



#### **PRESS RELEASE**

# Biocon Q1FY23 Revenue at Rs 2,217 Cr, Up 23%; Net Profit at Rs 144 Cr, Up 71%; Core EBITDA at Rs 660 Cr Up 25%

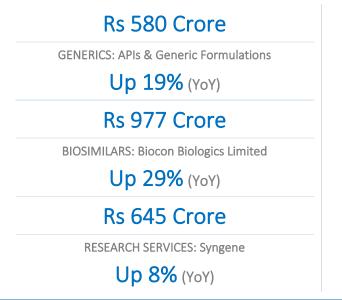
# Biosimilars Up 29%; Generics Up 19%; Research Services Up 8%

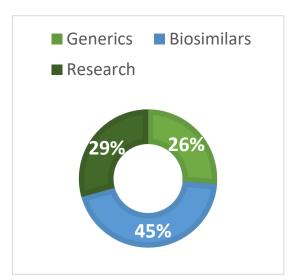
# Bengaluru, Karnataka, India: July 27, 2022:

**Biocon Ltd** (BSE code: 532523, NSE: BIOCON), an innovation-led global biopharmaceuticals company, today announced its consolidated financial results for the first quarter ended June 30, 2022.

Q1FY23   Financial Highlights				
Rs 2,217 Crore Consolidated Revenue Up 23% (YoY)	Rs 478 Crore EBITDA Up 9% (YoY)	Rs 660 Crore CORE EBITDA Up 25% (YoY)		
Rs 144 Crore Net Profit Up 71% (YoY)	<b>22%</b> EBITDA Margin (Q1FY22: 24%)	31% CORE EBITDA Margin (Q1FY22: 30%)		

# Q1FY23 | Business Segments Revenue









# **Leadership Comments**

#### **BIOCON GROUP**

"We have had a strong start to the year. At a consolidated level, y-o-y revenues grew 23% backed by robust growth in both Biosimilars (29%) and Generics (19%). Core EBITDA grew 25% and margin improved to 31% compared to 30% in Q1FY22. and Net Profit grew 71% to Rs 144 Crore. Our financial performance this quarter includes the impact of annual increments in personnel costs as well as increased input and freight costs, pursuant to pandemic and geopolitical disruptions of global supply chains. R&D investments increased significantly by Rs 87 Crore this quarter reflecting pipeline progression to deliver future growth. All our three businesses are poised for the next phase of strong and sustainable growth which has been challenged during the two years of the COVID-19 pandemic."

## -- Kiran Mazumdar-Shaw, Executive Chairperson, Biocon and Biocon Biologics.

#### **BIOCON GENERICS**

"The strong year-on-year growth of the segment was driven by both our API and Formulations businesses, on a lower base in the corresponding period of the previous fiscal, which was impacted by COVID-related operational and supply chain challenges.

"Key new products launched in previous quarters continue to perform well. Our base business continued to encounter pricing pressure and rising input costs. Our commitment to bring affordable medicines to patients was reinforced with the launch of Mycophenolic Acid delayed release tablets, our vertically integrated formulation, for prophylaxis of organ rejection in adult patients who received kidney transplants.

"During the quarter, we undertook planned capacity expansions that required temporary manufacturing stoppages. These expansions will augment growth in the second half of this fiscal.

"Looking ahead, we will continue to invest in strengthening our product pipeline, optimizing cost structures and operationalizing our capacity enhancement projects."

## -- Siddharth Mittal, CEO & Managing Director, Biocon Limited.

## **BIOCON BIOLOGICS**

"Biocon Biologics reported a year-on-year growth of 29% for Q1FY23 with revenues at Rs 977 Crore. Core EBITDA at Rs 361 Crore was up 33%, representing healthy margins of 37%. The strong performance was driven by sales of Glargine in the US, and key biosimilars in emerging markets.

"Initiation of global clinical trials for two monoclonal antibodies and advancement of our other pipeline assets led to a 120% increase in our R&D investments this quarter. Whilst this impacts EBITDA in the near term, such investments will create a strong portfolio to secure our future growth.

"Our strategic alliance with Serum Institute Life Sciences for vaccines and the acquisition of Viatris' global biosimilars business are on track for closure in the second half of this calendar year."

#### -Dr Arun Chandavarkar, Managing Director, Biocon Biologics Ltd.





#### **SYNGENE**

"The first quarter results were in line with our expectations and reflect strong underlying performance of Syngene across all business divisions. The contribution from the Development and Manufacturing Services divisions drove the growth momentum against a low base in the previous year. The Dedicated Centers and Discovery Services divisions delivered continued growth. The decline in profit in the quarter compared to the same period last year was as expected given the strong sales of Remdesivir last year when India was in the midst of the second wave of the pandemic. No sales of Remdesivir were recorded in the first quarter this year."

-- Jonathan Hunt, CEO & Managing Director, Syngene.

# FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q1FY23

## In Rs Crore

Particulars	Q1FY23	Q1FY22	YoY%
INCOME			
Generics	580	486	19%
Biosimilars	977	758	29%
Novel Biologics	-	11	-100%
Research services	645	595	8%
Inter-segment	(61)	(89)	-31%
Revenue from operations #	2,140	1,761	22%
Other income	78	47	65%
Total Revenue	2,217	1,808	23%
EBITDA	478	437	9%
РВТ	197	166	19%
Net Profit for the Period	144	84	71%
R&D Expenses in P&L	198	120	65%
Gross R&D Spend	223	136	64%
EBITDA Margins	22%	24%	
Core EBITDA*	660	530	25%
Core EBITDA Margins*	31%	30%	
Net Profit Margins	7%	5%	

Figures above are rounded off to the nearest Crore; % based on absolute numbers. #Includes Licensing income.

<sup>\*</sup>Core EBITDA is EBITDA net of R&D expense, licensing, forex, dilution gain in Bicara, mark-to-market movement on investments.





#### **CORPORATE HIGHLIGHTS**

#### **Board Announcement**

Mary Harney and Daniel Bradbury, Independent Directors of Biocon Limited, having completed their second term of tenure with the Company as of July 27, 2022 and have stepped down from the Board, effective this date. On behalf of Biocon's Board of Directors and management, we express our deep appreciation and gratitude to Mary and Daniel for their invaluable guidance and stewardship that has contributed immensely to the organization's growth.

## **Management Announcement**

Biocon Biologics has appointed Michael Cutter as the Chief Quality Officer (CQO). He has over three decades of experience in managing global quality functions in leading multinational pharma companies. He will be responsible for leading Biocon Biologics' Global Quality Organization across locations.

## **Publication of ESG report**

During the quarter, we published our first Environment, Social & Governance (ESG) report, 'Transform Action' for FY22. The report has been developed by following the SEBI Business Responsibility & Sustainability Reporting (BRSR) and the Global Reporting Initiative (GRI) disclosure guidelines. The purpose of this report is to share our value creation journey across patients, people, environment, social and governance parameters and provide insights into the non-financial performance of Biocon. Through this report, our aim is to uphold the values of accountability, responsibility and transparency, that resonate across everything we do. It also describes the strategic direction from our leadership on our long-term ESG objectives and initiatives.

#### **BUSINESS HIGHLIGHTS**

**GENERICS: APIs & Generic Formulations** 

Q1FY23 revenue at Rs 580 Crore, up 19% (YoY) from Rs 486 Crore in Q1FY22.

## **Business Performance**

During the quarter, we launched Mycophenolic Acid (MPA) Delayed-Release Tablets, the generic version of Myfortic® Delayed-Release Tablets, in the US. Introduced in strengths of 180 mg and 360 mg, Mycophenolic Acid is an antimetabolite immunosuppressant indicated for prophylaxis of organ rejection in adult patients receiving kidney transplants. It is also targeted at children over five years old who have crossed at least six months after kidney transplant.

We obtained approvals for our oncology product Lenalidomide in the EU, Fingolimod capsules in the UAE, and Rosuvastatin tablets in Singapore.

We received a GMP certificate of compliance from the MHRA, UK for an audit conducted by the agency at our Oral Solid Dosage facility in Bengaluru.

Our greenfield immunosuppressant API facility in Visakhapatnam remains on track, with qualification and validation activities planned in FY23.





# **BIOSIMILARS: Biocon Biologics Limited (BBL)**

Q1FY23 revenue at Rs 977 Crore, up 29% (YoY) from Rs 758 Crore in Q1FY22.

## **Business Performance**

Biocon Biologics recorded a strong year-on-year (YoY) **revenue** growth of **29%** in Q1FY23 at **Rs 977 Crore.** With two of BBL's non-partnered monoclonal antibodies in clinical trials and continued progress on other pipeline molecules, BBL's **R&D investments** this quarter grew by **120%** YoY to **Rs 130 Crore**, representing **13%** of BBL revenue.

**Core EBITDA** which excludes R&D, forex, licensing income and mark-to-market movement on investments, stood at **Rs 361 Crore**, reflecting a growth of **33%** YoY. **Core EBITDA margin** remained healthy at **37%** for the quarter. **EBITDA** for the quarter was lower by **12%** YoY at **Rs 190 Crore** on account of higher R&D investments and non-cash foreign currency translational loss of **Rs 43 Crore** on Goldman Sachs OCD investment. **Profit Before Tax stood at Rs 71 Crore**.

We expanded our product reach to impact 5.51 million patients at the end of the quarter (MAT June 2022)\*.

## **Developed Markets**

In Q1FY23, the Viatris-led developed markets business reported a strong YoY growth, led primarily by sales of interchangeable bGlargine in the U.S. In Europe, bPegfilgrastim and bTrastuzumab reported an increase in market share.

- bBevacizumab (Abevmy) launched in Canada.
- bAspart received marketing authorization approval in UK.

## **Emerging Markets**

During the quarter, the Biocon Biologics-led commercial business reported strong performance of key biosimilars in the APAC and LATAM regions.

- bTrastuzumab and rh-Insulin were launched in additional markets.
- Regulatory submissions for key biosimilars were made in over 20 emerging markets.

Core Oncology and Immunology brands of the Branded Formulations – India business, reported a strong growth in prescriptions & patient acquisition, this quarter.

## **Development Updates**

- Clinical development of two non-partnered, Biocon-led assets, bUstekinumab and bDenosumab, advanced further. These will be key additional drivers for our medium to longterm growth, on top of our current portfolio partnered with Viatris.
- We continued to progress on the development of other pre-clinical assets.





## **B3 mAbs Facility Approved by EMA**

 Received EU GMP certificate from the Health Products Regulatory Authority (HPRA), Ireland, for our new, integrated, multi-product mAbs drug substances facility at Biocon Park, Bengaluru. This is one of India's largest monoclonal antibodies manufacturing facilities.

## **Progress on Acquisition of Viatris' Global Biosimilars Business**

Our strategic deal to acquire Viatris' global biosimilars business made progress with respect to statutory approvals, deal funding and integration readiness.

Deal is on track for closure in the second half of calendar year 2022 (H2 CY22).

## **Progress on Vaccines Alliance with Serum Institute**

The Competition Commission of India (CCI) approved the merger of Covidshield Technologies Pvt. Ltd. (CTPL), a wholly owned subsidiary of Serum Institute Life Sciences (SILS), with Biocon Biologics in May.

Deal is on track for closure in H2 CY22.

Once completed, these strategic deals will position Biocon Biologics, as a unique fully integrated global biologics company.

\*Moving 12-month patient population (July 2021 to June 2022)

#### **NOVEL BIOLOGICS**

During the quarter, **patient dosing** was initiated by our partner, Equillium, for the pivotal **Phase III** clinical study of **Itolizumab** in patients with acute graft-versus-host disease (**aGVHD**), as recruitment continues for the **Phase 1b** clinical study of Itolizumab for **Lupus Nephritis**.

Our Boston based associate, **Bicara's** lead molecule, BCA101, has demonstrated encouraging safety, pharmacokinetic, pharmacodynamic and efficacy profiles based on the findings from the dose escalation phase of the ongoing Phase 1/1b trial, which was initiated in February 2022. **BCA101**, as a monotherapy and in combination with pembrolizumab, is currently being evaluated in several indications, such as head and neck squamous cell carcinoma, advanced squamous cell carcinoma of the anal canal as well as cutaneous squamous cell carcinoma. Primary results for the dose expansion arm of this study are expected in the second half of 2022.

#### **RESEARCH SERVICES: Syngene**

## Q1FY23 revenue at Rs 645 Crore, up 8% (YoY) from Rs 595 Crore in Q1FY22.

The Company signed a long-term agreement with **Zoetis** for the commercial manufacturing of the drug substance for Librela®, a first-of-its-kind injectable monoclonal antibody to alleviate pain associated with osteoarthritis in dogs.

The Company continued to invest in infrastructure: a kilo lab was established for polymer and speciality materials in the Development Services division.

Additionally, as part of the phase three expansion in Hyderabad, a lab was commissioned in the newly constructed Innopolis building with over 150 scientists and analysts dedicated to PROTACs, a targeted





protein degradation technology that offers therapeutic interventions not achievable with existing drug discovery approaches.

**Enclosed: Fact Sheet – with Financials as per IND-AS** 

#### **About Biocon Limited:**

**Biocon Limited**, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is an innovation-led global biopharmaceuticals company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune. It has developed and commercialized novel biologics, biosimilars, and complex small molecule APIs in India and several key global markets as well as Generic Formulations in the US and Europe. It also has a pipeline of promising novel assets in immunotherapy under development. **Website: www.biocon.com; Follow-us on Twitter: @bioconlimited** for company updates.

Biocon Biologics Ltd., a subsidiary of Biocon Ltd., is a unique, fully integrated global biosimilars organization. It is leveraging cutting-edge science, innovative tech platforms and advanced research & development capabilities to lower costs of biologics therapies while improving healthcare outcomes. It has a strong research pipeline of biosimilar molecules across diabetes, oncology, immunology and other non-communicable diseases. Seven molecules from Biocon Biologics' portfolio have been commercialized in key emerging markets and developed markets like U.S., EU, Australia, Canada, Japan. It has many firsts to its credit including the most recent U.S. FDA approval of the world's first interchangeable biosimilar, awarded to its Insulin Glargine, which has been commercialized in the U.S. in 2021. Biocon Biologics has signed a strategic alliance with Serum Institute Life Sciences (subject to certain closing conditions) to address the inequitable access to life saving vaccines and biologics globally. With a team of ~5,000 people, Biocon Biologics is committed to transforming healthcare and transforming lives by enabling affordable access to millions of patients' worldwide. Website: www.bioconbiologics.com; Follow us on Twitter: @BioconBiologics for company updates.

FOR MORE INFORMATION		
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#### **Earnings Call**

The management of the Company will host an Earnings Call on 28<sup>th</sup> July, 2022 at 9:00 hrs, over a Zoom Webinar, where the senior management will discuss the company's performance and answer questions from participants. Details of the Zoom webinar are given below as well as on the company website <a href="www.biocon.com">www.biocon.com</a> under Investors>>Financial Calendar>>Earnings Call for period ended June 30, 2022. Transcript of the conference call will be uploaded on the company website in due course.

Zoom Webinar Details	
Date	28 <sup>th</sup> July, 2022
Time	9:00hrs -10:30hrs IST
Join Zoom Webinar	https://bit.ly/3RYxdv3 to attend earnings call

Or Copy this URL in your browser: <link>

#### Forward-Looking Statements: Biocon

This press release may include statements of future expectations and other forward-looking statements based on management's current expectations and beliefs concerning future developments and their potential effects upon Biocon and its subsidiaries/ associates. These forward-looking statements involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from our expectations include, amongst other: general economic and business conditions in India and overseas, 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 currency changes, 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 and global biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither Biocon, nor our Directors, or any of our subsidiaries/associates assume any obligation to update any particular forward-looking statement contained in this release.