

Biocon Limited

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CIN: L24234KA1978PLC003417

www.biocon.com

November 15, 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: Investor Presentation - Q2 FY23.

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 www.biocon.com.

Kindly take the above said information on record.

Thanking You,

Yours faithfully,

For Biocon Limited

Mayank Verma

Company Secretary & Compliance Officer

PIVGALO

Membership No.: ACS 18776

Enclosed: Investor Presentation



Q2 FY23 Investor Presentation

November 2022



Biocon 5.0

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

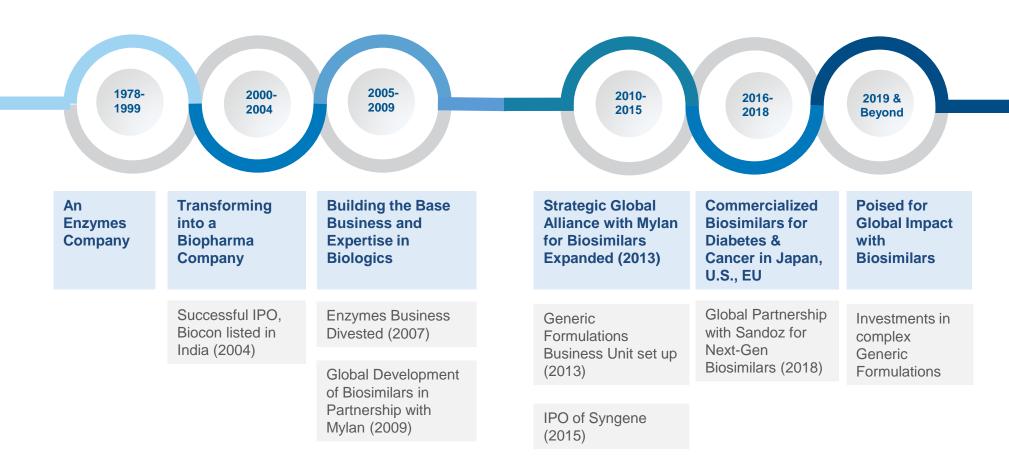


assurance

- 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 growth

Biocon Today: Strategically poised for a strong global play





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



~15,000
Total Employees*



~1,300 Patents*



50+cGMP approvals from International regulatory agencies



120+
Countries where our products are available



Ranked 5
Among Top 10 Global
Biotech Employers by
Science magazine



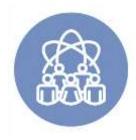
TransformAction: Transforming Sustainability at Biocon through Action





PATIENT

- 5.3M patients reached through biosimilars
- 13% revenue in gross R&D spend (Ex Syngene)



PEOPLE

- Top 5 among global pharma & biotech employer since 2012
- Recognized by UN Women for efforts to promote diversity
- o 13% increase in women in workforce



SOCIAL

- Published Human Rights Policy
- o Rs. 11 Crore in CSR Spend
- 120+ students graduated from Biocon Academy



ENVIRONMENT

- 58% electricity came from green power
- 100% waste water recycled & reused
- o 118K tCO₂ GHG offset



- Board Committees, policies for global governance
- Published 1st Tax Policy & Transparency Report, Supplier Code of Conduct

FY22 Achievements



Published 1st GRI aligned ESG & BRSR Report for FY22



Featured for 1st time in 2021 in Emerging Markets Index with a score of 45; among top 15 in India



Improved score of 'B' in 2021 in Climate Change & Water Security Secured

'Bronze' place,
improved score
of 52 in 2021

Click here to view our 1st ESG Report FY22

Business Segments

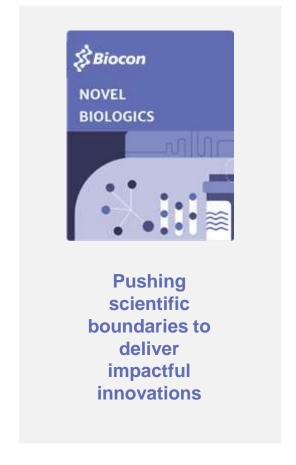
Growth Verticals: Aligned With Shifting Paradigms



From pipeline to production, from drug discovery to drug delivery, we bring differentiated, high-quality and affordable healthcare products & services globally.









Generics : API – the building blocks



BUSINESS OVERVIEW

- Among world's largest manufacturers of statin & immunosuppressant 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 quality compliance & regulatory approvals track record U.S. FDA, EMA, TGA Australia, Health Canada, Cofepris Mexico

GROWTH DRIVERS ACROSS STRATEGIC PRIORITIES



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



Expanding in select key markets



Augmenting capacities & capabilities:

bio transformation

- *Immunosuppressants* (*Vishakhapatnam*)
- **Synthetic** API (Hyderabad)
- Additional **fermentation** capacities (Bengaluru)



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









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



5 Facilities in

Generics: Forward integrating to 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 & nonpotent), topical, parenteral & device dependent products
- Commercialised in the US; now expanding to select **European & MoW markets; directly & through partners**

GROWTH DRIVERS ACROSS STRATEGIC PRIORITIES



- Expanding portfolio through
- Vertical integration &
- 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



Global Generics Drugs Market Size 2021*



Commercial US

Formulations



Approved/ tentatively approved ANDAs







Ex US Approvals

Generics: Q2 FY23 update



KEY HIGHLIGHTS

- Strong YoY growth both in API & generic formulations
- Sitagliptin and Vildagliptin API launches in EU
- Generic Formulations Approvals in EU & MoW markets to aid geographical expansion
- Vizag immunosuppressant and Bangalore peptides facilities –
 Process validation batches are scheduled to commence in Q3 FY23

Q2 FY23

Q2 FY22

Revenue

₹623Cr

₹530Cr

+18%

Profit Before Tax (PBT)

₹54Cr

₹50Cr

+9%

9% of revenue

9% of revenue

Biosimilars: Overview



Leadership in biologics R&D, manufacturing and commercialization built over two decades



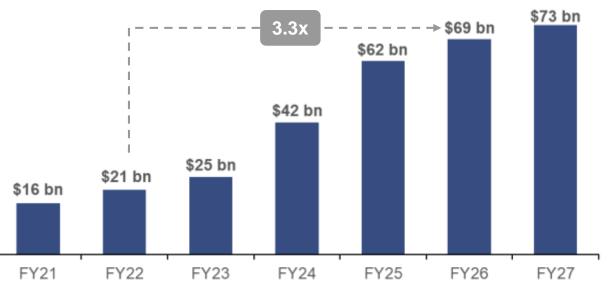






- Driven by high scientific acumen with analytical and clinical capabilities in a complex regulatory setting
- Expertise in large scale biologics manufacturing across diverse technology platforms
- Product reach in over 75 countries including US, Europe, Canada, Japan and Australia
- Serve patients through commercial partners and direct sales force in India²





Reported Innovator + Biosimilar³ Sales (2021)

1 Includes Adalimumab and Etanercept which have been in-licensed by Viatris and Biocon Biologics has economic interest. | 2 Branded Formulations India (BFI) is the commercial platform in India | 3 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



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



Acquisition* of Viatris' biosimilar business to build a fully-integrated global biosimilar enterprise



Set of next-gen biosimilars being co-developed



(2018)



Independently developing several biosimilar assets



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

\$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 along with a 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.

Biosimilar Value Chain

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





POST ACQUISITION OF VIATRIS' BIOSIMILARS BUSINESS

Emerging Markets

Developed Markets

Global Markets

PRODUCT DEVELOPMENT
CLINICAL TRIALS







REGULATORY







MANUFACTURING







SUPPLY CHAIN







COMMERCIALIZATION





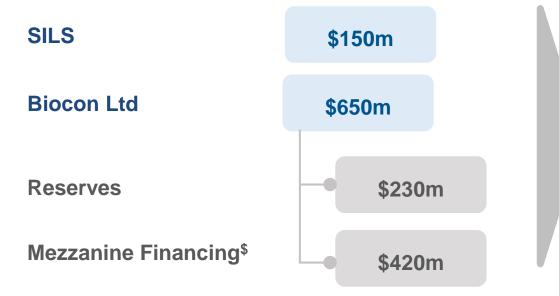
Funding the acquisition of Viatris' biosimilar business



- Acquisition of Viatris' biosimilar business expected to close shortly
- BBL has secured \$1.2 bn in debt, balance amount to be funded through equity infusion.



EQUITY INFUSION IN BBL



On closing of the Viatris and Serum transactions, Biocon's stake in Biocon Biologics will be 68%

Note: Transaction subject to regulatory approvals

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

Comprehensive portfolio of 20 biosimilars and vaccines...



BIOSIMILAR PRODUCT STATUS

Therapeutic	Molecule	US	Dev. Markets: ex-US	MoW ⁴	Commentary
Area	Double and the 1	03		IVIOVV	
Oncology	Pegfilgrastim ¹		Europe, CANZ		- bBevacizumab: Approved in EU, Canada
	Trastuzumab ¹		Europe, CANZ		and Australia; US approval awaiting site
	Bevacizumab ¹		Europe, AU, CA		inspection
	Denosumab		Europe, CANZ, JP		- bDenosumab: Ph-1 and Ph-3 clinical trial
	Pertuzumab ¹				ongoing
Immunology	Adalimumab ^{1,2}		Europe, CA, JP		- bAdalimumab: US launch expected in
	Etanercept ^{1,2}		Europe		mid-2023
	Ustekinumab		UK, CANZ, JP		
Diabetes	Glargine 100U ^{1,3}		Europe, CANZ, JP		- bUstekinumab: Ph-1 and Ph-3 clinical
	Glargine 300U ¹		Europe		trial ongoing
	Aspart ¹		Europe, CA		- rHI (US): BLA filing for various
	rHI				presentations
Bone Health	Denosumab		Europe, CANZ, JP		- bAflibercept: First-to-file in US
Undisclosed	7 Assets				Early Dev./
					Preclinical Clinical Filed Approved
Ophthalmology	Aflibercept ⁵				

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

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

Today < 2 years		2-4 years	>4 years
 Pegfilgrastim Trastuzumab Bevacizumab (EU) Glargine 100 IU Aspart (EU) Adalimumab (EU) Etanercept (EU) 	- Bevacizumab (US) - Aspart (US) - Adalimumab (US) - rH-Insulin (US) - Vaccines ¹ (SILS collaboration)	 - Aflibercept² - Ustekinumab - Denosumab 	PertuzumabGlargine 300 IUSeven undisclosed programs

¹ Subject to completion of the acquisition of Covishield Technologies Private Limited (CTPL);

² 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)

Biosimilars: Q2 FY23 Update



KEY HIGHLIGHTS

- Year-on-year revenue growth of 34%, reflecting the growth of insulin Glargine in US
- Core EBITDA margin benefitted from rupee depreciation and accrual of Performance Linked Incentives (PLI) benefits
- Progressing R&D pipeline with bDenosumab and bUstekinumab in clinic; R&D expense up 142% YoY
- Non-cash foreign currency translation loss of ₹35 Cr on GS OCD; ₹55 Cr gain in Q2 FY22 from mark-to-market movement on Adagio investment
- Fulphila's US market shares surpassed 10% and Ogivri has started recovering following a temporary dip in Q1
- Submitted CAPA plan to US FDA for observations made in August site inspections

Q2 FY23

Q2 FY22

Revenue

₹997 Cr

₹743 Cr

+34%

Core EBITDA*

₹449 Cr

₹304 Cr

+48%

46% of revenue

42% of revenue

PBT before exceptions

₹78 Cr

₹174 Cr

-55%

8% of revenue

23% of revenue

*Core EBITDA defined as EBITDA excluding R&D, forex, licensing income and mark-to-market movement 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

- Biocon Biologics
- 3 Comprehensive portfolio of insulins, mAbs 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



Itolizumab*

- A novel humanized CD6 antibody

Graft-Versus-Host Disease (GVHD)

- Pivotal Phase III Study initiated in Mar '22 for use in First-Line treatment of Acute GVHD; patient dosing initiated
- European Commission granted an 'Orphan Medical Product' designation for treatment of GVHD in Jul '21

Systemic Lupus Erythematosus/Lupus Nephritis (SLE/LN) indication

- Encouraging interim data from the Type B portion of the EQUALISE study evaluating Itolizumab in patients with LN
- Study continues to enroll patients in the Type B portion, expects to share topline data in mid 2023

Ulcerative Colitis

• Application for Phase 2 clinical trials in India for the treatment of Ulcerative Colitis using Itolizumab, approved by the DCGI



Inflammation

BCA101**

Formerly FmAb2

First-in-class EGFR / TGFβtrap bifunctional antibody

- Phase I/II study initiated at leading US and Canadian cancer centers in Jul '20
- Under evaluation, both as a single agent & in combination with the checkpoint inhibitor, Pembrolizumab
- o Completed enrollment for dose finding part of Phase I trial & established highest dose with desired level of safety & tolerability.
- o **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)
- Primary results expected in 2H22
- Securing external funding to support clinical development

^{*}partnered with Equillium Inc.

^{**}part of Bicara Therapeutics Inc., a US based clinical-stage biotechnology company. In Q4FY21, Biocon ceded control over the Board of Directors and Operations of Bicara 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 FY23 Update



KEY HIGHLIGHTS

- Itolizumab: Equillium announced encouraging interim data from EQUALISE study in Lupus Nephritis
- Application to conduct Phase II Clinical Trial with Itolizumab for Ulcerative Colitis approved by DCGI
- Bicara#: Continued progress in BCA 101



^{**}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

XX Biocon

- 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; 5200+talented team of scientists, incl. ~500 PhDs
- ~400+ active 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 FY23 Update



KEY HIGHLIGHTS

- Positive performance across all divisions
- Sustained growth in research divisions Discovery Services, including Synvent*, and the Dedicated Centres
- Growth in Development Services led by existing clients renewing contracts and setting up collaborations on additional projects
- Continued to invest in new infrastructure and capability-building

Q2 FY23

Q2 FY22

Revenue from operations

₹768 Cr

₹610 Cr

+26%

Profit Before Tax (PBT)

₹130 Cr

₹113 Cr

+15%

17% of revenue

19% of revenue

^{*}Part of Syngene's novel cancer drug discovery strategy for clients

Financial Highlights

Financial Highlights: Q2 FY23 (1/2)



		Q2 FY23	Q2 FY22
Revenue	+23%	₹2,384 Cr	₹1,945 Cr
Core EBITDA*	+34%	₹816 Cr	₹609 Cr
% margin		35%	33%
EBITDA	-3%	₹535 Cr	₹551 Cr
% margin		22%	28%
Profit Before Tax (before exceptional charge)	-11%	₹246 Cr	₹276 Cr
% margin		10%	14%
Net Profit (before exceptional charge)	-10%	₹168 Cr	₹188 Cr
% margin		7%	10%

Biosimilars +34% | Research +26% | Generics +18%

Adjusted for:

Dilution gain in Bicara of ₹33 Cr in Q2 FY23 MTM gain on investments ₹55 Cr Q2 FY22

Gross R&D spend at ₹252 Cr, up ₹86 Cr R&D spend in P&L ₹242 Cr, up ₹96 Cr Forex Loss of ₹82 Cr vs gain of ₹20 Cr in Q2 FY22

^{*} Core EBITDA defined as EBITDA before forex, dilution gain in Bicara, R&D, licensing income and mark to market gain on investments

Financial Highlights: Q2 FY23 (2/2)



Net Profit

(before exceptional charge)

₹168 Cr

₹188 Cr

Exceptional Items

₹122 Cr

₹50 Cr

Net Profit

(Reported)

₹47 Cr

₹138 Cr

Exceptional items during Q2 FY23:

MAT credit balance charge of ₹107 Cr on adoption of new tax regime of 25%. This move helps Biocon reduce tax outflow and P&L charge on a go-forward basis.

Professional fees, net of tax of ₹14 Cr towards the Viatris deal

In Q2 FY22, exceptional items net of tax and minority were ₹50 Cr

Financial Highlights: FY22



	FY22	FY21	Biosimilars +24% Research Services +19%
Revenue +14%	₹8,397 Cr	₹7,398 Cr	Generics -1% Dilution Gain in Associates of ₹30 Cr vs ₹160 Cr in FY21
Core EBITDA* +18%	₹2,669 Cr	₹2,270 Cr	Mark-to-market loss on investments of ₹28 Cr; Forex Gain of ₹58 Cr vs loss of ₹9 Cr in FY21
% margin	32 %	31%	TOTEX Gaill Of \$30 CT VS 1033 OF \$3 CT III T 121
EBITDA +14%	₹2,183 Cr	₹1,907 Cr	Gross R&D spend at ₹711 Cr R&D spend in P&L ₹595 Cr
% margin	26%	26%	
Profit Before Tax +4% (Before Exceptional Items)	₹1,094 Cr	₹1,055 Cr	Exceptional Loss at ₹111 Cr
% margin	13%	14%	
Net Profit (Before Exceptional Items)	₹722 Cr	₹744 Cr	Net Profit after exceptional items at ₹648 Cr
% margin	9%	10%	

^{*}Core EBITDA defined as EBITDA before forex, R&D, mark-to-market loss on investments, licensing income and gain on dilution of stake in associates.