

#### **Biocon Limited**

20th KM, Hosur Road Electronic City Bangalore 560 100, India T 91 80 2808 2808 F 91 80 2852 3423

CIN: L24234KA1978PLC003417

www.biocon.com

May 19, 2021

То	То
The Secretary	The Secretary
BSE Limited	National Stock Exchange of India Limited
Department of Corporate Services	Corporate Communication Department
Phiroze Jeejeebhoy Towers,	Exchange Plaza, Bandra Kurla Complex
Dalal Street, Mumbai – 400 001	Mumbai – 400 050
Scrip Code - 532523	Scrip Symbol- BIOCON

Dear Sir/Madam,

Sub: Investor Presentation - Q4 FY-21.

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.

Kindly take the above said information on record.

Thanking You,

Yours faithfully,

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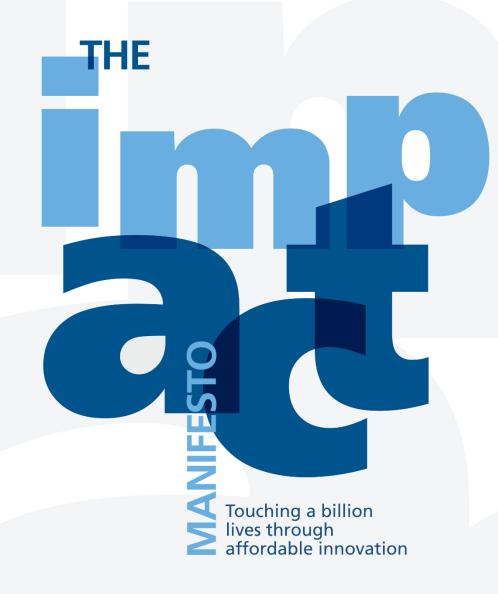
For Biocon Limited

Mayank Verma

**Company Secretary and Compliance Officer** 

**Encl: Investor Presentation** 





#### **INVESTOR PRESENTATION**

Q4FY21 | May 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.





#### **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

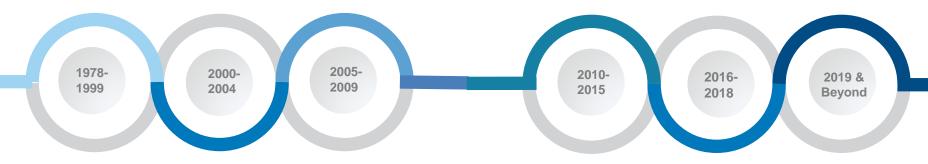
- Demonstrate the highest levels of ethics, compliance and governance
- Assure continuous supply of high-quality products conforming to international regulatory standards



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#### The Biocon Journey: A Continuous Evolution





An Enzymes Company

Transforming into a Biopharma Company

Successful IPO, Biocon listed in India (2004) Building the Base Business and Expertise in Biologics

Enzymes Business Divested (2007)

Global Development of Biosimilars in Partnership with Mylan (2009) Strategic Global Alliance with Mylan for Biosimilars Expanded (2013)

Generic Formulations Business Unit set up (2013)

IPO of Syngene (2015)

Commercialized Biosimilars for Diabetes & Cancer in Japan, U.S., EU

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

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





## **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 Business- Investing into capacities and capabilities for the future growth







- 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 synthesisbased molecules.
- Focus on developing niche, difficult-tomake, 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





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



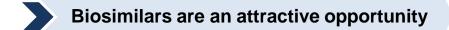
Metric ton cumulative weight of APIs supplied annually

Customers

Patents Obtained

#### Biocon Biologics: Developing biosimilars for global markets at all scale











Strong partners e.g., Viatris and Sandoz

					<b>Product Status</b>		
Therapeutic	Areas	Molecule	US	Europe	CANZ	Japan	MoW^^
		Pegfilgrastim					
Oncology		Trastuzumab					
Olicology		Bevacizumab					
		Pertuzumab			CA only  ANZ only  CA only		
		Adalimumab*			CA only		
Immunology		Etanercept*					
lmmunology		Undisclosed					
		Undisclosed					
		Glargine** 100U			ANZ only		
Diabetes		Glargine 300U					
		Aspart			CA only		
		RHI^					
		Undisclosed					
Others		Undisclosed					
Onlers	ers Undisclosed						
*Partner Viatris h	as in-licens	ed product (Biocon bene	efits from economic intere	est): ** Janan is outside of	Viatris		

\*Partner Viatris has in-licensed product (Biocon benefits from economic interest); \*\*Japan is outside of Viatris partnership; ^RHI completed Ph 1 and considering potential Ph 3 waiver to be confirmed with FDA advice, shown as Planned submission. ^^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





Filed



Branded Formulations India (BFI) forms a robust commercial platform in India







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

#### Novel Molecules: Pushing scientific boundaries to deliver impactful innovations



# Disease Area Diabetes

Asset

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

#### **Current Progress**

- Phase I multiple ascending dose studies in Type 1 DM patients making good progress in Germany. This trial is in partnership with the US-based Juvenile Diabetes Research Foundation (JDRF), a leading non-profit organization.
- Phase 1 component of this trial expected to be completed in FY22



**Itolizumab-** A novel humanized CD6 antibody

Insulin

- US, Canada, Australia and New Zealand rights out-licensed to the US-based Equillium Inc. Currently, Equillium is conducting clinical trials on the use of Itolizumab in the treatment of acute graft-versus-host disease (aGVHD), uncontrolled asthma and lupus nephritis.
- In 2020, Itolizumab was repurposed for the prevention and treatment of COVID-19 complications, and we were granted Restricted Emergency Use approval in July 2020 for the treatment of Cytokine Release Syndrome (CRS) in moderate to Severe Acute Respiratory Distress Syndrome (ARDS) patients in India.
- Additional data is being collected as part of Phase 4 (post-marketing study) and Real-World Evidence (RWE) from COVID-19 patients.



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

- Entered a Phase 1/2 study at leading US and Canadian cancer centers in July 2020.
- 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.
- Bicara anticipates transitioning to dose expansion studies in the second half of 2021.

\*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): A global CRO delivering innovative solutions



- 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





## Financial Highlights







#### **Q4FY21 and FY21 Financial Highlights**



Particulars <sup>1</sup>	Q4FY21	Q4FY20	Change	FY21	FY20	Change
Total Revenue	2,044	1,621	26%	7,360	6,462	14%
EBITDA	641	382	68%	1,907	1,765	8%
PBT Before Exceptional Items	354	213	66%	1,065	1,147	(7%)
PBT from Continuing Operations	366	213	72%	1,077	1,215	(11%)
Net Profit from Continuing Operations	254	132	92%	750	777	(3%)
Net Profit for the Period	254	123	105%	740	748	(1%)
R&D Expenses in P&L	127	125	2%	553	439	26%
Gross R&D Spend	136	139	(2%)	627	527	19%
EBITDA Margins excluding Bicara  Valuation Gain <sup>2</sup>	26%	24%		24%	27%	
Core EBITDA Margins excluding Bicara Valuation Gain <sup>2</sup>	32%	29%		32%	33%	
Net Profit Margins excluding Bicara Valuation Gain <sup>2</sup>	5%	8%		8%	12%	

<sup>1.</sup> All Figures in ₹ Crore except %, Net Profit before exceptional item and discontinuing operation

<sup>2.</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. Consequently, the investment in Bicara was fair valued resulting in a gain of Rs.160 Crore which is reported under "Other income" for the quarter

#### **Revenue by Segments**



Particulars <sup>1</sup>	Q4FY21	Q4FY20	Change	FY21	FY20	Change
Generics	578	562	3%	2,336	2,207	6%
Biosimilars	664	433	53%	2,800	2,315	21%
Novel Biologics	-	-	-	-	-	-
Research services	659	607	8%	2,184	2,012	9%
Inter-segment	(61)	(45)	35%	(215)	(234)	(8%)
Revenue from operations	1,839	1,558	18%	7,106	6,301	13%
Other income <sup>2</sup>	205	63	226%	255	161	58%
Total Revenue	2,044	1,621	26%	7,360	6,462	14%

<sup>1.</sup> All Figures in ₹ Crore except %

<sup>2.</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. Consequently, the investment in Bicara was fair valued resulting in a gain of Rs.160 Crore which is reported under "Other income" for the quarter

#### **Key Segment wise highlights**



Particulars <sup>1</sup>	Q4FY21	Q3FY21	Q4FY20	FY21	FY20
Segment revenue					
Generics	578	561	562	2,336	2,207
Biosimilars	664	769	433	2,800	2,315
Novel Biologics <sup>2</sup>	-	-	-	-	-
Research services	659	585	607	2,184	2,012
Total	1,900	1,914	1,603	7,320	6,534
Less: Inter-segment revenue	(61)	(63)	(45)	(215)	(234)
Net sales / Income from continuing operations	1,839	1,851	1,558	7,106	6,301
Profit before tax from each segment					
Generics	73	54	71	301	338
Biosimilars	68	111	(6)	365	428
Novel Biologics	81	(51)	(18)	(20)	(104)
Research services	157	117	153	434	446
	380	230	200	1,080	1,108
Less: Other un-allocable expenditure / (income), net	26	(7)	(12)	15	(40)
Profit before tax and before exceptional items	354	236	213	1,065	1,147
Capital employed					
Generics	3,727	3,961	2,836	3,727	2,836
Biosimilars	1,595	1,576	2,394	1,595	2,394
Novel Biologics	180	(165)	(73)	180	(73)
Research services	2,821	2,617	2,174	2,821	2,174
	8,323	7,988	7,330	8,323	7,330
Unallocable	185	116	53	185	53
Total capital employed	8,508	8,104	7,383	8,508	7,383

All Figures in ₹ Crore except %

<sup>2.</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. Consequently, the investment in Bicara was fair valued resulting in a gain of Rs.160 Crore which is reported under "Other income" for the quarter



### Thank You

#### **INVESTOR RELATIONS CONTACT:**

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