



PRESS RELEASE

Biocon Q2FY24 Revenue at Rs 3,620 Cr, Up 52%; Biosimilars Up 97%; Research Services Up 18% EBITDA at Rs 900 Cr, Up 68%; Core EBITDA at Rs 1,100 Cr, Up 35% Net Profit at Rs 126 Cr, Up 168%

Bengaluru, Karnataka, India: November 10, 2023:

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

Q2FY24 Financial Highlights					
Rs 3,620 Crore CONSOLIDATED REVENUE	Rs 1,100 Crore CORE EBITDA		Rs 900 Crore EBITDA		
Up 52% (YoY)	Up 35% (YoY)		Up 68% (YoY)		
Rs 126 Crore NET PROFIT Up 168% (YoY)	32% CORE EBITDA MARGIN		25% EBITDA MARGIN		
Q2FY24 Business Segments Revenue					
Rs 676 Crore GENERICS: APIs & Generic Formulations Up 4% (YoY)		SEGMENTAL REVENUE CONTRIBUTION			
Rs 1,969 Crore BIOSIMILARS: Biocon Biologics Limited Up 97% (YoY)			Bosiniars Research Services Generics		
Rs 910 Crore RESEARCH SERVICES: Syngene Up 18% (YoY)		26%	55%		





Leadership Comments

BIOCON GROUP

Kiran Mazumdar-Shaw, Executive Chairperson, Biocon and Biocon Biologics, said: *"Biocon reported a strong revenue growth this quarter of 52% YoY at Rs 3,620 crore led largely by a revenue rise of 97% in Biosimilars. EBITDA increased by 68% YoY to Rs 900 crore, a margin of 25%. Biocon Biologics is now driving the business in North America and most of the Emerging Markets, and integration of the acquired business in Europe and a few remaining countries is expected to be completed during the year. The Generics Business has expanded its geographic manufacturing presence with the acquisition of an oral solid dosage manufacturing facility in the U.S. Syngene expects Biomanufacturing to drive future growth which will be bolstered by the proposed acquisition of a large-scale facility in Bengaluru. The three businesses are focused on their strategic goals aimed at profitable growth, going forward."*

BIOCON GENERICS

Siddharth Mittal, CEO & Managing Director, Biocon Limited, said: *"The Generics business delivered a modest year-on-year revenue growth. Our Generic Formulations business gained momentum on the back of an uptick in statin volumes, recently launched products and expansion in MoW markets. The performance of our API business was subdued as customer demand moderated and a planned maintenance shutdown for one of our key products led to a phasing of supplies.*

"In line with our expansion strategy for the North American market, we acquired the U.S. FDAapproved oral solid dosage manufacturing facility in the United States, which will enable us to add capacities for new products and better support our customers. Looking ahead, we expect an improved performance in the second half of the fiscal with sustained delivery in Generic Formulations and some recovery in our API business."

BIOCON BIOLOGICS

Shreehas Tambe, CEO & Managing Director, Biocon Biologics Limited, said, *"Biocon Biologics has continued its growth momentum and delivered a nearly 100% year-on-year revenue growth. This is largely driven by the acquisition of Viatris' biosimilars business and the growth in market shares for our products in the U.S. and Europe, as we win new customers. The robust demand for our Insulins portfolio in Emerging Markets will continue to drive growth in these markets and expand access to affordable life-changing treatments. This quarter we successfully transitioned the acquired business from Viatris in North America, and now look forward to integrating the remaining markets, including Europe, Japan, Australia, and New Zealand, later during the year, which is a significant acceleration over plan."*

SYNGENE

Jonathan Hunt, CEO & Managing Director, Syngene, said, "I'm pleased with the positive performances across all divisions of Syngene, led by Development and Manufacturing Services. We continued to add capabilities and commissioned a non-GMP facility to meet market demand for agile, cost-efficient, early phase development and scale-up services. We also commissioned a state-of-the-art, digitally enabled Quality Control laboratory that will play a pivotal role in maintaining the standards that underpin all biologics operations."





FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q2FY24

Particulars	Q2FY24	Q2FY23	YoY (%)
INCOME			
Generics	676	652	4
Biosimilars	1,969	997	97
Novels	_	_	_
Research services	910	768	18
Inter-segment	(93)	(98)	(5)
Revenue from operations #	3,462	2,320	49
Other income	158	65	145
Total Revenue	3,620	2,384	52
Net R&D Expenses	264	242	9
Gross R&D Spend	278	252	10
EBITDA	900	535	68
EBITDA Margins	25%	22%	
Core EBITDA*	1,100	815	35
Core EBITDA Margins*	32%	35%	
PBT (before exceptional items^)	238	246	(3)
РВТ	214	229	(6)
Net Profit (before exceptional items)	142	168	(16)
Net Profit	126	47	168

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

Notes to financials above:

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

^Exceptional items during Q2 FY24 amount to Rs 24 crore, pertaining to Product Linked Incentive accrual reversal for FY23 consequent to cap on annual claim allocation, and transaction costs on the proposed acquisition of Stelis unit by Syngene

Financial Commentary: Q2FY24

Consolidated Revenues for Q2FY24 grew 52% year-on-year (YoY) to Rs 3,620 crore. Core EBITDA grew 35% to Rs1,100 crore, representing healthy core operating margins of 32%. Net R&D investments for the quarter grew by 9% to Rs 264 crore, representing 10% of revenues ex-Syngene.

EBITDA for the quarter increased by **68%** to **Rs 900** crore, representing an **EBITDA margin of 25%** versus 22% in the same period last year. **Depreciation, amortisation and interest** increased by Rs 376 crore over last year. This is primarily related to the biosimilar business acquisition cost.

Profit Before Tax and exceptional items stood at Rs 238 crore. Reported Net Profit for the quarter stood at Rs 126 crore vs Rs 47 crore last year.





CORPORATE HIGHLIGHTS

Management Announcements

Biocon Limited

Biocon Limited has appointed **Peter Bains** as the **Group CEO**, reporting directly to Biocon Group Chairperson Kiran Mazumdar-Shaw. Peter will be responsible for driving synergies between the three group entities to maximize the combined value for the stakeholders at the group level. The Biocon Group CEO is an executive position with a strategic advisory role.

Siddharth Mittal, CEO & MD Biocon Ltd, Shreehas Tambe, CEO & MD Biocon Biologics Ltd. and Jonathan Hunt, CEO & MD, Syngene International Ltd., will continue to have independent charge of their businesses and will work with Peter to strengthen synergies at a Group level to capitalize on the shared value created by the three businesses.

Nitin Tiwari has been appointed as **Head of Quality** for the Generics business. He has close to three decades of experience at leading pharma companies, ensuring quality and compliance for a diverse range of dosage forms including oral solids, sterile injectables, vaccines, biologics and APIs.

Biocon Biologics

Kedar Upadhye has been appointed as the **Chief Financial Officer** to lead **Biocon Biologics into the next phase of profitable growth**. Kedar brings over 23 years of experience in senior global leadership roles spanning Corporate Finance, Strategy, Accounting, FP&A, Business Finance, Governance and Investor Relations at leading pharma, energy and FMCG companies. Prior to joining Biocon Biologics, he was CFO for a Nasdaq-listed energy company and was previously the Global CFO of a leading pharma company.

The Company has appointed **Dr. Uwe Gudat** as the **Chief Medical Officer** to support its global ambitions and its rich product pipeline. He has over 10 years of experience with biosimilars and has worked at leading global pharmaceutical companies for 28 years.

Dr. Arlene Wolny has also joined Biocon Biologics as the **Global Head of Regulatory Affairs**. She brings with her over 20 years of experience in regulatory affairs and a proven track record of successfully engaging with key agencies to accelerate drug development and submission timelines. Prior to joining Biocon, she led regulatory affairs for the Biosimilars business of a leading global pharma company.

Ramprasad Bhat has joined Biocon Biologics as **Vice President – Head of Branded Formulations India**. He has rich experience of over 28 years with leading pharma companies, including MNCs.

Purpose and ESG

Business Achievements:

• Biocon Biologics received the 'Acquisition of the Year' Award at the Global Generics & Biosimilars Award 2023 held alongside CPhI Worldwide in Barcelona, Spain.





Endorsed as a Premier Global Employer:

 Biocon (including Biocon Biologics) has retained its No. 8 rank among the Top 10 Employers in the global biotech, pharma and biopharma sector in 2023. This is an endorsement of Biocon's key attributes such as being an 'innovative leader in the industry,' being 'socially responsible,' and a company with 'loyal employees' by the U.S.-based *Science* magazine.

Being Recognized for ESG Practices:

- Biocon received the **Golden Peacock Award for ESG** in recognition of its outstanding initiatives in the field of ESG at the 2023 Annual London Global Convention on Corporate Governance & Sustainability, London (UK).
- **Biocon Biologics** has been conferred with the **Special Jury Appreciation 2023 Award** in the 'Healthcare' category for supporting 'Oral Cancer Control Program (OCCP) using the mHealth App' at the 10th edition of the **National CSR Times Summit and Awards**.
- Biocon Foundation has been awarded the prestigious 9th Dalmia Bharat- CSRBOX CSR Impact Award 2023 in the 'Healthcare (Small)' category for its Oral Cancer Screening Program.
- Biocon Foundation also received the 'Gold Green Environment Stewardship Award' for its urban resilience program aimed at rejuvenating lakes in Bengaluru at the 10th edition of the National CSR Times Summit and Awards.

Awarded for Patient-Centric Initiatives:

 Biocon Biologics has won two 'Patients First Awards' from the India Health and Wellness (IHW) Council; Gold Award as a 'Patient-Centric Pharmaceutical Company in Diabetes Care' and Silver Award as a 'Patient-Centric Pharmaceutical Company in Kidney Care' for its doctorpatient support programs.

Business Highlights

GENERICS: APIs & Generic Formulations

• Q2FY24 Revenue at Rs 676 Crore up 4% (YoY) from Rs 652 Crore in Q2FY23.

Business Performance

Performance during the quarter was led by growth in the Generic Formulations business, resulting from higher statin volumes, as well as contributions from recently launched products in the U.S. The Company launched an in-licensed product, **Famotidine oral suspension**, used in the treatment of ulcers and gastroesophageal reflux disease (GERD), in the U.S. In line with its MoW expansion strategy, the business launched its first drug product, **Mycophenolic Sodium tablets**, in Israel.

A contraction in demand for some API products on account of pricing pressures, coupled with phasing of supplies due to a planned maintenance shut down, impacted the performance of the API business.

Approvals were obtained for an in-licensed product, **Rivaroxaban tablets** in the EU, as well as for **Posaconazole tablets**, **Mycophenolic Acid tablets**, **Tacrolimus capsules** and **Sacubitril/Valsartan tablets** in select MoW markets.





In the U.S., the Company **acquired an oral solid dosage manufacturing facility** of Eywa Pharma Inc. located in Cranbury, New Jersey, through its step-down, wholly owned subsidiary, Biocon Generics Inc. The acquisition will enhance Biocon's existing manufacturing capabilities and provide impetus to the region's growth strategy by enabling capacities for new products earlier than planned and ensuring continuity of supply. The transition of employees to Biocon is complete and the qualification process of the site for some of the Company's products has commenced.

In October 2023, the Company **signed a partnership agreement** with Juno Pharmaceuticals in Canada, for the commercialization of **Liraglutide**, used in the treatment of Type 2 diabetes and obesity. The partnership will add momentum to Biocon's strategic focus on geographical expansion.

Process validation was successfully completed at the greenfield immunosuppressant API facility in **Visakhapatnam**, with qualification activities to commence shortly. Commercial supplies from the site are expected to begin in FY25, post qualification by global regulators.

NOVEL BIOLOGICS

Biocon's Boston-based associate **Bicara Therapeutics** presented recent, positive interim data from its ongoing, open-label Phase 1/1b dose expansion study of BCA101, at the European Society for Medical Oncology (ESMO) Congress evoking strong investigator interest. The Company is in an advanced stage of a Series C fund raise.

Bicara had previously announced a USD 108 million Series B financing, which is being realized in a staggered manner. As a result, during the quarter, a step-up gain of Rs 75 crore was recorded in the consolidated P&L statement.

BIOSIMILARS: Biocon Biologics Limited (BBL) -

- Q2FY24 Revenue at Rs 1,969 Crore, up 97% (YoY) from Rs 997 Crore in Q2FY23.
- 4 launches and 11 approvals in Emerging Markets.
- Served ~5.5 million patients (MAT September 2023) ##

##12-month moving annual patient population (October 2022 to September 2023)

Business Performance

Biocon Biologics reported a YoY **growth** of **97%** for Q2FY24 with **revenues** at **Rs 1,969 crore**, driven by the consolidation of the acquired business and sustained growth from the core business across Advanced and Emerging Markets.

Core EBITDA at **Rs 660 crore**, grew by 47%, reflecting healthy **margins** of **34%**. During the quarter, **Net R&D investments** stood at **Rs 211 crore**, representing **11%** of Biocon Biologics' revenue for the quarter, a reflection of the continued progression of its pipeline assets.

EBITDA for the quarter reported a growth of 112 % at **Rs 453 crore**, **representing** an **EBITDA margin** of **23%**.





Advanced Markets

North America

In-market products continue to perform well with double-digit market shares, reflecting customer and key stakeholder confidence. Fulphila[®] (bPegfilgrastim) has consolidated its position as a leading biosimilar in its category with its share in the U.S. market growing to ~19%. Unbranded bGlargine along with Semglee[®] and Ogivri[®] (bTrastuzumab) held steady market shares at ~12% and 11%, respectively. For Adalimumab, the adoption of biosimilars has been slower than anticipated across the market, which has softened adoption of our brand Hulio[®] as well.

The Company has focused on expanding market access to drive adoption of Hulio[®], a biosimilar to HUMIRA[®](Adalimumab). It continues to engage customers to add Hulio[®]/Adalimumab-fkjp Injection to their formularies across all channels. CVS Caremark has added Biocon Biologics' unbranded Adalimumab-fkjp Injection, as a formulary option for a select number of its formularies, effective October 1, 2023. Similarly, one of the largest Medicaid managed care organizations in the U.S. has added unbranded Adalimumab-fkjp Injection to its National Preferred Formulary for Medicaid members covering seven million lives. A large U.S. payor covering 100 million lives has added Ogivri[®] and Fulphila[®] to their 2024 preferred medical drug list.

Europe

In Europe, Abevmy[®] (bBevacizumab) reported a significant increase in market share over the last two quarters to 6%, while Fulphila[®] saw a steady uptick in its market share to 7%. Hulio[®] maintained a steady market share of 6% overall in Europe with shares of 18% in Germany and 11% in France. Fulphila[®] improved its market share to ~14% in France. *(Source: IQVIA Q2 CY 2023).* The Company also launched bAspart in Germany.

Biocon Biologics received the European Commission's approval for YESAFILI[®], a biosimilar Aflibercept that could make a meaningful difference to patients in the EU impacted by macular degeneration and diabetic retinopathy. The EU brand sales of Aflibercept stood at ~USD1.8 billion *(MAT December 2022 IQVIA)*.

Emerging Markets

The business in Emerging Markets continued to see a steady performance with growth being largely driven by bGlargine and bTrastuzumab in LATAM and APAC regions. There were four product launches and 11 approvals of key products in Emerging Markets, which augur well for the future.

Biocon Biologics has divested two non-core business units, Dermatology and Nephrology, of its Branded Formulations India (BFI) business through a 'slump sale' to Eris Lifesciences for a total transaction value of Rs 366 crore inclusive of working capital adjustment. This value accretive deal allows the Company to unlock value from the BFI business and sharpen focus on its core therapy areas like Diabetes, Oncology and Immunology.

Integration of Viatris Business

The transition of the acquired biosimilars business in North America was successfully completed ahead of schedule in September 2023 and Biocon Biologics is now leading the commercial operations in the U.S. and Canada. The business transition plans in Europe, JANZ (Japan, Australia and New





Zealand and the remaining few Emerging Markets are on track for completion later during the year, which will complete the integration of the acquired business.

RESEARCH SERVICES: Syngene

• Q2FY24 revenue at Rs 910 Crore, up 18% (YoY) from Rs 768 Crore in Q2FY23

Business Performance

In Q2FY24, the Research Services business delivered positive performances across all divisions led by Development and Manufacturing Services, while the Dedicated Centers business showed sustained growth. The Manufacturing Services vertical reported good progress on the back of their biologics manufacturing agreement with Zoetis.

Syngene continued to invest in capacity building and commissioned a state-of-the-art, digitally enabled Quality Control laboratory to support the growing biologics operations. It also commissioned a non-GMP facility in Bengaluru to add to its capability of doing early-phase development projects in an agile and cost-effective manner.

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., Europe, Australia, Canada, and Japan. The Company has a pipeline of 20 biosimilar assets across diabetology, oncology, immunology, ophthalmology, 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 and LinkedIn: <u>Biocon Biologics</u> for company updates.





FOR MORE INFORMATION

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Earnings Call

The management of the Company will host an Earnings Call on 10th November 2023 at 18:30 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 is given below as well as on the company website <u>www.biocon.com</u> under Investors>>Financial Calendar>>Earnings Call for period ended September 30, 2023. Transcript of the conference call will be uploaded on the company website in due course.

Zoom Webinar Details		
Date	10th November, 2023	
Time	18:30 - 20:00 IST (UTC+05:30)	
Join Zoom Webinar	Click here 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, conditions 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.