## Q3FY22 Investor Presentation

January 2022





## **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.





## **The Biocon Manifesto**

As a committed stakeholder of the global health agenda under the **UN Sustainable Development** Goals (SDGs), **Biocon has** drawn up a manifesto to deliver on its commitment to universal healthcare.



## accessibility

- Use our science, scale and expertise to enhance access to essential drugs for patients on the lowest rung of the economic ladder
- Uncover new medical insights aimed at expanding the scope of therapy to address unmet needs



### affordability

- Focus on the kind of innovation that adds the condition of affordability to accessibility
- Bring competition for expensive innovator medicines through our generics and biosimilars



## availability

- Build strategic global and regional partnerships to make high-quality biopharmaceuticals available to the maximum number of people
- Create a robust portfolio of 'blockbuster' drugs with the potential to benefit a billion patients

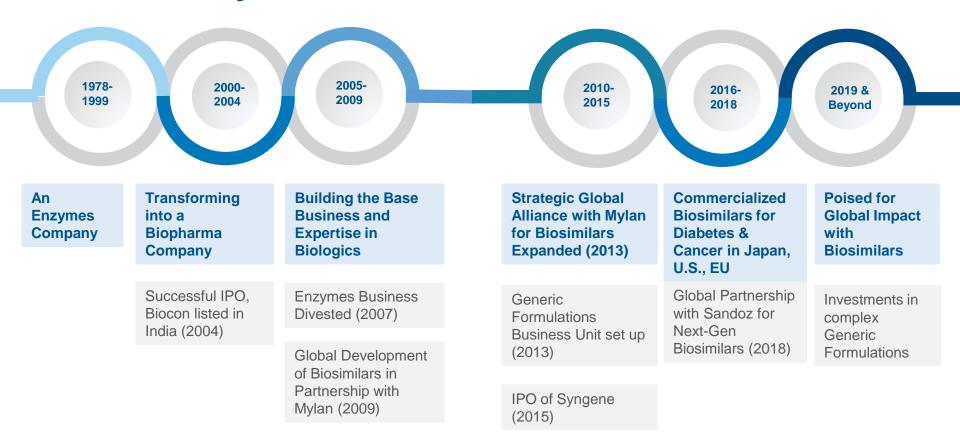


#### assurance

- Demonstrate the highest levels of ethics, compliance and governance
- Assure continuous supply of high-quality products conforming to international regulatory standards



## The Biocon Journey: A Continuous Evolution



Unwavering focus through the years on innovation & difficult to make, niche products to create tangible differentiators for sustainable growth



## Biocon Today: Strategically poised for a strong global play



Rs 7,360 Cr Revenue\*



**12000+**Total Employees\*



**1,200+** Patents



**25+**cGMP approvals from
International regulatory
agencies

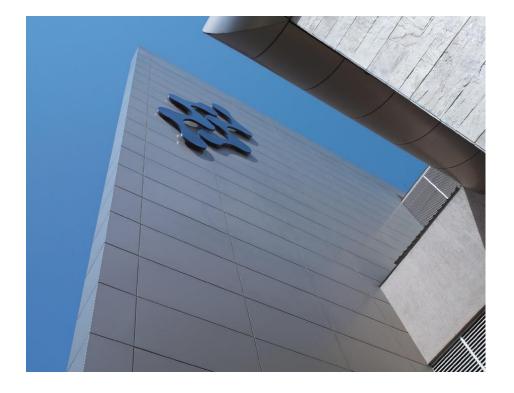


**120+**Countries where our products are available



Among Top 10 Global Biotech Employers by Science magazine

Ranked 5





## **Sustainability at Biocon**



- Featured for the 1<sup>st</sup> time in 'Dow Jones

  Sustainability Emerging Markets Index' for 2021
- Among **Top 15 from India** to be featured

Received a 'B' score in Climate Change & Water Security in CDP Score Report 2021

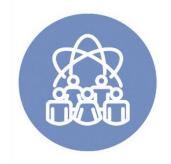


## Philosophy of Unconditional Equity through...



#### PATIENT EQUITY

- 3.1M patients reached through biosimilars for diabetes & cancer in FY21
- ~2B statin pills delivered in the U.S. in FY21



#### PEOPLE EQUITY

- Top 5 among global pharma & biotech employer since 2012
- Recognized by **UN Women** for efforts to promote diversity



SOCIAL EQUITY

- o ~**₹97M** CSR Spend in FY21
- Focus on Primary healthcare, Environmental stability, Rural development & COVID relief



#### ENVIRONMENTAL EQUITY

- 53% electricity came from green power in FY21
- 100% waste water recycled & reused



#### STAKEHOLDER EQUITY

- Independent Boards;Professional Management
- Board Committees, policies for global governance

# **Business Segments**

Unwavering Purpose



## **Growth Verticals: Aligned With Shifting Paradigms**

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



Ensuring
access through
quality,
affordability,
reliability



Expanding access through innovative, inclusive healthcare solutions



Pushing scientific boundaries to deliver impactful innovations



Partnering to deliver innovative scientific solutions



## Generics: Investing in capacities & capabilities for future growth



#### **Differentiated API business**

- 5 state-of-the-art facilities across Bangalore, Hyderabad and Visakhapatnam, India
- Among the world's largest manufacturers of immunosuppressant & statin APIs
- Expertise in fermentation technology, large scale chromatography and synthetic chemistry
- Consistent track record of quality compliance and manufacturing of high quality products with reliability and efficiency
- 1,000+ customers in 100+ countries incl. the U.S, Europe and large emerging markets, with a track-record of excellence for over 20 years



#### **Growing Formulations Footprint**

- Oral solids (potent & non-potent), parenteral & device dependent products
- Focus therapeutic segments Metabolics, Oncology, Immunology & Auto-immune indications
- 8 Generic Formulations commercialized in the US
- Entered into partnerships to enhance presence in China, Singapore, Thailand, Brazil and Middle East.



#### **Investments for future growth**

- **Expanding our R&D capabilities** for fermentation-derived, chemical synthesis-based molecules, peptides and potent APIs
- Focus on developing niche, difficult-to-make, complex molecules with relatively higher entry barriers by also leveraging our deep expertise in Fermentation based APIs
- Investing ₹ 6 B in greenfield, fermentationbased manufacturing facility in Visakhapatnam, India
- Focus on further strengthening quality and related functions and improving efficiency through digitization and other strategic initiatives



1000+
Customers



280+
Patents Obtained



50%
Global MS in orlistat API
& world's leaders in immunosuppressants



800+
Metric ton cumulative weight of APIs supplied annually



## **Generics: Q3 FY22**

#### KEY HIGHLIGHTS

- Revenue growth due to launch of Everolimus in the US & uptake in API business
- Continued pricing pressure, higher RM/solvent & logistics cost
- Partnered with Tabuk pharmaceuticals to commercialize speciality products in the Middle East
- Three dossier approvals received: Mycophenolic Acid Delayed-Release Tablets USP in the US; Everolimus Tablets & Fingolimod Capsules in EU
- On track to commission greenfield Immunosuppressant API facility in Visakhapatnam in FY22

Q3 FY22

Q3 FY21

#### Revenue

₹607Cr

₹567Cr

7% YoY increase

### **Profit Before Tax (PBT)**

₹67Cr

₹53Cr

11% of revenue

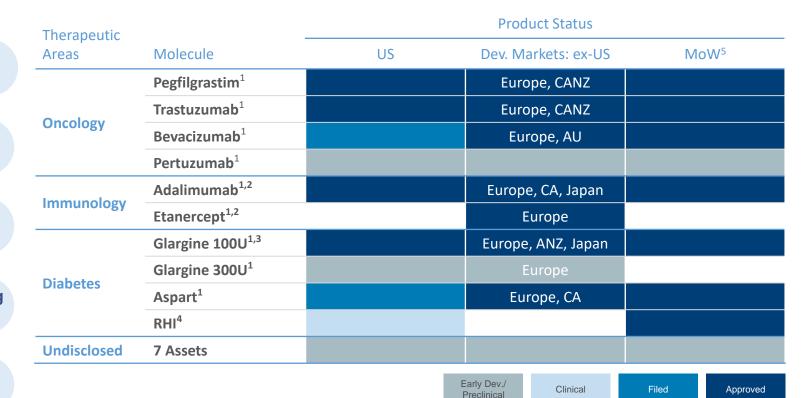
9% of revenue



## Biosimilars: Fully integrated global player in an attractive market



- Robust pipeline across multiple therapeutic areas
- Launched the first 'interchangeable' biosimilar approved by US FDA (bGlargine)
- Expertise in large scale biologics manufacturing across diverse technology platforms
- Serve patients globally through commercial partners and direct sales force in India<sup>6</sup>
- Forged strong local and global partnerships e.g., Viatris, Libbs and Sandoz









25+



cGMP approvals (incl. FDA & EMA)

<sup>1</sup> In partnership with Viatris; 2 Partner Viatris has in-licensed product (Biocon benefits from economic interest); 3 Japan is outside of Viatris partnership; 4 RHI non-partnered asset completed Ph 1 and considering potential Ph 3 waiver to be confirmed with US FDA advice, shown as Planned submission; 5 MoW represents Most of the World markets. Chart represents the status of the country where the product is in most advanced stage. Every country has a different status; 6 Branded Formulations India (BFI) is the commercial platform in India; 7 Includes Adalimumab and Etanercept which have been in-licensed by Viatris and Biocon Biologics has economic interest.



## Entering adjacencies in communicable disease: infectious disease antibodies and vaccines

#### **Key Commercial Products**









#### **Recent Collaborations**





50,000+ lives impacted

**Continued portfolio expansion** 



## **Key terms of alliance with SILS**

Access to 100m doses
of vaccines annually for
15 years

Commercialization rights of the SILS portfolio for global markets

Committed revenue stream and related margins from H2 FY23







~15% stake in
BBL at a post-money
valuation of ~\$4.9bn

Alliance to commercialize SILS COVID portfolio and other next generation vaccines



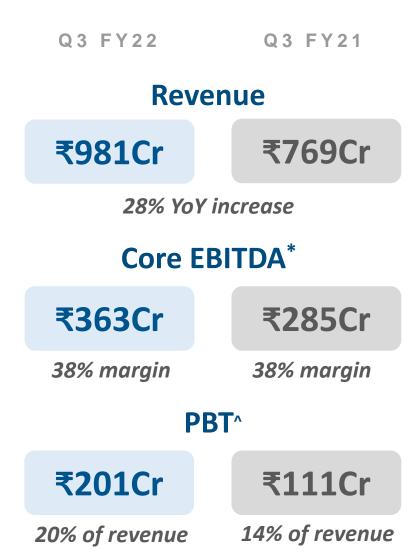
## **Biosimilars: Q3 FY22**

#### KEY HIGHLIGHTS

- Strong performance of bGlargine in US evidenced by several commercial arrangements (e.g., ESI & Prime formulary listing)
- Robust growth in Biocon Biologics led commercial franchise in emerging markets

Wave 2 pipeline programs to enter clinic in Q4 FY22

Initiated investments for the expansion of insulin manufacturing facility in Malaysia



<sup>\*</sup>Core EBITDA defined as EBITDA before R&D, forex, licensing and mark-to-market loss on Adagio investment



# Novel Molecules: Pushing scientific boundaries to deliver impactful innovations

#### **Disease Area**

#### **Asset**

#### **Current Progress**



**Diabetes** 

**Insulin Tregopil-** a first-in-class oral, prandial Insulin

- Phase I multiple ascending dose studies in Type 1 DM patients ongoing in Germany; in partnership with US-based Juvenile Diabetes Research Foundation (JDRF), a leading nonprofit organization
- Phase I component of this trial expected to be completed in FY22



Itolizumab- A novel humanized CD6 antibody

- US based partner, **Equillium to initiate a Pivotal Study in early 2022** for use in First-Line treatment of Acute Graft-Versus-Host Disease (aGVHD).
- Equillium conducting a Proof of Concept study for SLE / LN\*
- European Commission granted an 'Orphan Medical Product' designation in the treatment of Graft Versus Host disease in Jul '21
- Repurposed for prevention & treatment of COVID-19 complications in India in 2020;
   granted 'Restricted Emergency Use' approval in Sep '20 for treatment of Cytokine
   Release Syndrome in 'Moderate to Severe' Acute Respiratory Distress Syndrome patients



**BCA101**- (formerly FmAb2, a first-in-class EGFR / TGFβ-trap bifunctional antibody) - part of **Bicara Therapeutics**, a clinical-stage biotechnology company based in US\*\*

- Entered a Phase I/II study at leading US and Canadian cancer centers in Jul '20
- Under evaluation, both as a single agent and in combination with the checkpoint inhibitor, Pembrolizumab, in patients with advanced EGFR-driven solid tumors, who no longer respond to the standard of care
- Completed enrollment for dose finding part of Phase I trial, both in monotherapy & in combination with a PD1 inhibitor; 3 expansion cohorts to open at start of 2022

<sup>\*</sup>Systemic Lupus Erythematosus/Lupus Nephritis



## **Novels: Q3 FY22**

#### KEY HIGHLIGHTS

- On track to initiate a pivotal study on Itolizumab in first-line acute GVHD\* in early 2022
- Part B of Phase 1b EQUALISE study for SLE / LN\*\* expanded to clinical centers in India
- Bicara# completed enrolment in dose finding part of Phase 1 trial for its lead program, BCA101; on track to open three expansion cohorts at the start of 2022



<sup>\*</sup>Graft-Versus-Host Disease \*\*Systemic Lupus Erythematosus/ Lupus Nephritis

<sup>#</sup>In Q4FY21, Biocon ceded control over the Board of Directors and Operations of Bicara Therapeutics Inc. to enable it to operate independently under a US based leadership team and raise funds to advance its development programs. As a result of this change, Bicara was classified as an Associate from a Subsidiary under IND-AS.



## Research Services (Syngene)

- Offering integrated research, development & manufacturing services for small & large molecules, antibody-drug conjugates & oligonucleotides backed by best-in-class bioinformatic services
- World-class R&D and manufacturing infrastructure spread over 2 million square feet
- Audited successfully by US FDA, EMA, AAALAC and major life sciences partners
- Talented scientific & techno-commercial teams, led by experienced management, moving beyond cost arbitrage to innovation; 4700+ talented team of scientists, incl. ~490 PhDs
- 400+ active marquee clients across multiple sectors
- Strong track record of top-line growth with best-in-class EBITDA margins and Net Profit margin
- Listed in India on BSE and NSE in 2015



## **Research Services: Q3 FY22**

#### KEY HIGHLIGHTS

- Discovery & Dedicated Centers were growth drivers in Q3
- Development & Manufacturing Services delivered sustained performances in Q3
- Extension and expansion of collaboration with Amgen until 2026; to add a dedicated laboratory
- Updated full year guidance for revenue growth to high teens from mid-teens

Q3 FY22

Q3 FY21

#### Revenue

₹641Cr

₹585Cr

10% YoY increase

#### **PBT**

**₹128Cr** 

₹117Cr

20% of revenue

20% of revenue

# Financial Highlights

Unwavering Purpose



## **Annual Financial Highlights**

	FY21	F Y 2 0
Revenue +13%	₹7,360Cr	₹6,462Cr
Core EBITDA <sup>1</sup> +15%	₹2,430Cr	₹2,108Cr
% margin	33%	33%
EBITDA +8%	₹1,907Cr	₹1,765Cr
% margin	26%	27%
Profit Before Tax <sup>2</sup> (11)%	₹1,077Cr	₹1,215Cr
% margin	15%	19%
Net Profit # (4)%	₹754Cr	₹789Cr
% margin	5%	9%

**Biosimilars +21% | Research Services** +9% | Generics +6%

Forex loss of ₹9Cr in FY21 vs **₹65Cr** of **Forex gain** in FY20

Gross R&D spends at ₹627Cr in FY21 (13% of ex-Syngene revenues) **R&D spends in P&L ₹533Cr** for FY21

Excluding Bicara Fair Valuation gain of 160 Cr:

Core EBITDA 32%, dn 1% EBITDA **₹1,747Cr** at **24% Net profit** at ₹594Cr



## Financial Highlights: Q3 FY22

	Q3 FY22	Q3 FY21
Revenue +18%	₹2,223Cr	₹1,885Cr
Core EBITDA* +23%	₹715Cr	₹581Cr
% margin	33%	31%
EBITDA +25%	₹537Cr	₹428Cr
% margin	24%	23%
Profit Before Tax +14%	₹269Cr	₹236Cr
% margin	12%	12%
Net Profit +11%	₹187Cr	₹169Cr
% margin	8%	9%

Biosimilars +28% | Research Services +10% | Generics 7%

Mark-to-market loss on Adagio investment of ₹77Cr
Forex Gain of ₹19Cr vs ₹6Cr in Q3 FY21

Gross R&D spend at ₹178Cr R&D spend in P&L ₹138Cr

PBT adjusted for mark-to-market loss on Adagio investment of ₹346Cr

<sup>\*</sup>Core EBITDA defined as EBITDA before R&D, forex, mark-to-market loss on Adagio investment and licensing income

## **Thank You**

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