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September 21, 2021

To The Secretary <b>BSE Limited</b> Department of Corporate Services Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai – 400 001 <b>Scrip Code - 532523</b>	To The Secretary <b>National Stock Exchange of India Limited</b> Corporate Communication Department Exchange Plaza, Bandra Kurla Complex Mumbai – 400 050 <b>Scrip Symbol- BIOCON</b>
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Dear Sir/Madam,

**Sub: Investor Presentation – Q1 FY-22.**

**Ref: Regulation 30 of the SEBI Listing Obligations and Disclosure Requirements (LODR) Regulations, 2015.**

With reference to the captioned subject, please find enclosed Investor Presentation under regulation 30 of the SEBI Listing Obligations and Disclosure Requirements (LODR) Regulations, 2015.

The above information will also be available on the website of the Company at [www.biocon.com](http://www.biocon.com).

Kindly take the above said information on record.

Thanking You,

Yours faithfully,

For **Biocon Limited**

*Mayank*



**Mayank Verma**  
**Company Secretary and Compliance Officer**

**Encl: Investor Presentation**



**Investor  
Presentation**

**Q1 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



## 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



## affordability

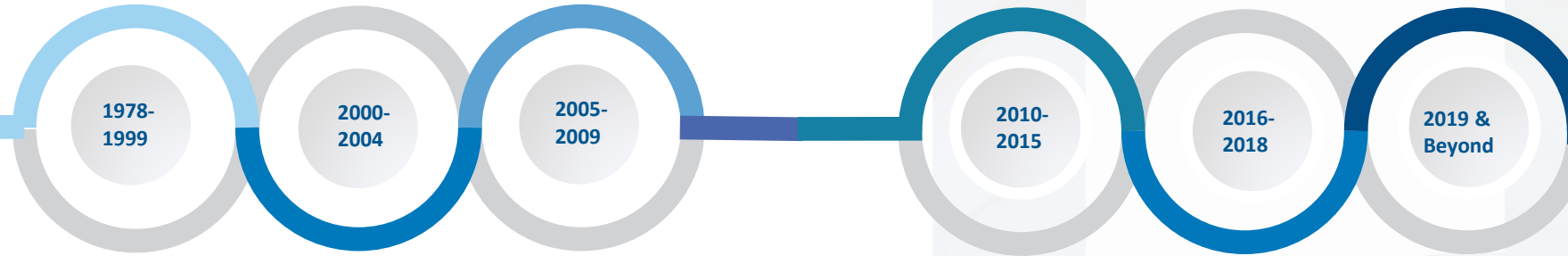
- Focus on the kind of innovation that adds the condition of affordability to accessibility
- Bring competition for expensive innovator medicines through our generics and biosimilars



## 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



**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)

Global Development of Biosimilars in Partnership with Mylan (2009)

Generic Formulations Business Unit set up (2013)

IPO of Syngene (2015)

Global Partnership with Sandoz for Next-Gen Biosimilars (2018)

Investments in complex Generic Formulations

**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



Unwavering  
Purpose

\*Fiscal year 2020-21

# Battling the pandemic!



- Mounting 'on-site' infections coupled with lockdown posed significant operational challenges
- 20,000+ COVID-19 vaccines administered to employees, their families and our neighbouring communities
- Ramped up production of Itolizumab to serve patients in the second wave: 27,000+ lives impacted
- With vaccinations picking up pace, we are hopeful of the situation improving

“  
When I came off the ventilator, I was told to be prepared for convalescent plasma therapy. But its need was mitigated by the administration of ALZUMAb-L (Itolizumab), which foiled the life-threatening impact of cytokine storm due to COVID-19. My turnaround was miraculous.  
- Dr. Belani, Mumbai  
”

“  
I was admitted in the ICU when the doctors administered Itolizumab, following which my condition improved. I was moved out of the ICU the next day. Within a few days, I was helping other patients, even those in wheelchairs.  
- Sanjai Rai, Mumbai  
”



# 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



Expanding access through innovative, inclusive healthcare solutions



Partnering to deliver innovative scientific solutions



Pushing scientific boundaries to deliver impactful innovations

# Generics: Investing into capacities and capabilities for the future growth



## Differentiated API business

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



## Growing Formulations Footprint

- **Solid oral & parenteral products** in both potent & non-potent categories
- **Focus therapeutic segments** – Metabolics, Oncology, Immunology & Auto-immune indications
- Generic Tacrolimus, Rosuvastatin, Simvastatin & Atorvastatin launched in the **United States**
- Entered partnerships to **expand Generic Formulations** footprint in **China, Singapore, Thailand**
- Regulatory licenses received from **MHRA** for import and distribution of our formulations in **UK**



## Investments for future growth

- **Expanding our R&D capabilities** for newer fermentation-derived and chemical synthesis-based molecules.
- Focus on **developing niche, difficult-to-make, complex molecules** with relatively higher entry barriers.
- **Investing Rs. 6 billion in greenfield, fermentation-based manufacturing facility** in Visakhapatnam, Andhra Pradesh
- Focus on **adopting best-in-class quality practices and implement digital processes** in our quality and related functions
- Retaining leadership in key APIs with **structured cost improvement programs**



**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: Q1 FY22

## KEY HIGHLIGHTS

- COVID-19 led operational and supply chain challenges in API manufacturing, expected to normalize in the coming quarter
- Gradual ramp-up of Tacrolimus in US while statins' market share was resilient
- Entered Labetalol and Esomeprazole in the US with estimated market size\* of \$63m and \$230m, respectively
- Delay in site inspections, consequently launches, due to travel restrictions
- On track to commission greenfield Immunosuppressant API facility in Visakhapatnam in FY 2022

\*US Market value based on IQVIA



Q1 FY22

Q1 FY21

### Revenue

₹486Cr

₹621Cr

22% YoY decrease

### Profit Before Tax

₹29Cr

₹96Cr

6% of revenue

15% of revenue

Unwavering  
Purpose



# Biosimilars: Developing biologics for global markets at all scale



- Biosimilars are an attractive opportunity
- Robust biosimilar portfolio coupled with adjacent biologics (e.g., ADG20)
- Fully integrated – lab to market
- Global Footprint (120+ countries)
- Strong partners e.g., Viatris, Sandoz and Adagio
- Branded Formulations India (BFI) forms a robust commercial platform in India

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



**8** Approved Products<sup>6</sup>

**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 Includes Adalimumab and Etanercept which have been in-licensed by Viatris and Biocon Biologics has economic interest.*

# Biosimilars: Key updates in Q1 FY22



## KEY HIGHLIGHTS

- Strong growth in BFI business with significant contribution from COVID-19 portfolio, serving 50,000+ patients
- Steady performance of non-COVID products
- Continued improvement in market share for commercial products in the US
- Additional growth in US expected by launch of bBevacizumab and bAspart, and bGlargine interchangeability
- Near-term growth in EU to be driven by entry in new markets and product launches (bBevacizumab)

Q1 FY22

Q1 FY21

### Revenue

₹758Cr

₹692Cr

10% YoY increase

### Core EBITDA<sup>1</sup>

₹271Cr

₹249Cr

36% of revenue

### Profit Before Tax

₹101Cr

₹105Cr




13% of revenue

15% of revenue

<sup>1</sup> Core EBITDA defined as EBITDA before R&D, forex and licensing income

# Novel Molecules: Pushing scientific boundaries to deliver impactful innovations



Disease Area	Asset	Current Progress
 <p><b>Diabetes</b></p>	<p><b>Insulin Tregopil</b>- a first-in-class oral, prandial Insulin</p>	<ul style="list-style-type: none"> <li>Phase I multiple ascending dose studies in Type 1 DM patients making progress in Germany. This trial is in partnership with the US-based Juvenile Diabetes Research Foundation (JDRF), a leading non-profit organization .</li> <li>Phase 1 component of this trial expected to be completed in FY22</li> </ul>
 <p><b>Inflammation</b></p>	<p><b>Itolizumab</b>- A novel humanized CD6 antibody</p>	<ul style="list-style-type: none"> <li>US, Canada, Australia and New Zealand rights out-licensed to the US-based Equillum Inc. Currently, Equillum is conducting clinical trials on the use of Itolizumab in the treatment of acute graft-versus-host disease (aGVHD), uncontrolled asthma and lupus nephritis.</li> <li>The European Commission granted an ‘Orphan Medical Product’ designation to Itolizumab in the treatment of Graft versus Host disease in July 2021</li> <li>In 2020, Itolizumab was repurposed for the prevention and treatment of COVID-19 complications and we were granted Restricted Emergency Use approval in September 2020 for the treatment of Cytokine Release Syndrome (CRS) in moderate to Severe Acute Respiratory Distress Syndrome (ARDS) patients in India. Phase 4 studies are making good progress.</li> </ul>
 <p><b>Immuno-oncology</b></p>	<p><b>BCA101</b>- (formerly FmAb2, a first-in-class EGFR / TGFβ-trap bifunctional antibody).This asset is part of <b>Bicara Therapeutics</b>, a clinical-stage biotechnology company based in US*</p>	<ul style="list-style-type: none"> <li>Entered a Phase 1/2 study at leading US and Canadian cancer centers in July 2020.</li> <li>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.</li> <li>Bicara anticipates transitioning to dose expansion studies in the second half of 2021.</li> </ul>

\*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: Q1 FY22



## KEY HIGHLIGHTS

- Equillium had Positive End-of-Phase 1 meeting with the US FDA on Itolizumab for acute GvHD\*
- To initiate a Phase 3 pivotal study on Itolizumab in first-line acute GvHD\* in Q4 CY 2021
- COMP\*\* approved an Orphan Designation for Itolizumab for the treatment of acute and chronic GvHD\* in EU
- Completed dosing for Phase 4 study of Itolizumab for treating CRS^ in moderate to severe ARDS# patients due to Covid-19



\*Graft-versus-host disease \*\* Committee for Orphan Medicinal Products ^Cytokine Release Syndrome #Acute Respiratory Distress Syndrome



# Research Services (Syngene): A global CRO delivering innovative solutions

*Syngene*

- Offering integrated research, development and manufacturing services for both small and large molecules, antibody-drug conjugates and oligonucleotides backed by best-in-class bioinformatic services
- Combining world class research expertise, technology and infrastructure to reduce costs and time to market
- Talented scientific and techno-commercial teams, led by experienced management, moving beyond cost arbitrage to innovation
- World class infrastructure audited successfully by US FDA, EMA, AAALAC and major life sciences partners
- 400+ active marquee clients across multiple sectors
- World-class R&D and manufacturing infrastructure spread over 1.9 million square feet
- 4700+ talented team of scientists, including ~490 PhDs
- 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: Q1 FY22

## KEY HIGHLIGHTS

- Growth across all divisions – Discovery, Development and Manufacturing services
- Significant contribution of Remdesivir in topline growth
- Mangalore API facility successfully completed ISO 9001:2015 certification audit
- Signed a five-year agreement with IAVI for manufacturing three anti-HIV mAbs for use in Phase 1 and 2 clinical trials

**Syngene**

Q1 FY22

Q1 FY21

### Revenue

₹595Cr

₹422Cr

*41% YoY increase*

### Profit Before Tax

₹95Cr

₹66Cr

*16% of revenue*

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# Financial Highlights

# Annual Financial Highlights



		FY 21	FY 20	
<b>Revenue</b>	+13%	<b>₹7,360Cr</b>	<b>₹6,462Cr</b>	Biosimilars +21%   Research Services +9%   Generics +6%
<b>Core EBITDA<sup>1</sup></b>	+15%	<b>₹2,430Cr</b>	<b>₹2,108Cr</b>	Forex loss of ₹9Cr in FY21 vs ₹65Cr of Forex gain in FY20
<i>% margin</i>		33%	33%	
<b>EBITDA</b>	+8%	<b>₹1,907Cr</b>	<b>₹1,765Cr</b>	Gross R&D spends at ₹627Cr in FY21 (13% of ex-Syngene revenues) R&D spends in P&L ₹533Cr for FY21
<i>% margin</i>		26%	27%	
<b>Profit Before Tax<sup>2</sup> (11)%</b>		<b>₹1,077Cr</b>	<b>₹1,215Cr</b>	Excluding Bicara Fair Valuation gain of 160 Cr: Core EBITDA 32%, dn 1% EBITDA ₹1,747Cr at 24% Net profit at ₹594Cr
<i>% margin</i>		15%	19%	
<b>Net Profit #</b>	(4)%	<b>₹754Cr</b>	<b>₹789Cr</b>	
<i>% margin</i>		5%	9%	

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



# Quarterly Financial Highlights



		Q1 FY22	Q1 FY21	
<b>Revenue</b>	+6%	<b>₹1,808Cr</b>	<b>₹1,712Cr</b>	Biosimilars +10%   Research Services +41%   Generics (22)%
<b>Core EBITDA*</b>	(1)%	<b>₹531Cr</b>	<b>₹532Cr</b>	Forex Gain of ₹17Cr in Q1 FY22 vs ₹4Cr of Forex loss in Q1 FY21
<i>% margin</i>		30%	31%	
<b>EBITDA</b>	+1%	<b>₹437Cr</b>	<b>₹432Cr</b>	Gross R&D spends at ₹136Cr in Q1 FY22 vs ₹142Cr in Q1FY21 R&D spends in P&L ₹120Cr for Q1 FY22
<i>% margin</i>		24%	25%	
<b>Profit Before Tax</b>	(33)%	<b>₹166Cr</b>	<b>₹249Cr</b>	PBT ex Bicara of ₹224Cr in Q1 FY22
<i>% margin</i>		9%	15%	
<b>Net Profit</b>	(44)%	<b>₹84Cr</b>	<b>₹149Cr</b>	Net Profit ex Bicara of ₹142Cr in Q1 FY22
<i>% margin</i>		5%	9%	

\*Core EBITDA defined as EBITDA before R&D, forex and licensing income

# *Thank You*

## INVESTOR RELATIONS CONTACT:

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