Services |
| % Margin | 28% | 31% | | |
| EBITDA | 808 | 478 | 69 | Net R&D spend at ₹315 Cr, up ₹117 Cr vs Q1 FY23, representing 12% of revenues ex-Syngene Forex Loss of ₹9 Cr vs. loss of ₹38 Cr last year. |
| % Margin | 23% | 22% | | |
| Profit Before Tax | 184 | 197 | (7) | Increase in depreciation, amortization and interest expense by ₹353 Cr, primarily related to acquisition of Viatris' biosimilar business |
| % Margin | 5% | 9% | | |
| Net Profit | 101 | 144 | (30) | Increase in minority interest due to dilution of shareholding in Syngene and Biocon Biologics on account of the Viatris deal |
| Net Profit Margin % | 3% | 7% | | |

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



Biocon Generics: Q1 FY24 Highlights

➤ Revenue growth driven primarily by U.S. generic formulations business; new product launches in key ex-US markets

➤ Continued traction in immunosuppressant API portfolio

➤ Received 'Tentative Approval' in U.S. for Lenalidomide capsules

➤ Successfully closed two U.S. FDA inspections, EIRs with 'NAI status' received for both

➤ Work on new injectable facility and expansion of peptide and non-immunosuppressant fermentation capacities commenced in Bengaluru

| In INR Cr | Q1 FY24 | Q1 FY23 | YoY % |
|------------------------|---------|---------|-------|
| Segment Revenue | 700 | 607 | 15 |
| PBT | 64 | 63 | 1 |
| % of revenue | 9% | 10% | |



Biocon Biologics: Biosimilars – Q1 FY24 Business Update

- Significant growth in market shares of key commercial products
- Increase in NRx to 15% for Insulin Glargine in the U.S., demonstrates strong ongoing adoption
- New Insulin Glargine customers added in the U.S. with exclusive status
- Fulphila is the biosimilar market leader in the U.S., demonstrating physician and payor confidence
- Hulio launched in the U.S. – biosimilar uptake across the industry for Adalimumab has been more gradual than expected

Key Products' Market Share¹

United States

| | Jun-23 | Jun-22 |
|--|--------|--------|
| Fulphila (bPegfilgrastim) | 16% | 8% |
| Ogivri (bTrastuzumab) | 11% | 9% |
| Semglee (bGlargine)² | 12% | 8% |

Europe

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

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

Biocon Biologics: Biosimilars – Q1 FY24 Financial Update

- Revenues doubled Y-o-Y with driven by increased market share and consolidation of Viatris' biosimilar business
- Sequentially, revenues largely flat due to phasing of the tender business in EMs and a one-off impact of rebates in the US for Fulphila
- Higher rebates in Fulphila for select customers on legacy contracts which will normalize in the coming quarters
- Core EBITDA¹ margin expected to return to mid-30s by the end of FY24

| In INR Cr | Q1 FY24 | Q1 FY23 | YoY % |
|--------------------------|---------|---------|-------|
| Revenue | 2,015 | 977 | 106 |
| Core EBITDA ¹ | 513 | 361 | 42 |
| % of revenue | 28% | 37% | |
| EBITDA | 457 | 190 | 141 |
| % of Revenue | 23% | 19% | |
| PBT | 24 | 71 | (66) |
| % of Revenue | 1% | 7% | |

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



Novels: Q1 FY24 Update

- 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. Top line data expected in 1H2024
- BCA101 demonstrates 65% ORR in Combination with Pembrolizumab in 1L HPV-negative Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma (HNSCC), with a tolerable safety profile - a significant improvement over existing standard of care
- Bicara completed an oversubscribed USD 108 million Series B financing in March 2023, which will help to advance this asset



Syngene: Q1 FY24 Update

➤ Strong performance led by Development and Manufacturing Services; supported by sustained growth in Discovery Services and the Dedicated Centers

➤ Announced deal to acquire multimodal biologics plant from Stelis along with high speed fill-finish facility; strengthens Syngene's position as a leading biologics contract development and manufacturing service provider

➤ Completed acquisition of additional land in Hyderabad, to support long term growth in Research Services division

| In INR Cr | Q1 FY24 | Q1 FY23 | YoY % |
|--------------|---------|---------|-------|
| Revenue | 808 | 645 | 25 |
| PBT | 123 | 93 | 33 |
| % of revenue | 15% | 14% | |





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 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 2022



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

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)

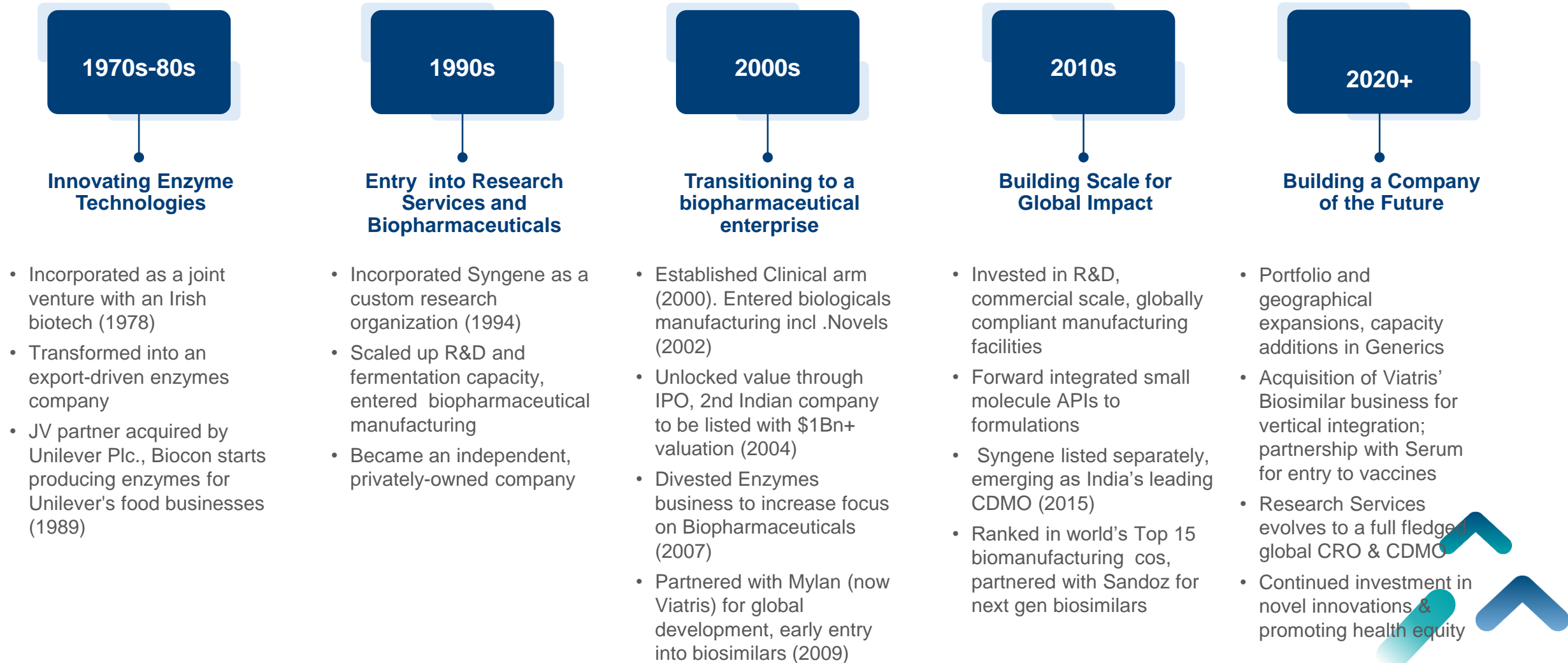




Annexures

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

- 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



**Relentless Pursuit.
Differentiated Growth.**

Integrated Annual Report FY 2023

