

#### **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

April 29, 2022

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,

Subject: Updated Investor Presentation – Q4 FY22.

With reference to the captioned subject and in furtherance to our disclosure dated April 28, 2022, please find enclosed the updated Investor Presentation under Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 ("SEBI Listing Regulations").

The above information will also be available on the website of the Company at <a href="https://www.biocon.com">https://www.biocon.com</a>.

Kindly take the above said information on record.

Thanking You,

Yours faithfully,

Meinel.

For Biocon Limited

**Mayank Verma** 

**Company Secretary & Compliance Officer** 

**Enclosed: Investor Presentation** 

# **Q4 and Full Year FY22 Investor Presentation**

April 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

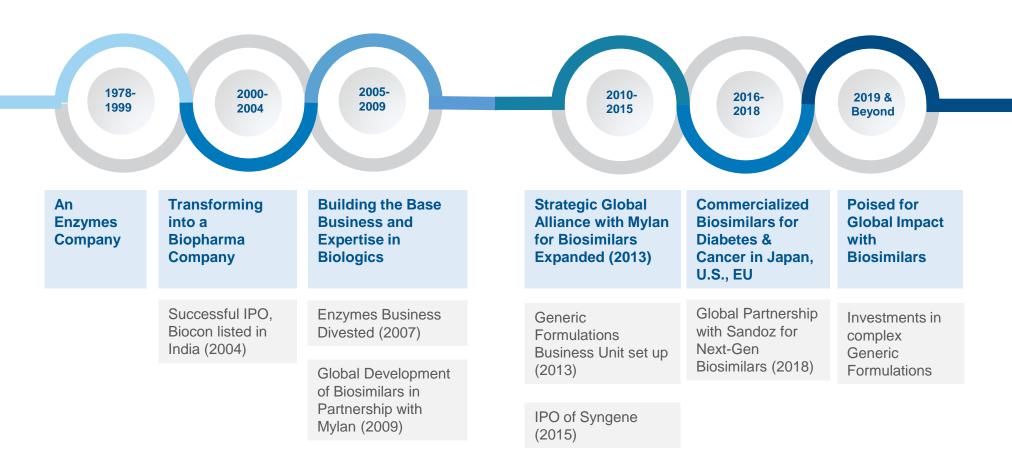


#### assurance

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



### **The Biocon Value Creation Journey**



Unwavering focus through the years on research and innovation to create tangible differentiators for sustainable growths



# Biocon Today: Strategically poised for a strong global play



Rs 8,397 Cr | \$1.1bn Revenue\*



13,500+
Total Employees\*



**1,280+** 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





### **Sustainability at Biocon**

#### Philosophy of 'Unconditional Equity'



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



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



 Focus on Primary healthcare, Environmental stability, Rural development & COVID relief



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



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

FY22 Achievements



## Featured for 1<sup>st</sup> time in 2021

- Included in 'Emerging Markets Index' in 2021
- Among Top 15 from India
- Scored 45 with 93rd percentile

## Improved score in 2021



#### ecovadis

# Secured 'Bronze' place, improved scores in 2021

- Received overall score of 52
- Among top 50 companies assessed

# **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: API – the building blocks**

#### **API Business: Overview**

- Among world's largest manufacturers of immunosuppressant & statin APIs; leadership in Fermentation based APIs
- Expertise in fermentation technology, large scale chromatography & synthetic chemistry
- Balanced portfolio across cardiovascular, anti-diabetes, immunosuppressants, high potent API & few niche molecules for hospitals/institutions
- Consistent track record of quality compliance & regulatory approvals (U.S. FDA, EMA, TGA Australia, Health Canada, Cofepris Mexico)

#### API : Growth Drivers across Strategic Priorities



- Expanding beyond fermentation-based APIs (e.g. peptides, potent APIs)
- Investing in R&D continuous manufacturing, bio transformation



• Expanding in select key markets



- Augmenting capacities & capabilities:
- *Immunosuppressants* (Vishakhapatnam)
- **Synthetic** API (Hyderabad)
- Additional **fermentation** capacities (Bengaluru)



- Large customer acquisitions
  - **De-risking** dependence for **critical intermediates**









75+
Countries served by API across US, Europe & large emerging markets





## **Generics: Forward integrating to Generic Formulations**

Generic Formulations Business - Overview

Leveraging in-house API expertise to forward integrate and move up the value chain

Portfolio across therapeutic segments – CVS, Metabolics, Oncology, Immunology & Auto-immune indications

Development pipeline includes oral solids (potent & non-potent), topical, parenteral & device dependent products

Commercialised in the US; now expanding to select European and MoW markets; directly & through partnerships





- Expanding portfolio through
- Vertical integration &
- an in-licensing strategy



Adding capabilities

- injectable facility in Bengaluru



- Expanding beyond the US, either direct or through partners
- Launched in EU, MoW
- Direct Presence currently in select European markets & UAE
- Partnerships in place in Southeast Asia, Mexico, Brazil and MENA



~\$335b

Global Generics Drugs Market Size 2021\*



10
Commercial US
Formulations



Approved/
tentatively
approved
ANDAs



### **Generics: Q4FY22 and full year FY22 Update**

#### KEY Q4 HIGHLIGHTS

- Robust sequential and YoY growth in Q4 driven by API sales ramp up, new launches in the US & normalization of operations
- Posaconazole and Dorzolamide, launched in the US;

  1st MoW market launch in Mexico; 1st approval in Singapore & in the UAE
- Successful site inspection by Health Canada at Bengaluru API manufacturing unit
- On track to qualify & validate Vizag API facility in FY23; to commence new manufacturing expansion projects in Hyderabad & Bengaluru
- Diversified renewable power consumption to solar & wind energy





#### **Biosimilars: Overview**

- Leadership in biologics R&D, manufacturing and commercialization built over two decades
- Driven by high scientific acumen with analytical and clinical capabilities in a complex regulatory setting
- Expertise in large scale biologics manufacturing across diverse technology platforms
- Product reach in over 75 countries including US, Europe, Canada, Japan and Australia
- Serve patients through commercial partners and direct sales force in India<sup>2</sup>



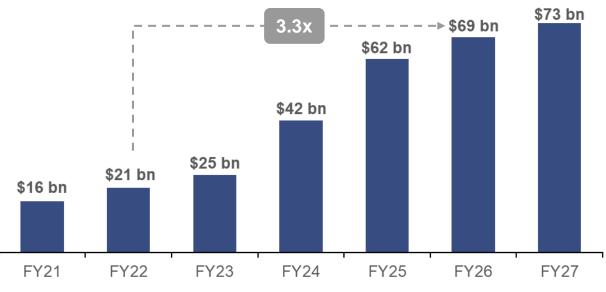






cGMP approvals (incl. FDA & EMA)



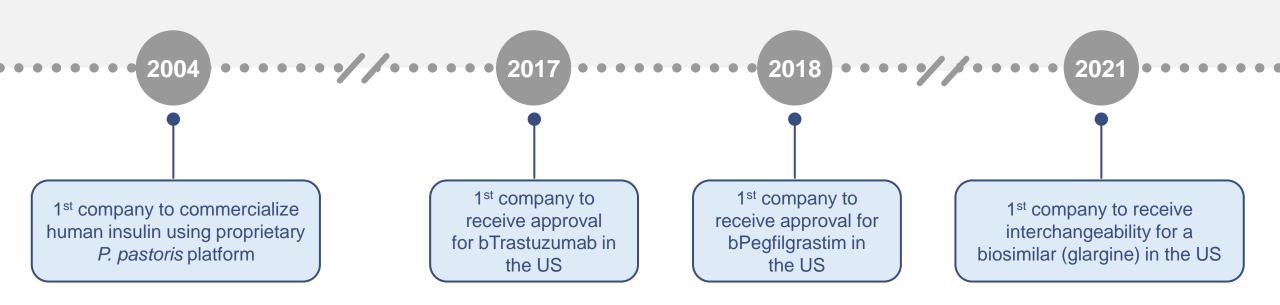


Reported Innovator + Biosimilar<sup>3</sup> Sales (2021)



## Biosimilar strategy resulted in several 'firsts'

Achieved many firsts in the space despite the nascent biosimilars regulatory pathway, setting new benchmarks for the industry





### **Growing participation in global biosimilars market**

PARTNER BBL ROLE BBL ECONOMICS



Biosimilars co-developed and co-commercialized with R&D and manufacturing led by BBL





(2018)

Set of next-gen biosimilars being co-developed





- Independently developing several biosimilar assets
- Acquisition of Viatris' biosimilar business to build a fully-integrated global biosimilar enterprise



Collaboration with partners to build complementary capabilities, de-risking the journey in an uncharted territory



# Acquisition of Viatris' biosimilars business to add financial depth and global commercial capabilities...

1

**Financial** 

BBL to realize full revenue and profits from all its collaboration programs

Revenue EBITDA
\$1.1b | \$250m
Viatris Biosimilars
CY23 estimate1

2

**Operational** 

Commercialization, Supply Chain and Regulatory capabilities in Developed Markets









3

New Growth Drivers Launch of collaboration products in the US

Option for new in-licensed biosimilar asset

bBevacizumab bAspart bAdalimumab bAflibercept

Viatris to provide commercial and transition services for an expected two-year period, at cost plus \$44m p.a.



#### ...transforming into a fully-integrated global biosimilars business



POST ACQUISITION OF VIATRIS' BIOSIMILARS BUSINESS

#### **Emerging Markets**

**Developed Markets** 

**Global Markets** 

Biosimilar Value Chain

PRODUCT DEVELOPMENT







CLINICAL TRIALS







REGULATORY







**MANUFACTURING** 







SUPPLY CHAIN







COMMERCIALIZATION









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

**Key Commercial Products (COVID-19)** 









50,000+ lives impacted

**Recent Collaborations** 





**Continued portfolio expansion** 



#### Asset-light entry into vaccines through SILS alliance

**BBL RIGHTS** 



Access to 100m doses of vaccines annually for 15 years



Commercialization rights of the SILS portfolio for global markets



BBL to have committed revenue stream and related margins from H2 FY23

Alliance to commercialize SILS COVID portfolio and other next generation vaccines

Note: Transaction pending regulatory approvals



#### Comprehensive portfolio of 20 biosimilars and vaccines...

#### **Biosimilar Product Status**

Therapeutic Area	Molecule	US	Dev. Markets: ex-US	$MoW^4$	Commentary
Oncology	Pegfilgrastim <sup>1</sup>		Europe, CANZ		<ul> <li>bBevacizumab: Approved in EU, Canada and Australia; US approval awaiting site inspection</li> <li>bDenosumab: Ph-1 clinical trial on-going</li> </ul>
	Trastuzumab <sup>1</sup>		Europe, CANZ		
	Bevacizumab <sup>1</sup>		Europe, AU, CA		
	Denosumab		Europe, CANZ, JP		
	Pertuzumab <sup>1</sup>				Ph-3 planned start in Q1 FY'23
Immunology	Adalimumab <sup>1,2</sup>		Europe, CA, JP		<ul> <li>bAdalimumab: US launch expected in mid-2023</li> <li>bUstekinumab: Ph-1 clinical trial on-going. Ph-3 clinical trial planned start in Q1 FY'23</li> <li>rHI (US): BLA filing for various presentation</li> <li>bAflibercept: First-to-file in US</li> </ul>
	Etanercept <sup>1,2</sup>		Europe		
	Ustekinumab		UK, CANZ, JP		
Diabetes	Glargine 100U <sup>1,3</sup>		Europe, CANZ, JP		
	Glargine 300U <sup>1</sup>		Europe		
	Aspart <sup>1</sup>		Europe, CA		
	rHI				
Bone Health	Denosumab		Europe, CANZ, JP		
Undisclosed	7 Assets				
Ophthalmology	Aflibercept <sup>5</sup>				Early Dev./ Preclinical Filed Approved

Access to SILS vaccine portfolio (Covishield and Covovax) and other next generation vaccines (e.g., mosquito-borne disease vaccines)<sup>6</sup>

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 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 | 5 Expected to be included in BBL portfolio post the completion of BBL's acquisition of Viatris' biosimilar business (Viatris has global rights to the program partnered with Momenta) | 6 Subject to completion of the acquisition of Covishield Technologies Private Limited (CTPL)



#### ...set up to deliver sustainable growth trajectory

#### BIOCON BIOLOGICS GROWTH DRIVERS

>4 years < 2 years 2-4 years Today - Pegfilgrastim - Bevacizumab (US) - Aflibercept<sup>2</sup> - Pertuzumab - Trastuzumab Ustekinumab - Aspart (US) - Glargine 300 IU - Bevacizumab (EU) - Adalimumab (US) Denosumab - Seven undisclosed programs - Glargine 100 IU - rH-Insulin (US) - Aspart (EU) - Vaccines<sup>1</sup> (SILS - Adalimumab (EU) collaboration) - Etanercept (EU)

<sup>1</sup> Subject to completion of the acquisition of Covishield Technologies Private Limited (CTPL);



13%

# **Biosimilars: Q4FY22 and full year FY22**

Q4 FY21 FY22 Q4 FY22 FY21 ₹2,800Cr ₹3,464Cr ₹982Cr ₹664Cr +24% Revenue +48% **Core EBITDA**\* ₹1,010Cr ₹215Cr ₹1,320Cr ₹382Cr +30% +78% 39% 33% 39% 36% % margin **Profit Before Tax** ₹144Cr ₹69Cr ₹543Cr ₹365Cr +49% +109% before Exceptional Items

10%

16%

*15%* 

% margin



# Biocon Biologics offers differentiated value proposition through its state-of-the-art platform

- 1 Fully integrated global biosimilars company (lab to market)
  - 2 Strong commercial presence in global markets

- **Biocon Biologics**
- 3 Comprehensive portfolio of biosimilars and vaccines
- 4 Global scale biologics manufacturing capacity
- 5 Experienced management team with strong execution capabilities
- 6 Strong business financials enabling long-term growth



# Novel Molecules: Pushing scientific boundaries to deliver impactful innovations

**Disease Area** 

Asset





Insulin Tregopil- a firstin-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



Itolizumab- A novel humanized CD6 antibody

- US based partner, **Equillium initiated a Pivotal Phase III Study in March 2022** for use in First-Line treatment of Acute Graft-Versus-Host Disease (GVHD)
- After observing positive trends in the Part A, Equillium expanded Part B portion of its Phase 1b EQUALISE study for Systemic Lupus Erythematosus/Lupus Nephritis indication to clinical centers in India
- European Commission granted an 'Orphan Medical Product' designation for treatment of GVHD in Jul '21
- Repurposed for prevention & treatment of COVID-19 complications in India in 2020; **granted 'Restricted Emergency Use' approval in Sep '20** for Cytokine Release Syndrome treatment in 'Moderate to Severe' Acute Respiratory Distress Syndrome



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

- Entered a Phase I/II study at leading US and Canadian cancer centers in Jul '20
- Under evaluation, both as a single agent & 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 & established highest dose with desired level of safety & tolerability, both in monotherapy & in combination with a PD1 inhibitor. Proof of concept is expected in second half of 2022
- In Feb '22, initiated dose expansion cohorts in patients with head & neck squamous cell carcinoma (HNSCC), squamous cell carcinoma of the anal canal (SCAC) and cutaneous squamous cell carcinoma (cSCC)
- Securing additional funding to support clinical development



## **Novels: Pipeline Progress made in Q4FY22**

KEY HIGHLIGHTS

Pivotal Phase III clinical study of Itolizumab for aGVHD\* initiated in March 2022

Bicara# initiated dose expansion cohorts evaluating BCA101 in patients with head and neck, anal canal & cutaneous squamous cell carcinoma



<sup>\*</sup>Acute Graft-Versus-Host Disease

<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): Overview

- 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; 5000+ talented team of scientists, incl. ~500 PhDs
- ~420+ 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: Q4FY22 and full year FY22

KEY Q4 HIGHLIGHTS

Performance across all divisions in Q4

- Particularly strong quarter for Development Services on account of catching up on earlier delayed projects
- Completed Phase III of Hyderabad research facility expansion



# Financial Highlights

Unwavering Purpose



# **Financial Highlights: Q4FY22**

% margin

		Q4FY22	Q4FY21	Biosimilars +48%   Generics +26%   Research Services +15% Dilution Gain in Bicara of ₹30Cr vs ₹160Cr in Q4FY21
Revenue	+21%	₹2,476Cr	₹2,048Cr	
				Morte to mortest loop on investments of
Core EBITDA*	+37%	₹815Cr	₹594Cr	Mark-to-market loss on investments of ₹6Cr
% margin		220/	32%	Forex Gain of ₹2Cr vs ₹7Cr in Q4FY21
70 margin		33%	32 70	TOTOX CANTOT VO CTOT III Q II 121
EDITOA	. 20/	<b>30500</b>	<b>30440</b>	0 000 1 4 70000
EBITDA	+3%	₹659Cr	₹641Cr	Gross R&D spend at ₹232Cr
% margin		27%	31%	R&D spend in P&L ₹191Cr
		2770	0170	
<b>Profit Before Tax</b>		₹384Cr	₹353Cr	Everytic mel I acc of 3440v
before Exceptional Items		<b>C304CI</b>	(33361	Exceptional Loss of ₹41Cr vs Gain of ₹13Cr in Q4FY21
% margin		15%	17%	VS Gaill Of C13C1 III Q4F121
		1070		
Net Profit Before exceptional items	6	₹262Cr	₹257Cr	Net Profit after exceptional items at ₹239Cr

13%

11%

<sup>\*</sup>Core EBITDA defined as EBITDA before forex, dilution gain in Bicara, R&D, mark-to-market loss on investments and licensing income



# **Financial Highlights: FY22**

% margin

	FY22	FY21	Biosimilars +24%   Research Services
Revenue +14%	₹8,397Cr	₹7,398Cr	+19%   Generics -1%  Dilution Gain in Bicara of ₹30Cr vs ₹160Cr in FY21
Core EBITDA* +18%	₹2,669Cr	₹2,270Cr	Mark-to-market loss on investments of ₹28Cr; Forex Gain of ₹58Cr vs loss of ₹9Cr
% margin	32%	31%	in FY21
EBITDA +14%	₹2,183Cr	₹1,907Cr	Gross R&D spend at ₹711Cr R&D spend in P&L ₹595Cr
% margin	26%	26%	
Profit Before Tax +4% before Exceptional Items	₹1,094Cr	₹1,055Cr	Exceptional Loss at ₹111Cr
% margin	13%	14%	
Net Profit Before Exceptional Items	₹722Cr	₹744Cr	Net Profit after exceptional items at ₹648Cr

10%

9%

<sup>\*</sup>Core EBITDA defined as EBITDA before forex, dilution gain in Bicara, R&D, mark-to-market loss on investments and licensing income

# **Thank You**

**INVESTOR RELATIONS CONTACT:** 

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