Biocon

Biocon Biologics

# Investor Presentation

## Q2 FY22

# 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.*


Biocon is a global biopharmaceutical company that is leveraging its affordable innovation model to reduce disparities in access to safe, high-quality medicines, as well as, address the gaps in scientific research to find innovative solutions to impact a billion lives.

# 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


| 1978-1999 | 2000-2004 | 2005-2009 | 2010-2015 | 2016-2018 | 2019 & Beyond |
|---|---|---|---|---|---|
| **An Enzymes Company** | **Transforming into a Biopharma Company** | **Building the Base Business and Expertise in Biologics** | **Strategic Global Alliance with Mylan for Biosimilars Expanded (2013)** | **Commercialized Biosimilars for Diabetes & Cancer in Japan, U.S., EU** | **Poised for Global Impact with Biosimilars** |
| | Successful IPO, Biocon listed in India (2004) | Enzymes Business Divested (2007) | Generic Formulations Business Unit set up (2013) | Global Partnership with Sandoz for Next-Gen Biosimilars (2018) | Investments in complex Generic Formulations |
| | | Global Development of Biosimilars in Partnership with Mylan (2009) | IPO of Syngene (2015) | | |

**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*

**12,000+**
Total Employees*

**1,200+**
Patents

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

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

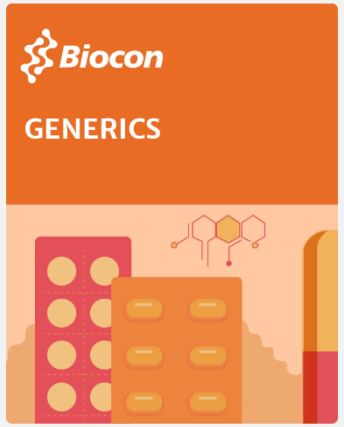
**Ranked 5**
Among Top 10 Global Biotech Employers by Science magazine

*FY21

# Business Segments

# 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


Pushing scientific boundaries to deliver impactful innovations


Expanding access through innovative, inclusive healthcare solutions


Partnering to deliver innovative scientific solutions

# Generics: Investing into capacities and capabilities for the 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 presence in **China, Singapore, Thailand and Brazil**

### 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, fermentation-based 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: Q2 FY22

KEY HIGHLIGHTS

- Pricing pressure in US
- Slower ramp-up of demand for APIs

Operational and supply chain challenges in the earlier part of the quarter

- Day 1 launch of Everolimus in the US
- Statins held on to market share

A Remote Interactive inspection of our OSD facility, Bengaluru, by the US FDA

On track to commission greenfield Immunosuppressant API facility in Visakhapatnam in FY22

| | Q2 FY22 | Q2 FY21 |
|---|---|---|
| **Revenue** | ₹530Cr | ₹604Cr |
| | *12% YoY decrease* | |
| **Profit Before Tax (PBT)** | ₹50Cr | ₹70Cr |
| | *9% of revenue* | *12% of revenue* |

# 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 non-profit organization<br>• **Phase I component** of this trial **expected to be completed in FY22** |
| Inflammation | **Itolizumab**- A novel humanized CD6 antibody | • US based partner, **Equillium to initiate a Phase III Pivotal Study in Q4 CY21** for use in First-Line treatment of Acute Graft Versus Host Disease (aGVHD), following regulatory feedback from U.S. FDA<br>• **European Commission granted an 'Orphan Medical Product'** designation in the treatment of Graft Versus Host disease in Jul '21<br>• 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 |
| Immuno-oncology | **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<br>• **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<br>• Bicara anticipates **transitioning to dose expansion studies by end of CY21** |

*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.

# Novels: Q2 FY22

KEY HIGHLIGHTS

- **Equillium on track to initiate a Phase 3 pivotal study on Itolizumab in first-line acute GvHD* in Q4 CY21**
- **Bicara# continues to make progress in dose finding part of the Phase 1 trial for its lead program, BCA101**

*Graft-versus-host disease

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# Biosimilars: Fully integrated global player in an attractive market

- Commercialized several biosimilars in developed and emerging markets
- Robust pipeline across multiple therapeutic areas
- Received the first 'interchangeable' biosimilar approval from US FDA (bGlargine)
- Expertise in difficult-to-manufacture, large-scale, biologics across platforms
- Serve patients globally through commercial partners and direct sales force in India[6]
- Forged strong local and global partnerships e.g., Viatris, Libbs and Sandoz

| Therapeutic Areas | Molecule | Product Status: US | Dev. Markets: ex-US | MoW[5] |
|---|---|---|---|---|
| Oncology | Pegfilgrastim[1] | | Europe, CANZ | |
| | Trastuzumab[1] | | Europe, CANZ | |
| | Bevacizumab[1] | | Europe, AU | |
| | Pertuzumab[1] | | | |
| Immunology | Adalimumab[1,2] | | Europe, CA, Japan | |
| | Etanercept[1,2] | | Europe | |
| Diabetes | Glargine 100U[1,3] | | Europe, ANZ, Japan | |
| | Glargine 300U[1] | | Europe | |
| | Aspart[1] | | Europe, CA | |
| | RHI[4] | | | |
| Undisclosed | 7 Assets | | | |

Early Dev./ Preclinical | Clinical | Filed | Approved

**8** Approved Products[7]

**2** Research & Development sites

**3** Manufacturing sites (2 Bengaluru, 1 Malaysia)

**25+** cGMP approvals (incl. FDA & EMA)

*1 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

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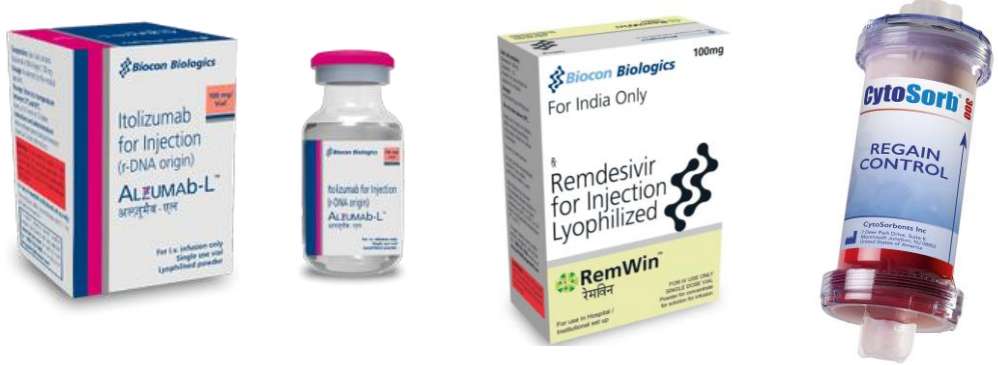
## Key Commercial Products




## Recent Collaborations

adagio

SII
SERUM INSTITUTE OF INDIA

50,000+ lives impacted

Continued portfolio expansion

# Key terms of alliance with SILS

1. Access to 100m doses of vaccines annually for 15 years
2. Commercialization rights of the SILS portfolio for global markets
3. Committed revenue stream and related margins from H2 FY23


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

Alliance will develop antibodies targeting infectious diseases like Dengue, HIV, etc.

# Biosimilars: Q2 FY22

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## KEY HIGHLIGHTS

- Strategic alliance with Serum Institute Life Sciences (SILS) to foray into vaccines with access to 100m doses/year for 15 years
- Partnered with Adagio Therapeutics to manufacture & commercialize a novel antibody, ADG20, for prevention & treatment of COVID-19
- Semglee approved as 1st interchangeable biosimilar in US; included by Express Scripts on the National Preferred Formulary, w.e.f. Jan 1, 2022
- Responded to the US FDA with a CAPA following their pre-approval inspection of Malaysia facility for bAspart
- Continued strong performance in emerging markets; continued improvement of performance in Europe - launched bBevacizumab in several EU countries

| | Q2 FY22 | Q2 FY21 |
|---|---|---|
| **Revenue** | ₹743Cr | ₹676Cr |
| | *10% YoY increase* | |
| **Core EBITDA*** | ₹304Cr | ₹265Cr |
| | *42% margin* | *39% margin* |
| **PBT (before exceptional charge)^** | ₹119Cr | ₹81Cr |
| | *16% of revenue* | *12% of revenue* |

*Core EBITDA defined as EBITDA before R&D, forex, licensing and Adagio revaluation gains

^Does not include revaluation gains from Adagio

# Research Services (Syngene)

- Offering integrated research, development and manufacturing services for both small and 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 and techno-commercial teams, led by experienced management, moving beyond cost arbitrage to innovation; 4700+ talented team of scientists, including ~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: Q2 FY22

Syngene

## KEY HIGHLIGHTS

- Strong performance across all divisions
- In Discovery Services, positive demand for newer services like Protein Degradation Technology (PROTACS) & peptide synthesis
- Uptick in Development Services as clients restarted activities
- Mangalore facility on track to achieve USFDA approval within two years
- Continued manufacturing of Remdesivir
- On track to deliver on FY22 guidance of mid-teens revenue growth

| | Q2 FY22 | Q2 FY21 |
|---|---|---|
| **Revenue** | ₹610Cr | ₹520Cr |
| | *17% YoY increase* | |
| **PBT** (before exceptional charge) | ₹113 Cr | ₹94Cr |
| | *19% of revenue* | *18% of revenue* |

# Financial Highlights

# Annual Financial Highlights

| | | FY21 | FY20 | |
|---|---|---|---|---|
| **Revenue** | *+13%* | **₹7,360Cr** | **₹6,462Cr** | **Biosimilars +21% \| Research Services +9% \| Generics +6%** |
| **Core EBITDA[1]** | *+15%* | **₹2,430Cr** | **₹2,108Cr** | **Forex loss** of **₹9Cr** in FY21 vs **₹65Cr** of **Forex gain** in FY20 |
| *% margin* | | *33%* | *33%* | |
| **EBITDA** | *+8%* | **₹1,907Cr** | **₹1,765Cr** | **Gross R&D spends** at **₹627Cr** in FY21 (**13%** of ex-Syngene revenues) **R&D spends in P&L ₹533Cr** for FY21 |
| *% margin* | | *26%* | *27%* | |
| **Profit Before Tax[2]** | *(11)%* | **₹1,077Cr** | **₹1,215Cr** | Excluding Bicara Fair Valuation gain of 160 Cr: Core EBITDA **32%, dn 1%** EBITDA **₹1,747Cr** at **24%** **Net profit** at **₹594Cr** |
| *% margin* | | *15%* | *19%* | |
| **Net Profit #** | *(4)%* | **₹754Cr** | **₹789Cr** | |
| *% margin* | | *5%* | *9%* | |

1 Core EBITDA defined as EBITDA before R&D, forex and licensing income; 2 from continued operations

# Financial Highlights: Q2 FY22

| | | Q2 FY22 | Q2 FY21 | |
|---|---|---|---|---|
| **Revenue** | *+10%* | **₹1,945Cr** | **₹1,765Cr** | **Biosimilars +10% \| Research Services +17% \| Generics (12)%** |
| **Core EBITDA*** | *+8%* | **₹609Cr** | **₹564Cr** | **Forex Gain** of **₹20Cr** vs **₹18Cr** of **loss** in Q2 FY21 |
| *% margin* | | *33%* | *32%* | |
| **EBITDA** | *+35%* | **₹551Cr** | **₹407Cr** | **Gross R&D spend** at **₹165Cr –** Similar to Q2 FY21<br>**R&D spend** in **P&L ₹146Cr** |
| *% margin* | | *28%* | *23%* | |
| **Profit Before Tax** *(before Exceptional charge)* | *+27%* | **₹276Cr** | **₹218Cr** | **Exceptional charge** of **₹70Cr** |
| *% margin* | | *14%* | *12%* | |
| **Net Profit** *(before Exceptional charge)* | *11%* | **₹188Cr** | **₹169Cr** | **Net Profit ₹138Cr** after exceptional charge |
| *% margin* | | *10%* | *10%* | |

*Core EBITDA defined as EBITDA before R&D, forex, Adagio revaluation gains and licensing income

# *Thank You*

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