



**Biocon Limited**

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April 28, 2022

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,

**Subject: Investor Presentation – Q4 FY22.**

With reference to the captioned subject, please find enclosed the 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 <https://www.biocon.com>.

Kindly take the above said information on record.

Thanking You,

Yours faithfully,

For **Biocon Limited**

*Mayank*



**Mayank Verma**  
**Company Secretary & Compliance Officer**

**Enclosed: Investor Presentation**

# Q4 and Full Year FY22 Investor Presentation

April 2022



Unwavering  
Purpose



# 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 enterprise that is led by a purpose to develop innovative solutions that provide affordable access to high quality, essential and life saving medicines for patients, payers and health systems across the world.**



**GENOMIC INSPIRATION**  
*yusuf trabulsi*

# 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

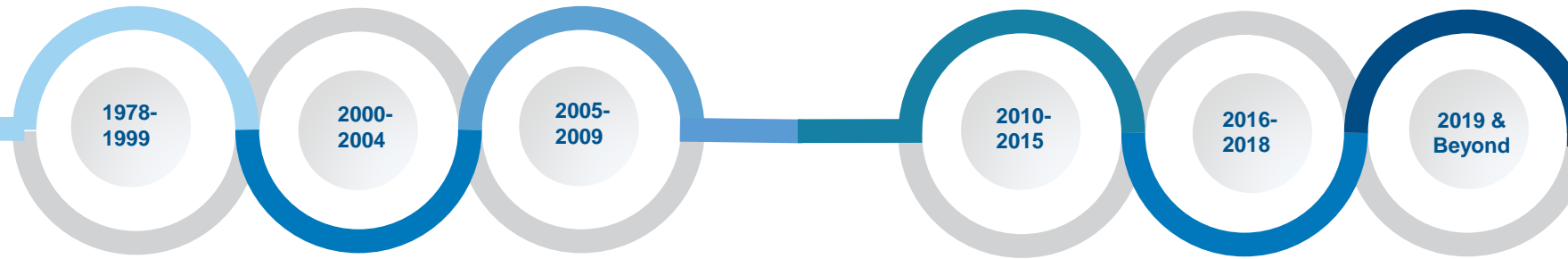
- Build strategic global and regional partnerships to make high-quality biopharmaceuticals available to the maximum number of people
- Create a robust portfolio of 'blockbuster' drugs with the potential to benefit a billion patients



## 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



**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 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



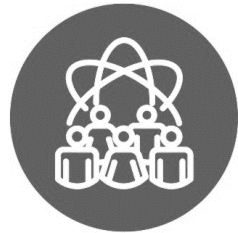
# Sustainability at Biocon

## Philosophy of 'Unconditional Equity'



### 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

- 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

## 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 93<sup>rd</sup> percentile



### Improved score in 2021

- Scored 'B' in Climate Change & Water Security



### Secured 'Bronze' place, improved scores in 2021

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

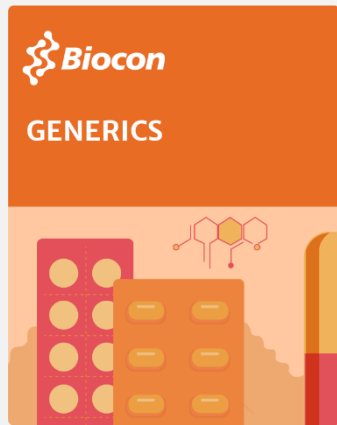


# Business Segments

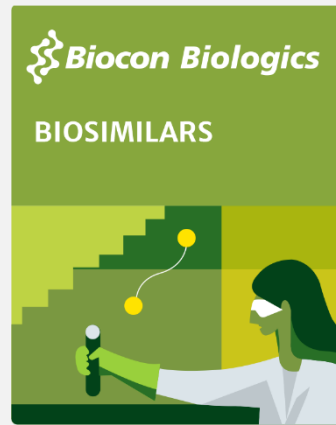
Unwavering  
Purpose

# 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

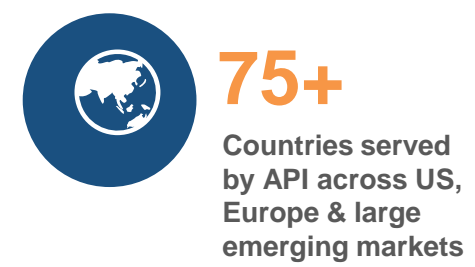
# Generics : API – the building blocks

## 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



\*Source: Global Industry Analysts Inc.'s 'Active Pharmaceutical Ingredients (API) - Global Market Trajectory & Analytics' Report, March 2022

# 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

## Growth Drivers across Strategic Priorities



- 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



6

Approved/tentatively approved ANDAs

\*Source: Research & Markets' Report on 'Global Generic Drugs Market Report 2021', March 2021

# 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; 1<sup>st</sup> MoW market launch in Mexico; 1<sup>st</sup> 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

Q4FY22

Q4FY21

### Revenue

₹717Cr

₹570Cr

+26%

### Profit Before Tax (PBT)

₹116Cr

₹73Cr

+59%

16% of revenue

13% of revenue

FY22

FY21

### Revenue

₹2,341Cr

₹2,363Cr

### Profit Before Tax (PBT)

₹261Cr

₹291Cr

11% of revenue

12% of revenue

# 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>

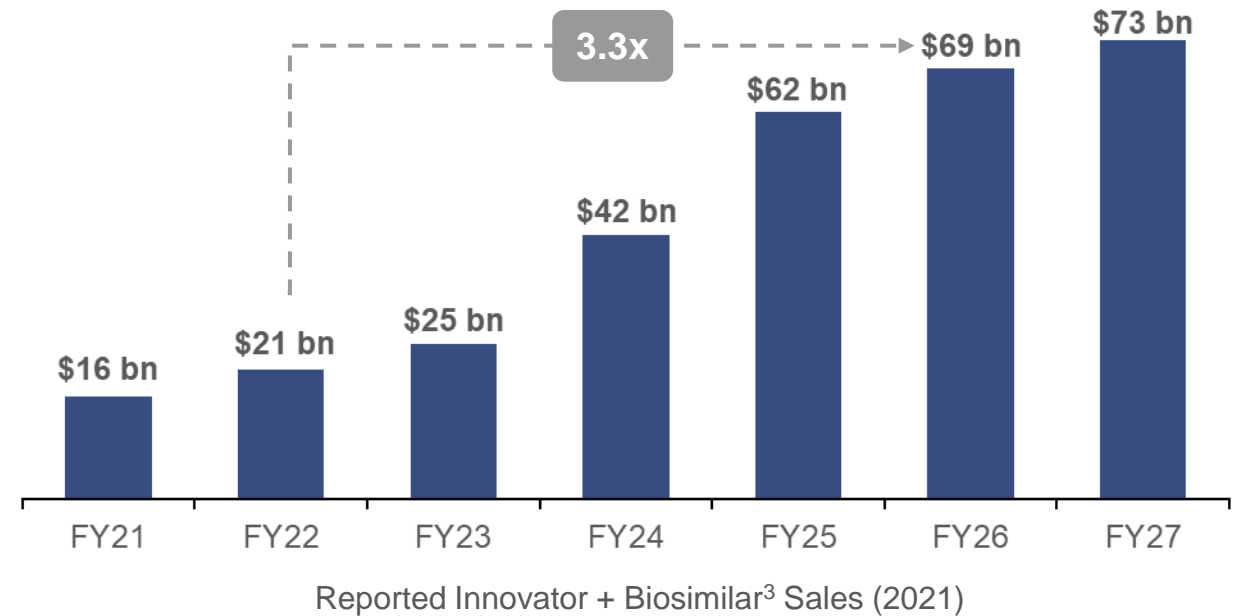
8 Approved Products<sup>1</sup>

2 Research & Development sites

3 Manufacturing sites (2 Bengaluru, 1 Malaysia)

25+ cGMP approvals (incl. FDA & EMA)

## BIOCON BIOSIMILARS TARGET ADDRESSABLE MARKET



<sup>1</sup> Includes Adalimumab and Etanercept which have been in-licensed by Viartis and Biocon Biologics has economic interest. | <sup>2</sup> Branded Formulations India (BFI) is the commercial platform in India | <sup>3</sup> Only includes products where there has been company reported sales (Biosimilar sales only included for companies that report the numbers)

# Biosimilar strategy resulted in several 'firsts'

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

2004

1<sup>st</sup> company to commercialize human insulin using proprietary *P. pastoris* platform

2017

1<sup>st</sup> company to receive approval for bTrastuzumab in the US

2018

1<sup>st</sup> company to receive approval for bPegfilgrastim in the US

2021

1<sup>st</sup> company to receive interchangeability for a biosimilar (glargine) in the US

# Growing participation in global biosimilars market

PARTNER

BBL ROLE

BBL ECONOMICS



(2009)



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



(2018)



Set of next-gen biosimilars being co-developed



(ONGOING)



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...



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

*Note: Transaction subject to regulatory approvals | 1 BBL estimates of Viatris' business*

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



CURRENT

POST ACQUISITION OF VIATRIS' BIOSIMILARS BUSINESS

Emerging Markets

Developed Markets

Global Markets

Biosimilar Value Chain

PRODUCT DEVELOPMENT



CLINICAL TRIALS



REGULATORY



MANUFACTURING



SUPPLY CHAIN



COMMERCIALIZATION



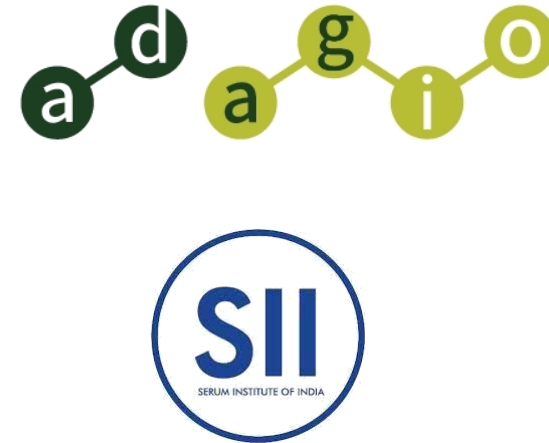
# Entering adjacencies in communicable disease: infectious disease antibodies and vaccines

## Key Commercial Products (COVID-19)



50,000+ lives impacted

## Recent Collaborations



Continued portfolio expansion

# Asset-light entry into vaccines through SILS alliance



**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

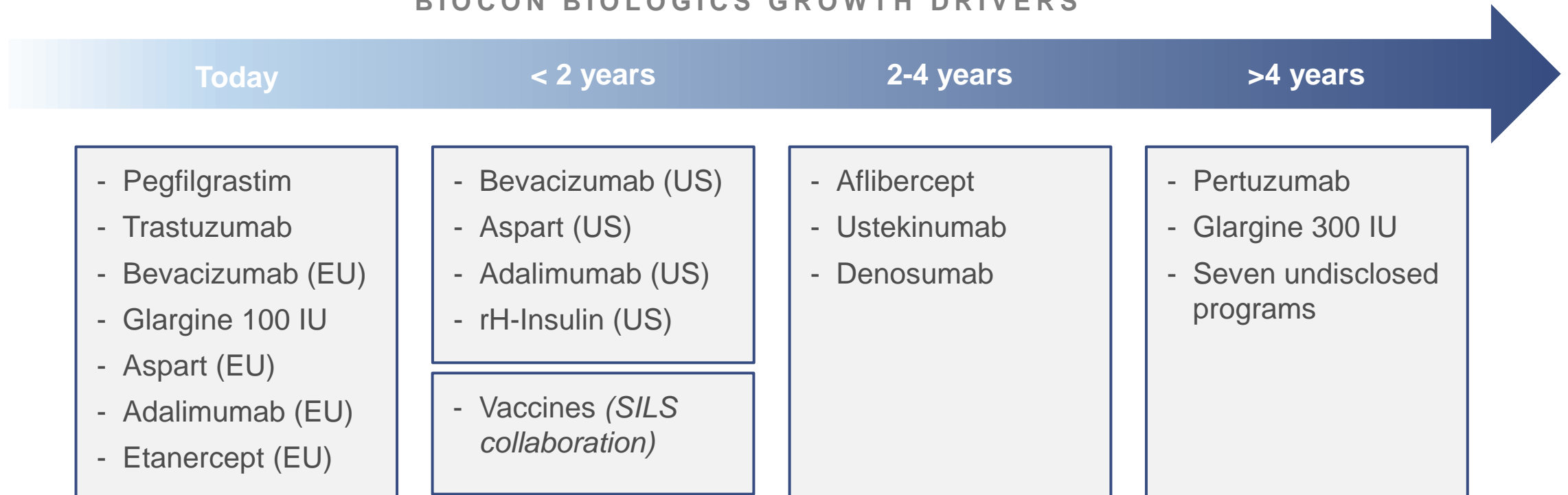
Therapeutic Area	Molecule	US	Dev. Markets: ex-US	MoW <sup>4</sup>	Commentary
Oncology	Pegfilgrastim <sup>1</sup>		Europe, CANZ		<ul style="list-style-type: none"> <li>- <b>bBevacizumab</b>: Approved in EU, Canada and Australia; US approval awaiting site inspection</li> <li>- <b>bDenosumab</b>: Ph-1 clinical trial on-going. Ph-3 planned start in Q1 FY'23</li> <li>- <b>bAdalimumab</b>: US launch expected in mid-2023</li> <li>- <b>bUstekinumab</b>: Ph-1 clinical trial on-going. Ph-3 clinical trial planned start in Q1 FY'23</li> <li>- <b>rHI (US)</b>: BLA filing for various presentation</li> <li>- <b>bAflibercept</b>: First-to-file in US</li> </ul>
	Trastuzumab <sup>1</sup>		Europe, CANZ		
	Bevacizumab <sup>1</sup>		Europe, AU, CA		
	Denosumab		Europe, CANZ, JP		
	Pertuzumab <sup>1</sup>				
Immunology	Adalimumab <sup>1,2</sup>		Europe, CA, JP		
	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>				<div style="display: flex; gap: 5px;"> <span>Early Dev./ Preclinical</span> <span>Clinical</span> <span>Filed</span> <span>Approved</span> </div>

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

<sup>1</sup> In partnership with Viatri; <sup>2</sup> Partner Viatri has in-licensed product (Biocon benefits from economic interest) | <sup>3</sup> Japan is outside of Viatri partnership | <sup>4</sup> 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 | <sup>5</sup> Expected to be included in BBL portfolio post the completion of BBL's acquisition of Viatri's biosimilar business (Viatri has global rights to the program partnered with Momenta) | <sup>6</sup> Subject to completion of the acquisition of Covishield Technologies Private Limited (CTPL)

# ...set up to deliver sustainable growth trajectory

## BIOCON BIOLOGICS GROWTH DRIVERS



# Biosimilars : Q4FY22 and full year FY22

	Q4 FY22	Q4 FY21		FY22	FY21	
<b>Revenue</b>	<b>₹982Cr</b>	<b>₹664Cr</b>	<b>+48%</b>	<b>₹3,464Cr</b>	<b>₹2,800Cr</b>	<b>+24%</b>
<b>Core EBITDA*</b>	<b>₹382Cr</b>	<b>₹215Cr</b>	<b>+78%</b>	<b>₹1,320Cr</b>	<b>₹1,010Cr</b>	<b>+30%</b>
<i>% margin</i>	<b>39%</b>	<b>33%</b>		<b>39%</b>	<b>36%</b>	
<b>Profit Before Tax before Exceptional Items</b>	<b>₹144Cr</b>	<b>₹69Cr</b>	<b>+109%</b>	<b>₹543Cr</b>	<b>₹365Cr</b>	<b>+49%</b>
<i>% margin</i>	<b>15%</b>	<b>10%</b>		<b>16%</b>	<b>13%</b>	

\*Core EBITDA defined as EBITDA before R&D, forex, licensing and mark-to-market loss on investments




# 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
- 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	Current Progress
 <p>Diabetes</p>	<p><b>Insulin Tregopil-</b> a first-in-class oral, prandial Insulin</p>	<ul style="list-style-type: none"> <li>• <b>Phase I multiple ascending dose studies</b> in Type 1 DM patients ongoing in Germany; in partnership with US-based Juvenile Diabetes Research Foundation (JDRF), a leading non-profit organization</li> </ul>
 <p>Inflammation</p>	<p><b>Itolizumab-</b> A novel humanized CD6 antibody</p>	<ul style="list-style-type: none"> <li>• US based partner, <b>Equillum initiated a Pivotal Phase III Study in March 2022</b> for use in First-Line treatment of Acute Graft-Versus-Host Disease (GVHD)</li> <li>• After observing positive trends in the Part A, Equillum expanded Part B portion of its Phase 1b EQUALISE study for Systemic Lupus Erythematosus/Lupus Nephritis indication to clinical centers in India</li> <li>• <b>European Commission granted an 'Orphan Medical Product'</b> designation for treatment of GVHD in Jul '21</li> <li>• Repurposed for prevention &amp; treatment of COVID-19 complications in India in 2020; <b>granted 'Restricted Emergency Use' approval in Sep '20</b> for Cytokine Release Syndrome treatment in 'Moderate to Severe' Acute Respiratory Distress Syndrome</li> </ul>
 <p>Immuno-oncology</p>	<p><b>BCA101-</b> (formerly FmAb2, a first-in-class EGFR / TGFβ-trap bifunctional antibody) - part of <b>Bicara Therapeutics**</b>, a US based clinical-stage biotechnology company</p>	<ul style="list-style-type: none"> <li>• <b>Entered a Phase I/II study</b> at leading US and Canadian cancer centers in Jul '20</li> <li>• <b>Under evaluation, both as a single agent &amp; in combination with the checkpoint inhibitor</b>, Pembrolizumab, in patients with advanced EGFR-driven solid tumors, who no longer respond to the standard of care</li> <li>• <b>Completed enrollment for dose finding part of Phase I trial &amp; established highest dose with desired level of safety &amp; tolerability</b>, both in monotherapy &amp; in combination with a PD1 inhibitor. <b>Proof of concept</b> is expected in <b>second half of 2022</b></li> <li>• <b>In Feb '22, initiated dose expansion cohorts in patients</b> with head &amp; neck squamous cell carcinoma (HNSCC), squamous cell carcinoma of the anal canal (SCAC) and cutaneous squamous cell carcinoma (cSCC)</li> <li>• Securing <b>additional funding</b> to support clinical development</li> </ul>

# 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**



\*Acute Graft-Versus-Host Disease

#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

Q 4 FY 22

Q 4 FY 21

### Revenue

₹758Cr

₹659Cr

+15%

### Profit Before Tax (PBT)

₹179Cr

₹158Cr

+14%

24% of revenue

24% of revenue

FY 22

FY 21

### Revenue

₹2,604Cr

₹2,184Cr

+19%

### Profit Before Tax (PBT)

₹515Cr

₹434Cr

+19%

20% of revenue

20% of revenue



# **Financial Highlights**

Unwavering  
Purpose

# Financial Highlights: Q4FY22

		Q 4 F Y 2 2	Q 4 F Y 2 1	
<b>Revenue</b>	+21%	<b>₹2,476Cr</b>	<b>₹2,048Cr</b>	Biosimilars +48%   Generics +26%   Research Services +15% Dilution Gain in Bicara of ₹30Cr vs ₹160Cr in Q4FY21
<b>Core EBITDA*</b>	+37%	<b>₹815Cr</b>	<b>₹594Cr</b>	Mark-to-market loss on investments of ₹6Cr Forex Gain of ₹2Cr vs ₹7Cr in Q4FY21
<i>% margin</i>		33%	32%	
<b>EBITDA</b>	+3%	<b>₹659Cr</b>	<b>₹641Cr</b>	Gross R&D spend at ₹232Cr R&D spend in P&L ₹191Cr
<i>% margin</i>		27%	31%	
<b>Profit Before Tax before Exceptional Items</b>	+9%	<b>₹384Cr</b>	<b>₹353Cr</b>	Exceptional Loss of ₹41Cr vs Gain of ₹13Cr in Q4FY21
<i>% margin</i>		15%	17%	
<b>Net Profit</b> (Before exceptional items)		<b>₹262Cr</b>	<b>₹253Cr</b>	Net Profit after exceptional items at ₹239Cr
<i>% margin</i>		11%	13%	

\*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

		FY 22	FY 21	
<b>Revenue</b>	+14%	<b>₹8,397Cr</b>	<b>₹7,398Cr</b>	Biosimilars +24%   Research Services +19%   Generics -1% Dilution Gain in Bicara of ₹30Cr vs ₹160Cr in Q4FY21
<b>Core EBITDA*</b>	+18%	<b>₹2,669Cr</b>	<b>₹2,270Cr</b>	Mark-to-market loss on investments of ₹28Cr; Forex Gain of ₹58Cr vs loss of ₹9Cr in FY21
<i>% margin</i>		32%	31%	
<b>EBITDA</b>	+14%	<b>₹2,183Cr</b>	<b>₹1,907Cr</b>	Gross R&D spend at ₹711Cr R&D spend in P&L ₹595Cr
<i>% margin</i>		26%	26%	
<b>Profit Before Tax before Exceptional Items</b>	+4%	<b>₹1,094Cr</b>	<b>₹1,055Cr</b>	Exceptional Loss at ₹111Cr
<i>% margin</i>		13%	14%	
<b>Net Profit</b> (Excluding Exceptional loss)		<b>₹722Cr</b>	<b>₹744Cr</b>	Net Profit after exceptional items at ₹648Cr
<i>% margin</i>		9%	10%	

\*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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