

Q1FY23 Investor Presentation

July 2022



Meta morphosis

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.

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

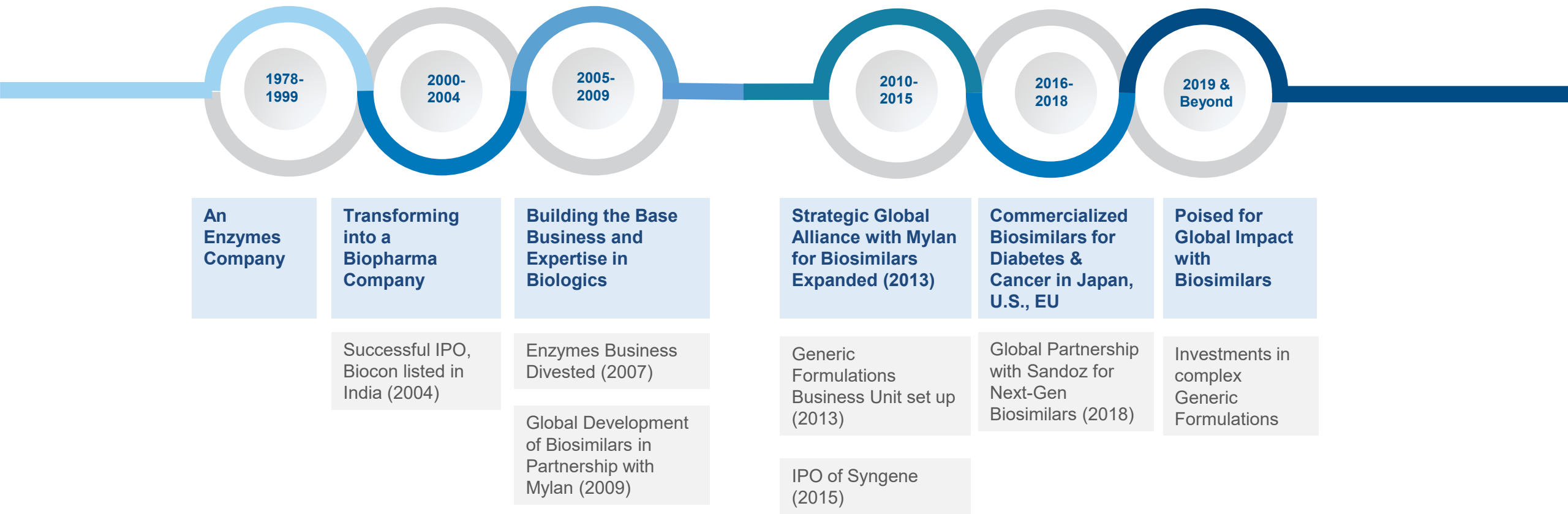
- Build strategic global and regional partnerships to make high-quality biopharmaceuticals available to the maximum number of people
- Create a robust portfolio of 'blockbuster' drugs with the potential to benefit a billion patients



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



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
- 13% increase in women in workforce



SOCIAL

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



ENVIRONMENT

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



STAKEHOLDER

- 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.



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

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)



- **Expanding in select key markets**



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

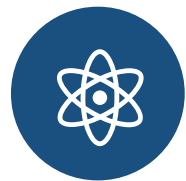


- **Large customer acquisitions**
- **De-risking dependence for critical intermediates**



~\$65b

Global Generic API Market Size 2022E*



40+

APIs



700+

API customers



75+

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



5

Facilities in India

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

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 & non-potent), 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



~\$335b

Global Generics Drugs Market Size 2021*



11

Commercial US Formulations



5

Approved/ tentatively approved ANDAs



Ex US Approvals

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

Generics: Q1FY23 Update

KEY HIGHLIGHTS

- YoY growth due to continued performance in API & recently launched generic formulations, coupled with lower base last year
- Launched vertically integrated formulation, Mycophenolic Acid Delayed Release tablet in the US
- Received approvals for Lenalidomide in the EU, Fingolimod capsules in the UAE and Rosuvastatin Tablets in Singapore
- Received a GMP certificate from MHRA, UK for oral solid dosage formulation facility located in Biocon Park, Bengaluru
- On track to qualify & validate Vizag API facility in FY23

Q1FY23

Q1FY23

Revenue

₹580Cr	₹486Cr	+19%
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Profit Before Tax (PBT)

₹63Cr	₹29Cr	+116%
11% of revenue	6% 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

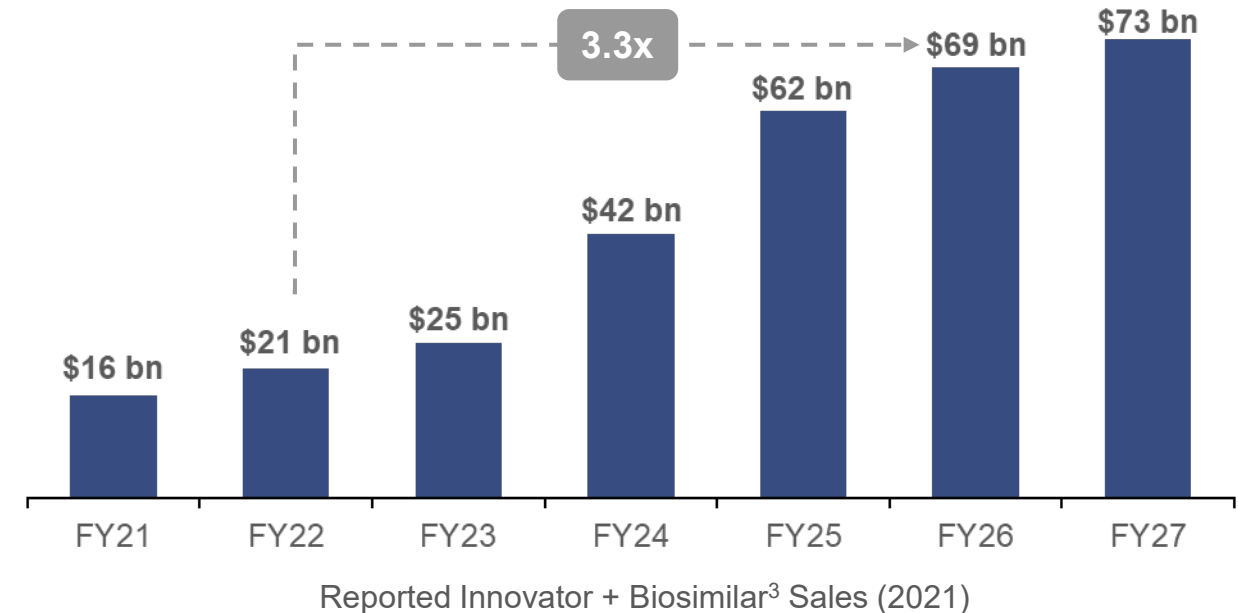
8 
Approved Products¹

2 
Research & Development sites

3 
Manufacturing sites
(2 Bengaluru, 1 Malaysia)

25+ 
cGMP approvals
(incl. FDA & EMA)

BIOCON BIOSIMILARS TARGET ADDRESSABLE MARKET



¹ Includes Adalimumab and Etanercept which have been in-licensed by Viartis 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

2004

1st company to commercialize human insulin using proprietary *P. pastoris* platform

2017

1st company to receive approval for bTrastuzumab in the US











2018

1st company to receive approval for bPegfilgrastim in the US

2021

1st 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...



Viatri 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 Viatri's 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



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

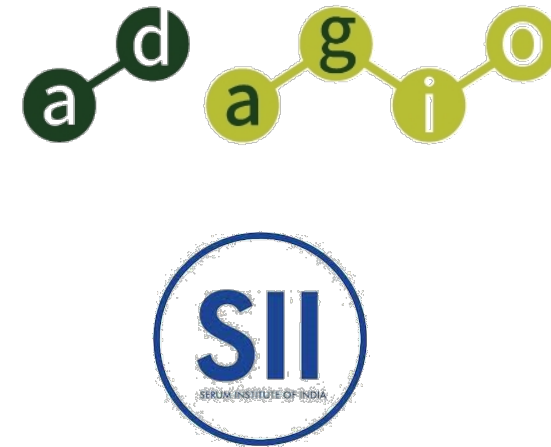
Entering agencies in communicable disease: infectious disease antibodies and vaccines

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

Comprehensive portfolio of 20 biosimilars and vaccines...

BIOSIMILAR PRODUCT STATUS

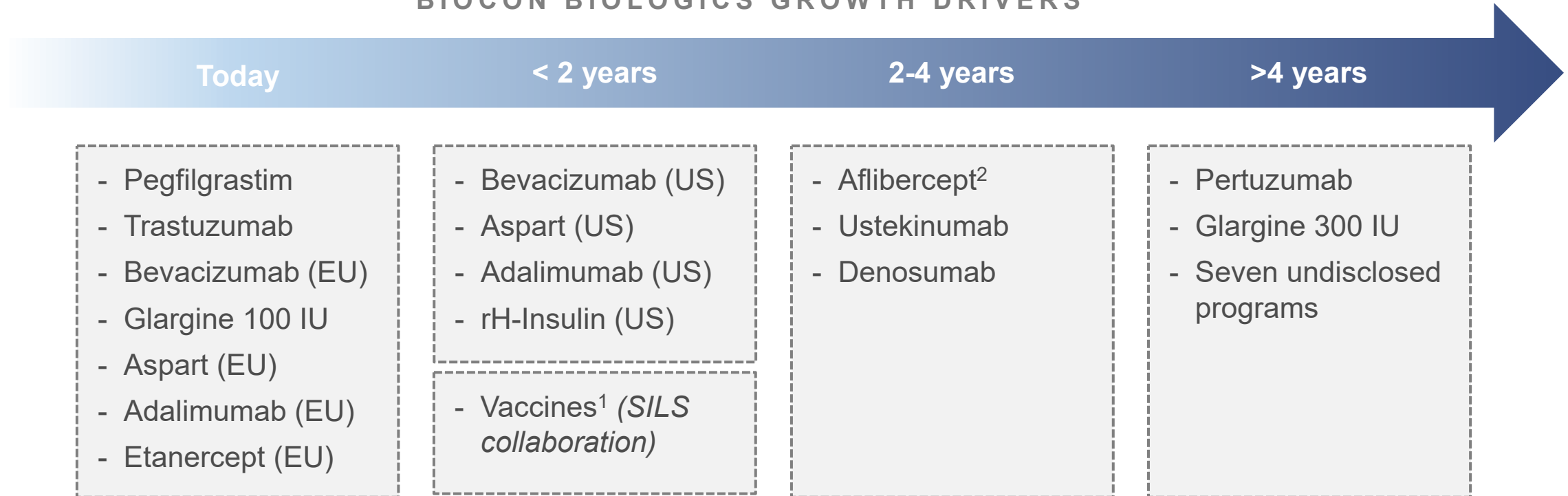
Therapeutic Area	Molecule	US	Dev. Markets: ex-US	MoW ⁴	Commentary
Oncology	Pegfilgrastim ¹		Europe, CANZ		<ul style="list-style-type: none"> - bBevacizumab: Approved in EU, Canada and Australia; US approval awaiting site inspection - bDenosumab: Ph-1 and Ph-3 clinical trial ongoing - bAdalimumab: US launch expected in mid-2023 - bUstekinumab: Ph-1 and Ph-3 clinical trial ongoing - rHI (US): BLA filing for various presentation - bAflibercept: First-to-file in US
	Trastuzumab ¹		Europe, CANZ		
	Bevacizumab ¹		Europe, AU, CA		
	Denosumab		Europe, CANZ, JP		
	Pertuzumab ¹				
Immunology	Adalimumab ^{1,2}		Europe, CA, JP		
	Etanercept ^{1,2}		Europe		
	Ustekinumab		UK, CANZ, JP		
Diabetes	Glargine 100U ^{1,3}		Europe, CANZ, JP		
	Glargine 300U ¹		Europe		
	Aspart ¹		Europe, CA		
	rHI				
Bone Health	Denosumab		Europe, CANZ, JP		<div>Early Dev./ Preclinical</div> <div>Clinical</div> <div>Filed</div> <div>Approved</div>
Undisclosed	7 Assets				
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 Viartis; ² Partner Viartis has in-licensed product (Biocon benefits from economic interest) | ³ Japan is outside of Viartis 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 Viartis' biosimilar business (Viartis 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



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 Viatri's biosimilar business (Viatri has global rights to the program partnered with Momenta)

Biosimilars: Q1 FY23 Update

KEY HIGHLIGHTS

- Revenue growth excluding COVID-19 related sales at 46% YoY
- Progress of our unpartnered biosimilars pipeline, including bUstekinumab & bDenosumab, increased R&D cost by 120% YoY
- Non-cash foreign currency translation loss of ₹43cr on Goldman Sach's OCD investment
- Strong performance of 351(k) interchangeable biosimilar insulin glargine in the US
- Canada: Launched bBevacizumab; bGlargine and bAspart expected to be launched in CY22
- Site inspections by the US FDA expected in August 2022, paving way for bBevacizumab and bAspart approval in US

Q1 FY23

Q1 FY22

Revenue

₹977Cr

₹758Cr

+29%

Core EBITDA*

₹361Cr

₹271Cr

+33%

37% of revenue

36% of revenue

Profit Before Tax (PBT)

₹71Cr

₹101Cr

-30%

7% of revenue

13% 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
- 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
 Inflammation	Itolizumab* - A novel humanized CD6 antibody	Graft-Versus-Host Disease (GVHD) <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Given positive trends in Part A, expanded Part B portion of Phase 1b EQUALISE study to clinical centers in India; patient recruitment continues
		Cytokine Release Syndrome treatment in 'Moderate to Severe' Acute Respiratory Distress Syndrome <ul style="list-style-type: none"> • Repurposed for prevention & treatment of COVID-19 complications in India in 2020; granted 'Restricted Emergency Use' approval in Sep '20
 Immuno-oncology	BCA101** Formerly FmAb2 First-in-class EGFR / TGFβ-trap bifunctional antibody	<ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> ○ Completed enrollment for dose finding part of Phase I trial & established highest dose with desired level of safety & tolerability. ○ 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 : Q1 FY23 Update

KEY HIGHLIGHTS

- Equillium initiated patient dosing for the pivotal Phase III clinical study of Itolizumab in patients with aGVHD*
- Patient recruitment continues for the pivotal Phase 1b clinical study of Itolizumab for Lupus Nephritis
- Recommended dose established** at 1500 mg once weekly for Bicara#’s BCA101
- BCA101 being evaluated** in head & neck squamous cell carcinoma, squamous cell carcinoma of the anal canal, cutaneous squamous cell carcinoma; primary results expected in 2H22



*Acute Graft-Versus-Host Disease

**as monotherapy and in combination with pembrolizumab

#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: Q1FY23 Update

KEY HIGHLIGHTS

- Results against a strong quarter last year due to Remdesivir sales. Excluding Remdesivir, ~30%YoY revenue growth
- Signed 10-year agreement with Zoetis for commercial manufacturing of drug substance for Librela[®], MAb used for pain alleviation in dogs
- Continued investment in infrastructure incl. PROTACs* lab commissioned in Hyderabad
- Revenue guidance for FY23 raised from mid-teens to high teens

Q4FY22

Q4FY21

Revenue

₹645Cr

₹595Cr

+8%

Profit Before Tax (PBT)

₹93Cr

₹95Cr

-2%

14% of revenue

16% of revenue

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

Financial Highlights



Financial Highlights: Q1FY23

		Q1FY23	Q1FY22	
Revenue	+23%	₹2,217Cr	₹1,808Cr	Biosimilars +29% Generics +19% Research Services +8%
Core EBITDA*	+25%	₹660Cr	₹530Cr	Forex Loss of ₹38Cr vs Gain of ₹17Cr in Q1FY22
<i>% margin</i>		31%	30%	
EBITDA	+9%	₹478Cr	₹437Cr	Gross R&D spend at ₹223Cr vs ₹136Cr in Q1FY22
<i>% margin</i>		22%	24%	R&D spend in P&L ₹198Cr vs ₹120Cr in Q1FY22
Profit Before Tax	+19%	₹197Cr	₹166Cr	
<i>% margin</i>		9%	9%	
Net Profit	+71%	₹144Cr	₹84Cr	
<i>% margin</i>		7%	5%	

*Core EBITDA defined as EBITDA before forex, R&D, licensing income and gain on dilution of stake in associates.

Financial Highlights: FY22

		FY 22	FY 21	
Revenue	+14%	₹8,397Cr	₹7,398Cr	Biosimilars +24% Research Services +19% Generics -1% Dilution Gain in Associates 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 in FY21
<i>% margin</i>		32%	31%	
EBITDA	+14%	₹2,183Cr	₹1,907Cr	Gross R&D spend at ₹711Cr R&D spend in P&L ₹595Cr
<i>% margin</i>		26%	26%	
Profit Before Tax	+4%	₹1,094Cr	₹1,055Cr	Exceptional Loss at ₹111Cr
before Exceptional Items				
<i>% margin</i>		13%	14%	
Net Profit		₹722Cr	₹744Cr	Net Profit after exceptional items at ₹648Cr
Before Exceptional Items				
<i>% margin</i>		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.