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

July 27, 2022

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

Dear Sir/Madam,

Subject: Investor Presentation – Q1 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 https://www.biocon.com.

Kindly take the above said information on record.

Thanking You,

Yours faithfully,

For **Biocon Limited**

BIOCON LIMITED ★ BANGALORE ★

Mayank Verma
Company Secretary & Compliance Officer

Enclosed: Investor Presentation

Q1FY23 Investor Presentation

July 2022

Biocon

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.**

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

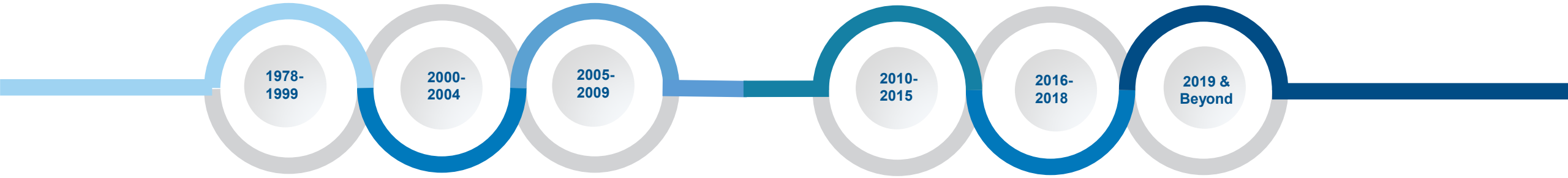
availability

- 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



1978-1999	2000-2004	2005-2009	2010-2015	2016-2018	2019 & Beyond
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)	Generic Formulations Business Unit set up (2013)	Global Partnership with Sandoz for Next-Gen Biosimilars (2018)	Investments in complex Generic Formulations
		Global Development of Biosimilars in Partnership with Mylan (2009)	IPO of Syngene (2015)		

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

*FY22

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 tCO_2 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

Product Pipeline

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

Regional Expansion

- *Expanding in **select key markets***

Manufacturing Expansion

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

Base Business

- ***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

Product Pipeline

- ***Expanding portfolio through***
  - *Vertical integration &*
  - *In-licensing strategy*

Manufacturing Expansion

- ***Adding capabilities***
  - *injectable facility in Bengaluru*

Regional Expansion

- ***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%*
Profit Before Tax (PBT)	₹63Cr	₹29Cr	*+116%*
	11% of revenue	*6% of revenue*	

Biosimilars : Overview

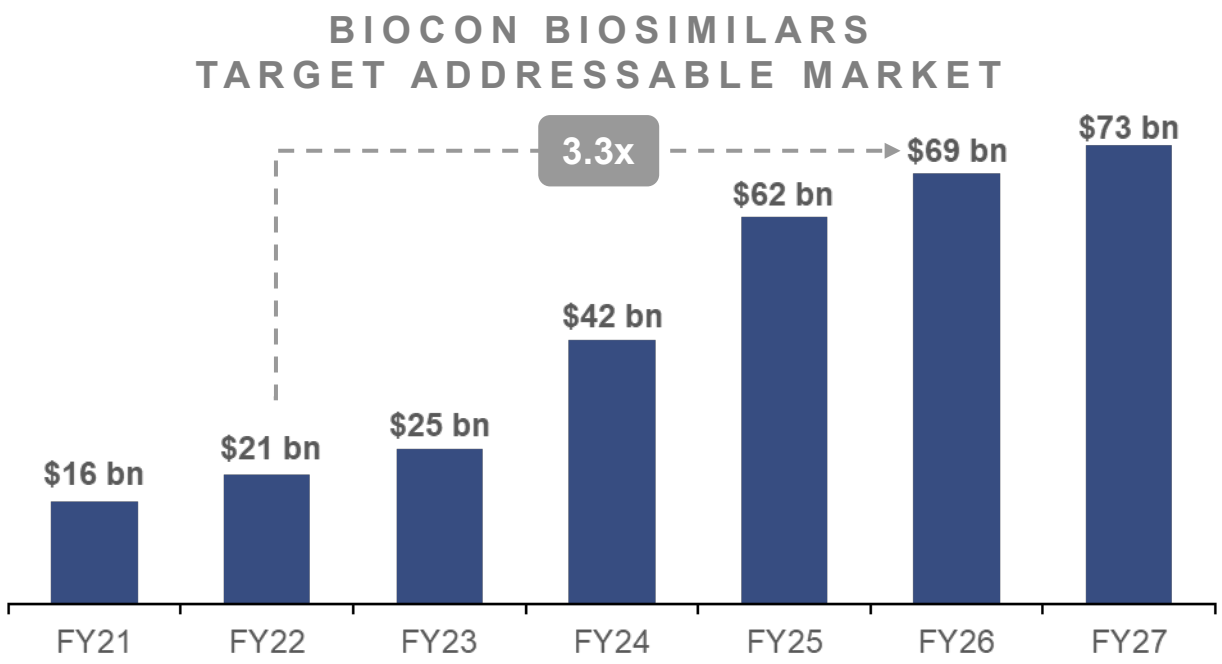
- Leadership in biologics R&D, manufacturing and commercialization built over two decades
- Driven by high scientific acumen with analytical and clinical capabilities in a complex regulatory setting
- Expertise in large scale biologics manufacturing across diverse technology platforms
- Product reach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

8 Approved Products[1]

2 Research & Development sites

3 Manufacturing sites (2 Bengaluru, 1 Malaysia)

25+ cGMP approvals (incl. FDA & EMA)



Reported Innovator + Biosimilar[3] 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

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
Mylan VIATRIS (2009)	Biosimilars co-developed and co-commercialized with R&D and manufacturing led by BBL	
SANDOZ A Novartis Division (2018)	Set of next-gen biosimilars being co-developed	
Biocon Biologics Transforming Healthcare. Transforming Lives. (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…

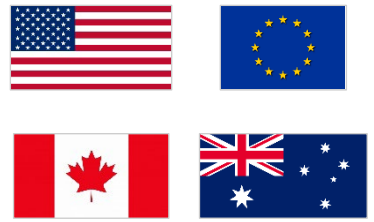
1 Financial

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

→ Revenue $1.1b | EBITDA $250m
Viatris Biosimilars CY23 estimate[1]

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.

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

…transforming into a fully-integrated global biosimilars business

Biocon

Biocon Biologics

CURRENT

POST ACQUISITION OF VIATRIS' BIOSIMILARS BUSINESS

Biosimilar **Value** Chain

	Emerging Markets	Developed Markets	Global Markets
PRODUCT DEVELOPMENT	✓	✓	✓
CLINICAL TRIALS	✓	✓	✓
REGULATORY	✓	✗	✓
MANUFACTURING	✓	✓	✓
SUPPLY CHAIN	✓	✗	✓
COMMERCIALIZATION	✓	✗	✓

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

Entering adjacencies in communicable disease: infectious disease antibodies and vaccines

Key Commercial Products (COVID -19)

50,000+ lives impacted

Recent Collaborations

adagio

SII
SERUM INSTITUTE OF INDIA

Continued portfolio expansion

Asset-light entry into vaccines through SILS alliance

BBL RIGHTS

1. Access to 100m doses of vaccines annually for ~15 years
2. Commercialization rights of the SILS portfolio for global markets
3. 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…

Therapeutic Area	Molecule	BIOSIMILAR PRODUCT STATUS		
		US	Dev. Markets: ex-US	MoW[4]
Oncology	Pegfilgrastim[1]		Europe, CANZ	
	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	
Undisclosed	7 Assets			
Ophthalmology	Aflibercept[5]			

Commentary

- **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

Early Dev./ Preclinical | Clinical | Filed | Approved

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)*	- Aflibercept[2] - Ustekinumab - Denosumab	- Pertuzumab - Glargine 300 IU - Seven 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: 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

	Q1FY23	Q1FY22	
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

Biocon Biologics

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)** • **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** • 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** • 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
		• **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
		  ○ **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
% margin		*31%*	*30%*	
EBITDA	*+9%*	**₹478Cr**	**₹437Cr**	**Gross R&D spend** at **₹223Cr** vs **₹136Cr** in Q1FY22 **R&D spend** in **P&L ₹198Cr** vs **₹120Cr** in Q1FY22
% margin		*22%*	*24%*	
Profit Before Tax	*+19%*	**₹197Cr**	**₹166Cr**	
% margin		*9%*	*9%*	
Net Profit	*+71%*	**₹144Cr**	**₹84Cr**	
% margin		*7%*	*5%*	

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

Financial Highlights: FY22

		FY22	FY21	
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
% margin		*32%*	*31%*	
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 **before Exceptional Items**	*+4%*	**₹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**
% 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.