



## PRESS RELEASE

# Biocon Q1FY24 Revenue at Rs 3,516 Cr, Up 59%; Biosimilars Up 106%; Research Services Up 25%

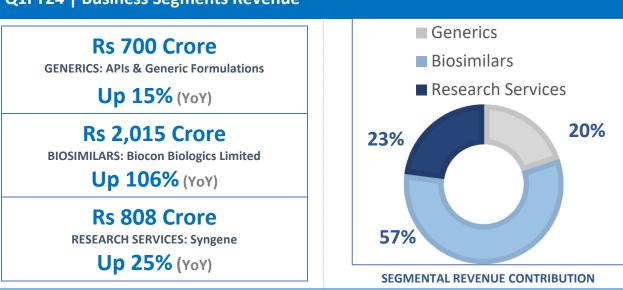
# EBITDA at Rs 808 Cr, Up 69%; Core EBITDA at Rs 936 Cr, Up 42% Net Profit at Rs 101 Cr

Bengaluru, Karnataka, India: August 10, 2023:

**Biocon Ltd** (BSE code: 532523, NSE: BIOCON), an innovation-led global biopharmaceuticals company, today announced its consolidated financial results for the fiscal first quarter ended June 30, 2023.

Q1FY24   Financial Highlights				
Rs 3,516 Crore CONSOLIDATED REVENUE	Rs 936 Crore CORE EBITDA	Rs 808 Crore EBITDA		
Up 59% (YoY)	Up 42% (YoY)	<b>Up 69%</b> (YoY)		
Rs 315 Crore  NET R&D INVESTMENT  Up 59% (YoY)	28% CORE EBITDA MARGIN	23% EBITDA MARGIN		

# Q1FY24 | Business Segments Revenue







## **Leadership Comments**

### **BIOCON GROUP**

"We have had a strong start to the year. At a consolidated level, revenues rose 59% YoY to Rs 3,516 crore driven primarily by the 106% jump in Biosimilars revenue. Research Services revenue rose 25%, and Generics reported 15% growth. Our Core EBITDA for the quarter was up 42% at Rs 936 crore, reflecting a margin of 28%. R&D investments at Rs 315 crore increased by Rs 117 crore this quarter, reflecting our advancing pipeline, which will support future growth.

"Our key biosimilars are gaining traction in both U.S. and Europe with Fulphila® becoming the leading biosimilar Pegfilgrastim in the U.S. and biosimilar Glargine's market share crossing the 12% mark. A higher new prescription share reflects the prescriber confidence in our portfolio and the overall improvement in the adoption of biosimilars."

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

### **BIOCON GENERICS**

"The Generics business delivered a healthy 15% year-on-year revenue growth, driven by growth in our formulations business in the U.S. and new product launches in a few key MoW markets. We also saw a volume increase in immunosuppressant APIs.

"Our product pipeline continues to advance with an approval for Vigabatrin tablets and a tentative approval for Lenalidomide capsules in the U.S., and for Mycophenolic acid tablets in Europe. The positive outcome of the two U.S. FDA inspections at our Hyderabad API and Bengaluru OSD sites will help in accelerating new product approvals.

"We continue to make investments for future growth, with work having commenced on the expansion of our peptide and fermentation capacities in Bengaluru, with a timeline for completion in the second half of FY25."

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

## **BIOCON BIOLOGICS**

"I am pleased to report that Biocon Biologics has delivered a strong revenue growth of over 100% for the first quarter. This was driven by the acquisition of Viatris biosimilars business and growth in market shares for our products in the U.S. and Europe. The recent launch of our fourth biosimilar in the U.S., Hulio®, biosimilar Adalimumab, demonstrates our commitment to expand access to life-changing treatments. Having successfully transitioned the acquired business from Viatris in over 70 countries in Emerging Markets, we are now looking forward to integrating the business in North America by the end of Q2 FY24."

- Shreehas Tambe, CEO & Managing Director, Biocon Biologics Ltd.

#### **SYNGENE**

"We have reported a strong performance in the first quarter with revenue growth of 25% year-on-year. This was led by our Development and Manufacturing Services divisions, well supported by steady delivery from Discovery Services as well as the Dedicated Centers. The key highlights this quarter were: the acquisition of additional biologics manufacturing capacity in Bengaluru; the regulatory approval by the U.S. FDA of the API manufacturing site in Mangaluru; and the land acquisition in Hyderabad for further expansion. These strategic build-outs will enable us to progress towards becoming a leading CDMO."

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





# FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q1FY24

### In Rs Crore

Particulars	Q1FY24	Q1FY23	YoY (%)
INCOME			
Generics	700	607	15
Biosimilars	2,015	977	106
Research services	808	645	25
Inter-segment	(101)	(89)	13
Revenue from operations #	3423	2140	60
Other income	94	78	20
Total Revenue	3516	2217	59
Net R&D Expenses	315	198	59
Gross R&D Spend	324	223	45
EBITDA	808	478	69
EBITDA Margins	23%	22%	
Core EBITDA*	936	661	
Core EBITDA Margins*	28%	31%	
PBT	184	197	(7)
Net Profit (before Minority Interest )	149	167	(11)
Net Profit	101	144	(30)

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

## Notes to financials above:

## **Financial Commentary: Q1FY24**

Consolidated Revenues for Q1FY24 grew 59% year-on-year (YoY) to Rs 3,516 crore.

**Core EBITDA** grew **42**% to **Rs 936** crore, representing healthy **core operating margins** of **28**% **Net R&D investments** for the quarter grew by **59**% to **Rs 315 crore**, representing 12% of revenues ex-Syngene.

**EBITDA** for the quarter increased by **69%** to **Rs 808** crore, representing an **EBITDA margin of 23%** versus 22% in the same period last year.

**Depreciation, amortisation and interest** increased by Rs 353 crores over last year. This is primarily related to the biosimilar business acquisition cost.

Consequently, Profit Before Tax stood at Rs 184 crore.

**Net Profit** for the quarter, before minority interest was **Rs 149 crore.** 

Net Profit for the quarter stood at Rs 101 crore.

<sup>\*</sup> Core EBITDA excludes R&D expense, licensing income, forex movement, dilution gain in Bicara and mark-to-market movement on financial instruments





## **CORPORATE HIGHLIGHTS**

## **Board Update**

**Dr. Vijay Kuchroo** has completed his second term as an Independent Director on the Board of Biocon Limited as of July 26, 2023. On behalf of Biocon's Board of Directors and management, the Company expresses its deep appreciation and gratitude to Dr. Kuchroo for his stewardship and extensive contribution to the organization's growth.

**Rekha Mehrotra Menon** has been appointed as an **Independent Director** on the Board of Biocon Limited with her term commencing from July 26, 2023 till the conclusion of 48th AGM to be held in 2026, subject to the approval of the shareholders of the Company at the ensuing 45th AGM.

Rekha is a leading industry voice on technology-fueled innovation and socio-economic progress. She was a key player in Accenture's growth for nearly 20 years including over 7 years as Chair of Accenture in India. She was the first woman to serve as the Chair of NASSCOM. She is currently on the boards of the XLRI Xavier School of Management and Invest India, the National Investment Promotion and Facilitation Agency.

**Nicholas Robert Haggar** has also been appointed as an **Independent Director** on the Biocon Limited Board, subject to the completion of necessary formalities under the Companies Act, 2013.

He has over 30 years of experience in leading and building pharmaceutical and healthcare enterprises and has been successfully guiding innovation and increasing access to medicines, with deep commitment to patients, compliance, quality and sustainability. Nicholas has held the position of Chairman of Zentiva SA; CEO, Insud Pharma SL; President of Medicines For Europe; and Regional Director, Sandoz. He is currently the CEO & Founder of HealthQube Ltd and a Non-Executive Director of Zentiva.

# **Management Announcement**

## **Biocon Limited**

Biocon Limited (BL) has appointed **Maninder Kapoor Puri** as **Head of Human Resources** for the Generics business and Biocon Academy. She will also be a member of BL's Executive Leadership Team. She joins BL from the Mastek Group and brings over 25 years of experience, having held leadership roles with Companies including Accenture, iGate and First Source Solutions. Maninder completed her Masters in English Literature, followed by a CHRO degree from Wharton Business School.

## **Biocon Biologics**

Biocon Biologics Limited (BBL) has appointed **Rhonda Duffy** as **Chief Operating Officer** (COO) to lead Quality, Supply Chain and Manufacturing. She brings over 30 years of experience in the global biopharmaceuticals industry and has successfully improved operational output and performance, accelerated the adoption of technology, enhanced quality standards and worked closely with R&D to develop and launch new products.

**David Gibson** has been appointed as **Global Head – Business Development** to lead all licensing, strategic partnering and business development activities. He has over 24 years of experience in leadership roles spanning Business Development, Product Development, Venture Capital and R&D at large pharma MNCs.





# **Environment, Social & Governance**

The Company published its **first Global Reporting Index (GRI)** aligned Integrated Report (IR) for **FY23**. The transition to an integrated report underscores our commitment to delivering sustainable value and presents a holistic overview of our performance over the last financial year both from a financial and non-financial perspective. By voluntarily adopting this practice, we are demonstrating our commitment to upholding good governance principles and responsible business practices. A copy of the IR FY23 can be downloaded from the Company's website.

In the latest report published by **FTSE Russell** that was released in June 2023, Biocon's score improved to 3.6 from 3.2, in the previous year, on a scale of 5. This is better than the global healthcare industry average of 2.3, as well as the average score of Indian companies, Biocon's percentile **rank jumped to 78** from 63. Biocon continues to be a constituent of the FTSE4Good Index Series.

Biocon's ongoing commitment towards sustainability continues to be recognized. During the quarter the Company featured among the **Top 30 sustainable companies** in India by BW Businessworld, a leading business magazine of India.

# **Business Highlights**

## **GENERICS: APIs & Generic Formulations**

Q1FY24 Revenue at Rs 700 Crore up 15% (YoY) from Rs 607 Crore in Q1FY23.

## **Business Performance**

The Generics business secured new contracts and delivered higher volumes from its products in the U.S., as well as launched new product in key MoW markets, which contributed to the segment's growth in the quarter. API immunosuppressants also saw an increase in volumes.

The Company received approval for Vigabatrin tablets and a tentative approval for Lenalidomide capsules in the U.S. In Europe, approval was obtained for Mycophenolic acid DR tablets. The Company also secured new tenders for two formulation products in Europe.

The US FDA conducted a GMP pre-approval inspection of the Oral Solid Dosage facility of Biocon Pharma Limited (BPL) in Bengaluru for which the Establishment Inspection Report was received in June 2023, with the inspection outcome categorized as No Action Indicated.

The Hyderabad API facility, at which a pre-approval inspection was conducted in May 2023, received the Establishment Inspection Report in August 2023, with the inspection outcome categorized as No Action Indicated.

During the quarter, ground-breaking for the new injectable facility in Bengaluru was conducted. Process validation for the immunosuppressant facility in Vizag and the Peptides facilities in Bengaluru are on track for completion by H1 FY24.





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

- Q1FY24 Revenue at Rs 2,015 Crore, up 106% (YoY) from Rs 977 Crore in Q1FY23.
- 7 product launches and five approvals across both Advanced & Emerging Markets.
- Served ~5.7 million patients (MAT June 2023)##

##12-month moving annual patient population (July 2022 to June 2023)

## **Business Performance**

**Biocon Biologics** reported a strong YoY **growth** of **106%** for Q1FY24 with **revenues** at **Rs 2,015** crore, led by the strong performance of its key biosimilars in Advanced and Emerging markets and the consolidation of revenues from the acquired business. Market shares of our key brands are gaining traction reflecting an increase in demand across several markets.

Core EBITDA stood at Rs 513 crore, up 42%, reflecting margins of 28%. During the quarter, Net R&D investments stood at Rs 259 crore, representing 13% of Biocon Biologics revenue for the quarter. EBITDA for the quarter stood at Rs 457 crore, up 141%, representing an EBITDA margin of 23%. Profit Before Tax for the quarter stood at Rs 24 crore.

The revenues and margins for the quarter were impacted due to phasing of the tender business in Emerging Markets and higher rebates for Pegfilgrastim in the U.S., based on legacy contracts with select customers which will normalize in the coming quarters.

### **Advanced Markets**

## **North America**

Biocon Biologics launched its fourth biosimilar in the U.S., **Hulio**<sup>®1</sup> (adalimumab-fkjp) injection, a biosimilar to Humira<sup>®2</sup>, in July after five years of experience in Europe and two years in Canada. This launch is an important milestone for Biocon Biologics as it builds on the Company's strong presence in oncology and diabetes and expands its patient offering in the U.S. to include a new product for immunology.

Market shares for the Company's existing commercialized biosimilars in the U.S. are trending positively. **Fulphila**® (bPegfilgrastim) has become the leading biosimilar in its category with a market share of 16%. Similarly, **Semglee**® + unbranded **bGlargine** together reported a market share of 12% in the U.S. and **Ogivri®** (bTrastuzumab) steadily improved its share to 11%. (Source: IQVIA June 2023).

The Company has unlocked new growth opportunities for its biosimilar Insulin Glargine. A large, managed care integrated network has selected our bGlargine as the exclusive long-acting insulin for its members in the U.S. effective July, while another large payor has signed up for our product as the exclusive Insulin Glargine for its formulary, effective January 2024.

## **Europe**

In Europe, the Company's product **Yesafili®** became the first biosimilar Aflibercept, to receive a positive opinion, from the European Medicines Agency's Committee for Medicinal Products for

<sup>1</sup> Hulio is a registered trademark of Fujifilm Kyowa Kirin Biologics Co., Ltd., licensed to the Viatris Companies. Effective November 29, 2022, Viatris completed the sale of substantially all of its biosimilars portfolio (including related product trademarks) to Biocon Biologics Limited and its subsidiaries ("Biocon") and the relevant marketing authorizations are in the process of being transferred.

<sup>&</sup>lt;sup>2</sup> Reference product, a registered trademark of AbbVie Inc.





Human Use (EMA- CHMP), recommending an approval of the product. The European Commission's decision on the approval is expected by the end of September 2023.

The Company's key biosimilars such as **Ogivri®**, **Hulio®**, **and Fulphila®** built on their strong position in key European countries. **Ogivri®** reported a robust 34%³ market share in Poland and 20%⁴ market share in Italy. **Hulio®**'s market share in Germany was 18% and 12% in France respectively. **Fulphila®** garnered a 13% market share in France. **Abevmy®** (bBevacizumab) also reported a substantial increase in market share, moving up to 5% from 1% last year (*Source: IQVIA May 2023*).

Biocon Biologics steadily progressed in exploring additional business opportunities in key clusters during the quarter. The Company launched its three key biosimilars, **Abevmy**<sup>®</sup> (bBevacizumab), **Ogivri**<sup>®</sup> (bTrastuzumab) and **Hulio**<sup>®</sup> (bAdalimumab), in four Advanced Markets.

## **Emerging Markets**

Post completion of the acquisition in November 2022, the integration process is in full swing. Biocon Biologics has completed the transition of the **acquired biosimilars business in over 70 countries** in emerging markets, effective July 1, 2023, thus increasing the scale and scope of its business.

This is a key milestone for the Company as it marks the completion of the first phase of the business integration plan, completed ahead of its schedule. This will allow the Company to meaningfully expand the geographic reach of the existing biosimilars portfolio and future pipeline into growth markets where Viatris has existing sales infrastructure and local market expertise. More than 60 customers related to the acquired business have been integrated into Biocon Biologics' emerging markets operations.

During Q1FY24, the Emerging Markets (EMs) business was driven by a steady performance of key products, **rh-Insulin, Insulin Glargine**, and **bTrastuzumab**, across many markets. The Company also launched two products in the LATAM region and received approvals for four products in five countries. Several tenders for **bTrastuzumab**, **bBevacizumab**, **bPegfilgrastim** and **bGlargine** were won in some countries in LATAM and AFMET regions. All these developments augur well for the business, going forward.

## **RESEARCH SERVICES: Syngene**

Q1FY24 revenue at Rs 808 Crore, up 25% (YoY) from Rs 645 Crore in Q1FY23

### **Business Performance**

Syngene reported a strong Q1FY24 performance, led by Development and Manufacturing Services and well supported by its research divisions: Discovery Services and the Dedicated Centers. In Manufacturing Services, the Company continued to make good progress on the long-term contract for Zoetis. Additionally, it acquired a facility from Stelis Biopharma Ltd, which adds 20,000 liters of installed biologics drug substance manufacturing capacity, and a high-speed, commercial scale fill-finish unit. This facility is expected to be operational in 2024, following upgrades and re-validation. In small molecule manufacturing, it received U.S. Food and Drug Administration (FDA) approval for its commercial manufacturing facility in Mangaluru.

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<sup>3,4</sup> Market share in intravenous market





Development Services continued the strong operational delivery of the previous quarter. In Discovery Services, Syngene acquired 17 acres of land in Genome Valley, Hyderabad, to accommodate future growth, and expects to procure statutory clearances for commencement of construction in 2024.

The Dedicated Centers continued to perform positively in line with the plan.

## 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, Europe & key emerging markets. 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. (BBL)**, a subsidiary of Biocon Ltd., is a unique, fully integrated, global biosimilars company committed to transforming healthcare and transforming lives by enabling affordable access to high quality biosimilars for millions of patients worldwide. It is leveraging cutting-edge science, innovative tech platforms, global scale manufacturing capabilities and world- class quality systems to lower costs of biological therapeutics while improving healthcare outcomes.

BBL has acquired the global biosimilars business of its long-standing partner Viatris, which is a historic milestone in its value creation journey. Biocon Biologics has commercialized eight biosimilars in key emerging markets and advanced markets like U.S., EU, Australia, Canada, Japan. The Company has a pipeline of 20 biosimilar assets across diabetology, oncology, immunology, and other non-communicable diseases. It has many 'firsts' to its credit in the biosimilars industry. As part of its environmental, social and governance (ESG) commitment, BBL is advancing the health of patients, people and the planet to achieve key UN Sustainable Development Goals (SDGs).

Website: www.bioconbiologics.com; Follow us on Twitter: @BioconBiologics for company updates.

FOR MORE INFORMATION		
MEDIA	INVESTORS	
Biocon Group & Biocon Biologics	Biocon	
Seema Ahuja	Saurabh Paliwal	
Global Head of Corporate Brand	Head - Investor Relations	
& Communications		
	+91 95383 80801	
+91 99723 17792	⊠ saurabh.paliwal@biocon.com	
seema.ahuja@biocon.com		
Biocon		
For Generics business		
Calvin Printer		
Head - Corporate Communications		
+91 70329 69537		

#### **Earnings Call**

The management of the Company will host an Earnings Call on 11th<sup>th</sup> August 2023 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 March 31, 2023. Transcript of the conference call will be uploaded on the company website in due course.





Zoom Webinar Details		
Date	11th August, 2023	
Time	9:00hrs -10:30hrs IST	
Join Zoom Webinar	< https://bit.ly/BLQ1FY24EarningsCall > to attend earnings call	

## **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.