



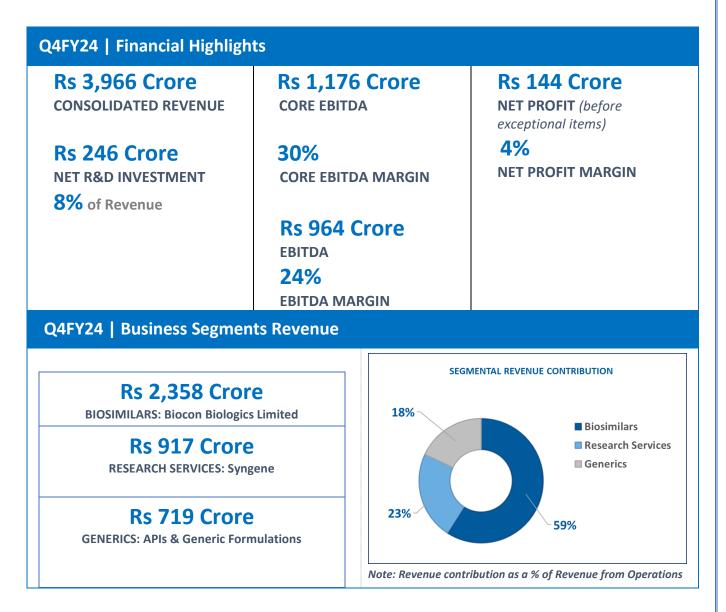
## PRESS RELEASE

# Biocon Q4FY24 Revenue at Rs 3,966 Cr, EBITDA at Rs 964 Cr; Net Profit (before exceptional items) at Rs 144 Cr

# FY24 Revenue at Rs 15,621 Cr, Up 35%; EBITDA at Rs 4,164 Cr, Up 44% Net Profit (before exceptional items) at Rs 1,030 Cr, Up 31% Biosimilars Revenue in FY24 Crosses USD 1 Bn

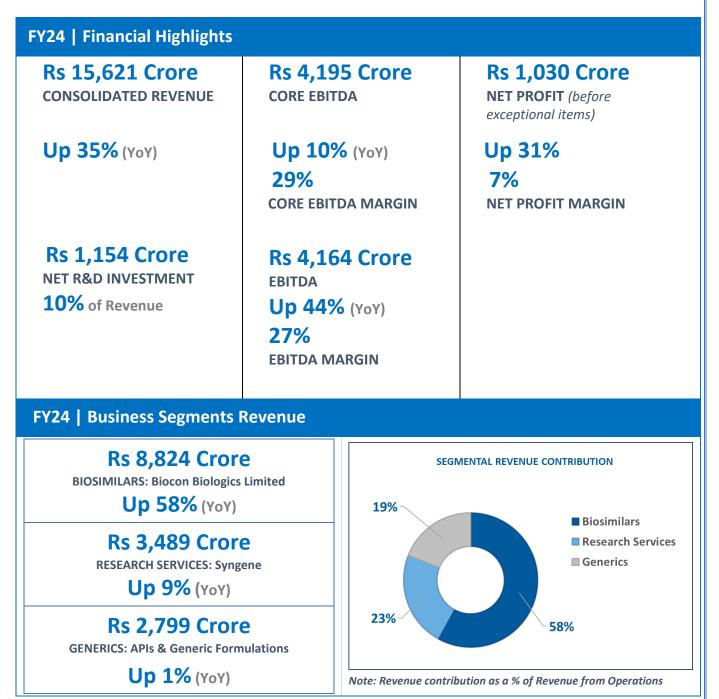
## Bengaluru, Karnataka, India: May 16, 2024:

**Biocon Limited** (BSE code: 532523, NSE: BIOCON), an innovation-led global biopharmaceuticals company, today announced its consolidated financial results for the fiscal fourth quarter and the financial year ended March 31, 2024.









## **Leadership Comments**

## **BIOCON GROUP**

"Q4FY24 performance was strongly led by Biologics that delivered the promised billion-dollar annual revenue milestone marking the successful transition of the Biosimilars acquisition from Viatris. Increased market shares of key products in the U.S., Europe and Emerging Markets coupled with significant volumes growth were the highlights of the Biosimilars business this quarter. With the recent approval of Liraglutide in the UK, we added to our list of 'global firsts' and demonstrated our capability in developing complex GLP-1 products which will be the key growth driver for the Generics business, going forward. Syngene is well positioned to benefit from the 'China Plus One' strategy which is being rapidly adopted by U.S. Pharma & Biotech companies.





"For the full year FY24, we reported consolidated revenue growth of 35% at Rs 15,621 crore and an EBITDA growth of 44 % at Rs 4,164 crore with healthy EBITDA margins of 27%. This growth was largely driven by Biosimilars which grew 58% to Rs 8,824 crore.

"The Biocon Group has strengthened business operations, expanded global reach and is now increasingly well positioned to deliver a new phase of growth spanning Biosimilars, GLP-1 peptides and CDMO services."

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

#### **BIOCON GENERICS**

"We concluded FY24 with the Generics business posting a modest revenue growth. Generic Formulations reported a healthy 36% growth, as our products, particularly statins and immunosuppressants, gained traction across multiple geographies. This was offset by a degrowth in APIs on account of pricing pressure the business encountered, which impacted demand.

"Our preparations for entering the GLP-1 market opportunity is building momentum and we are pleased with the recent approval of Liraglutide in the UK, making Biocon the first generics Company to be approved for this product in an ICH or major regulated market. More importantly, the approval validates our scientific and development capability in bringing vertically integrated, complex peptide drug-device products to the market. This augurs well for us to capture GLP-1 opportunities that will drive our future growth.

"Our focus in FY25 will be directed towards launching new products and expanding our geographic reach through a direct presence and strategic partnerships. We will continue to focus on multiple cost improvement initiatives. We also intend to build upon our initial regulatory success in our peptide and GLP-1 focused pipeline in strategic markets."

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

## **BIOCON BIOLOGICS**

"This has been a remarkable year for Biocon Biologics, as we evolved into a fully integrated global company with a presence in over 120 countries. We successfully integrated the acquired business 1 year ahead of plan, while ensuring business continuity and a seamless experience for our patients, customers, and partners. This is reflected in the numbers as our revenues crossed USD 1 billion for the full year with a healthy EBITDA margin, underpinned by a significant increase in market shares of our key products in the U.S., Europe, and Emerging Markets. Our R&D pipeline too has progressed as planned and having secured market entry dates for 2 new products in U.S. and Canada, these products will serve to accelerate growth in the coming years.

"During the year, we reduced our acquisition debt. We also entered into a long-term strategic collaboration to distribute our products in India while retaining exclusive supply rights. FY24 has been a transformational year as we leverage our expanded global reach to address patient needs globally and unlock value for the benefit of all stakeholders."

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





#### SYNGENE

"Despite the reduced demand for research and development services within the U.S. biotech sector, stemming from a difficult funding environment, we delivered a 9% growth for the full year. This resilience is the result of our broad operating span and the investments made to establish our development and manufacturing divisions with biologics, in particular, delivering a strong performance throughout the year."

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

## FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q4FY24 & Full Year FY24

Particulars	Q4FY24	Q4FY23	YoY (%)	FY24	FY23	YoY (%)
INCOME						
Generics	719	744	(3)	2,799	2,765	1
Biosimilars	2,358	2,102	12	8,824	5,584	58
Novel Biologics	-	19	-	-	19	-
Research services	917	994	(8)	3,489	3,193	9
Inter-segment	(76)	(86)		(356)	(387)	
Revenue from operations #	3,917	3,774	4	14,756	11,174	32
Other income <sup>\$</sup>	49	155	(69)	866	376	130
Total Revenue	3,966	3,929	1	15,621	11,550	35
Net R&D Expenses	246	342	(28)	1,154	1,119	3
Gross R&D Spend	228	356	(36)	1,161	1,195	(3)
EBITDA	964	1,152	(16)	4,164	2,888	44
EBITDA Margins	24%	29%		27%	25%	
Core EBITDA*	1,176	1,260	(7)	4,195	3,807	10
Core EBITDA Margins*	30%	35%		29%	34%	
PBT (before Exceptional Items^)	328	500	(34)	1,537	1,189	29
РВТ	319	497	(36)	1,525	897	70
<b>Net Profit</b> (before Exceptional Items^^)	144	335	(57)	1,030	787	31
<b>Net Profit</b> (after Exceptional Items^^)	136	313	(57)	1,022	463	121
		•	•	•		

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

#### Notes to financials above:

\*Revenue from operations Includes licensing income. FY24 revenue from operations includes income from the divesture of two non-core business assets of Biocon Biologics' Branded Formulations India business amounting to Rs 350 crore in Q3 FY24.

<sup>\$</sup>Other income for FY24 includes a gain of Rs 530 crore mainly from dilution/ fair valuation of Biocon's holding in Bicara Therapeutics, resulting from Bicara's Series B and Series C financing.

\*Core EBITDA is EBITDA net of R&D expense, licensing, forex, dilution/fair valuation gain in Bicara, sale of non-core BFI assets and markto-market movement on investments.

^Exceptional items during Q4 FY24 and FY24 amount to Rs 9 crore and Rs 12 crore, respectively.

^^Net of tax and minority interest, exceptional loss during Q4 FY24 and FY24 amounted to Rs. 8 crore each, resulting in a Net Profit of Rs. 136 crore and Rs 1,022 crore, respectively. Please refer to Note 16: Exceptional Items in the published Financial Results





# **Financial Commentary: Q4FY24**

Total Consolidated Revenue for Q4FY24 grew 1% year-on-year (YoY) to Rs 3,966 crore. Core EBITDA at Rs 1,176 crore, represents core operating margins of 30%. Net R&D investments for the quarter were Rs 246 crore, representing 8% of revenue ex-Syngene. EBITDA for the quarter stood at Rs 964 crore, representing an EBITDA margin of 24%. Profit Before Tax and exceptional items stood at Rs 328 crore. Net Profit for the quarter, before exceptional items, stood at Rs 144 crore. Reported Net Profit for the quarter stood at Rs 136 crore.

## **Dividend for FY24**

The Board of Directors has recommended a final dividend of Rs 0.50 per share at the rate of 10% of the face value of the share, for the financial year ended March 31, 2024.

## **CORPORATE HIGHLIGHTS**

## **Biocon Limited Board Update**

**Atul Dhawan** has been appointed as an **Independent Director** on the Board of Biocon Limited with his term commencing from May 16, 2024, till the conclusion of the 49<sup>th</sup> Annual General Meeting (AGM) to be held in 2027, subject to the approval of the shareholders of the Company at the ensuing 46<sup>th</sup> AGM.

Mr. Atul Dhawan has served as the Chairperson of Deloitte South Asia Co-ordinating Board and represented India on Deloitte's Asia Pacific and Global Boards. Deeply committed to Deloitte's impact initiatives, he served on the boards of Deloitte Foundation in India and Making an Impact Foundation. Mr. Dhawan has held the position of Chair at the American Chamber of Commerce. Additionally, he serves on the Board of The Indus Entrepreneurs (TiE) in Delhi. He served on the CII National Council and is an Advisor to the U.S. India Strategic Partnership Forum (USISPF) Board for diverse campaigns focused on India. Mr. Dhawan also holds a position on the Board of Plan India, a not-for-profit organization dedicated to promoting development initiatives for women and children.

## Management Update

## **Biocon Limited**

**Vishal Nayyar** has been appointed as **Head** - **Supply Chain Management** at Biocon. He has over 30 years of experience in general management and in supply chain in the pharmaceuticals industry, including planning, procurement, logistics, strategic sourcing, and contract manufacturing.

**Amit Kaptain** has been appointed as the **Head** - **Commercial APIs** at Biocon, to take responsibility for the global APIs business, as well as for generic formulations in select emerging markets. Amit has over 30 years of experience in leading pharma companies, including more than 10 years in diverse senior leadership roles with P&L responsibilities.

## **Biocon Biologics Limited**

**Dwight D. Hanshew, Jr.** has been appointed as **Chief Quality Officer** at Biocon Biologics. Dwight brings over 30 years of experience leading engaged teams in Quality, Operations, Manufacturing and Research and Development.





# **Business Highlights**

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

- Q4FY24 Revenue at Rs 719 Crore, down 3% YoY
- FY24 Revenue at Rs 2,799 Crore, up 1%

## **Business Performance**

The Generics business saw several operational successes during the quarter especially in the formulations business which offset the impact of a muted performance in the APIs business. Revenue stood at Rs 719 crore for the quarter and Rs 2,799 crore for the full year.

Biocon became the first company to receive approval from the MHRA, UK, for its vertically integrated, complex formulation Liraglutide (gVictoza<sup>®</sup> and gSaxenda<sup>®</sup>). Victoza<sup>®</sup> is a drug device combination formulation used in the treatment of Type 2 diabetes, and Saxenda<sup>®</sup> is an injection in pre-filled pen, for the treatment of weight management, as an adjunct to a reduced calorie diet and increased physical activity.

The Company launched Liothyronine Sodium tablets, an in-licensed product, in strengths of 5 mcg, 25 mcg and 50 mcg, in the U.S. Liothyronine is used in the treatment of hypothyroidism, pituitary thyroid-stimulating hormone (tsh) suppression and thyroid suppression tests.

In April 2024, the Company also received its first approval in South Africa, from the SAPHRA, for its vertically integrated, complex immunosuppressant product, Tacrolimus capsule, used in the treatment of organ transplant patients.

The Company entered into two important commercial agreements. In April 2024, it signed an exclusive licensing and supply agreement with Biomm S.A. for the commercialization of Semaglutide (gOzempic<sup>®</sup>) in Brazil. Biocon will develop, manufacture, and supply the drug product, and Biomm will commercialize it in the region, post obtaining regulatory approval. Semaglutide is used in the treatment of Type 2 diabetes of adults, to improve glycemic control.

In May 2024, the Company signed a semi-exclusive distribution and supply agreement with Medix, a specialty pharmaceutical company in Mexico, for the commercialization of its vertically integrated drug product, Liraglutide (gSaxenda<sup>®</sup>), used in the treatment of chronic weight management.

In line with its regional expansion strategy, tenders were won in several markets, such as the U.K., Scotland, Singapore, and Saudi Arabia.

The Company received approvals for Rosuvastatin tablets in Malaysia and Lenalidomide capsules in Singapore.

There is a sustained momentum being built up in the formulations business driven by new product launches, strengthening of the U.S. business footprint and further traction in business expansion through both direct-to- market and strategic partnership models.





## **Regulatory Inspections**

Biocon Limited received GMP certificates from the Brazilian Health Authority, ANVISA, for two products from its API facility at Visakhapatnam (site 5) in March 2024, and in April 2024 for one product from its Bengaluru API facility (site 1). ANVISA also concluded an audit at its Hyderabad API facility (site 3), for 13 products, with no observations.

<sup>@</sup>Victoza<sup>®</sup>, Saxenda<sup>®</sup> and Ozempic<sup>®</sup> are registered trademarks of Novo Nordisk A/S.

#### **NOVEL BIOLOGICS**

The novel molecule, Itolizumab, continues to make progress. On April 1, 2024, Equillium, Biocon's U.S.-based partner, announced positive topline data from a Phase 1b EQUALISE study of Itolizumab in patients with Lupus Nephritis. The study demonstrated clinically meaningful response in highly proteinuric subjects, with more than 80% of subjects achieving over 50% reduction in urine protein creatinine ratio. Itolizumab demonstrated a favorable safety and tolerability profile.

In FY24, the Company recorded a gain of Rs 530 crore, arising from the dilution of Biocon's shareholding in Bicara to 14%, leading to loss of significant influence over Bicara. Henceforth, it is no longer an 'associate company' of the Biocon Group.

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

- FY24 Revenue crosses USD 1 Billion; up 58% at Rs 8,824 Crore
- Q4FY24 Revenue at Rs 2,358 Crore, up 12% YoY
- Served ~5.5 million patients (MAT March 2024 basis)##

##12-month moving annual patient population (April 2023 to March 2024) Business Performance

#### Q4FY24

Biocon Biologics reported a YoY growth of 12% for Q4FY24 with revenue at Rs 2,358 crore. Core EBITDA stood at Rs 698 crore, with Core EBITDA margin at 30%. EBITDA margins for the quarter were a healthy 24%.

#### **Financial Year FY24**

On a full-year basis, Biocon Biologics crossed the **USD 1 billion** annual revenue mark in FY24, with revenue at **Rs 8,824 crore**, reflecting a **58%** year-on-year growth driven by the consolidation of the acquired business and robust growth in the core business across advanced and emerging markets.

**Core EBITDA** grew by **11%** to **Rs 2,458 crore**. **EBITDA** for the year stood at **Rs 2,190 crore**, reporting a year-on-year growth of **64% with a margin of 25%**. The Company continued to invest in its pipeline to drive future growth with **R&D investments** at 10% of its revenue.

#### North America@

In the **U.S. market**, Biocon Biologics is benefiting from the integration of the acquired business, as evidenced by its performance in Q4FY24. With Biocon Biologics now spearheading commercial operations, the Company witnessed a significant step up in the market shares of its biosimilars in the U.S. The market share for **Ogivri®** (bTrastuzumab) increased to 18% from 10% in the same period last year. Biocon Biologics also secured four new commercial formulary agreements for Ogivri®, including UnitedHealthcare® Commercial Medical Benefit Drug Policy, effective May 1, 2024, as a





UnitedHealthcare Preferred Oncology Product. The share of **Fulphila®** (bPegfilgrastim) increased to 21% from 14% a year ago. Fulphila<sup>®</sup> is the only brand in its category to expand its market share.

**Semglee**<sup>®</sup> and our unbranded bGlargine market share improved to 15% from 12% the previous year, with Semglee<sup>®</sup> becoming the fastest growing brand in the basal insulins category in the U.S. in the quarter. In addition, unbranded bGlargine holds a strong market share with a closed-door pharmacy network which would add an additional 3% market share.

The U.S. FDA has accepted Biocon Biologics' Biologics License Application (BLA) for **Bmab 1200** (bUstekinumab) for review under the 351(k) pathway. The Company has signed a settlement and license agreement with Janssen Biotech Inc. and Johnson & Johnson that clears the way to commercialize Bmab 1200, Biocon Biologics' proposed biosimilar referencing Stelara®\*\*(Ustekinumab), subject to regulatory approval, in the U.S. no later than February 22, 2025. This will position Biocon Biologics among the first wave of entrants in the U.S. for bUstekinumab.

**In Canada,** the Company maintained a steady position across all products. Hulio<sup>®</sup> (bAdalimumab) market share increased to 7.5% from 6% a year ago. Biocon Biologics has also secured a contract to supply bGlargine to the country's largest retail outlet.

The Company also signed a settlement agreement with Bayer Inc. and Regeneron Pharmaceuticals Inc. for the launch of YESAFILI<sup>®</sup>, a proposed biosimilar to EYLEA<sup>®</sup>\*\*\* (Aflibercept injection) in Canada no later than July 1, 2025. The product has already been approved by Health Canada.

#### **Europe and JANZ<sup>&</sup>**

The Company achieved double-digit year-on-year revenue growth in both Europe and the markets of Japan, Australia, and New Zealand (JANZ). Biocon Biologics has successfully integrated all 31 countries in Europe by strategically adopting country-specific business models that include self-led markets with dedicated teams and some partner-led markets.

In Europe overall, market shares improved from the previous year, with Fulphila<sup>®</sup> at ~8% vs ~6% (Q4 CY '22) and Abevmy<sup>®</sup> at ~6% vs ~1% (Q4 CY '22). Hulio<sup>®</sup> has held its share at ~6%. At a country level, Hulio <sup>®</sup> has garnered market shares of 20% in Belgium, 18% in Germany and 11% in France and continues to remain a key value and growth contributor.

The Company has successfully integrated the acquired business in JANZ markets and signed on partners, establishing a foundation to gain from market opportunities and sustain growth.

- <sup>@</sup> North America: Market shares based on IQVIA March 2024 data.
- <sup>&</sup> Europe & JANZ: Market shares based on IQVIA Q4 CY2023 data.
- \*\*Stelara® is a registered trademark of Johnson & Johnson.

\*\*\* EYLEA® is a registered trademark of Regeneron Pharmaceuticals Inc.

#### **Emerging Markets**

In Q4FY24, the Emerging Markets business posted the highest ever quarterly revenue reporting a strong year-on-year growth led by the robust performance of its biosimilars portfolio in LATAM, AFMET and APAC regions. This performance was driven by the consolidation of self-led and partner-led business, 7 product launches and key tender wins.





Notable highlights included good uptake of bBevacizumab in Brazil and successful launches in several other markets in LATAM. The Company also expanded its patients' reach in Mexico with additional supplies of insulins to its partner to address the unmet needs of insulin-dependent people grappling with the market shortage of insulins.

Both the insulins and monoclonal antibodies (mAbs) portfolios made good progress with our key products holding a dominant market share in several markets including Morocco, South Africa, and the Philippines.

The Company also capitalized on the opportunity to serve patients in new markets by winning many tenders this quarter, including a significantly large multi-year tender for mAbs in Tunisia. Several new approvals obtained this quarter will pave the way for future business growth.

Biocon Biologics has expanded its strategic collaboration with Eris Lifesciences, to provide access to its portfolio of Metabolics, Oncology and Critical Care brands in India, for a total transaction value of INR 1,242 crore<sup>^</sup>, which represents a revenue multiple of 3.4x and EBITDA multiple of 18x. This strategic collaboration with Eris aligns with Biocon Biologics' commercial strategy to maximize patient reach and market potential, while unlocking value from its branded formulations business in India. The Company has also signed a 10-year supply agreement with Eris for these products as a part of this collaboration.

^INR 1,242 crore is not included in Q4FY24 earnings

## **RESEARCH SERVICES: Syngene**

- Q4FY24 Revenue at Rs 917 Crore, down 8% YoY
- FY24 Revenue at Rs 3,489 Crore, up 9%

## **Business Performance**

**Revenue** at **Rs 917 crore** in Q4FY24 was impacted due to reduced demand for research and development services within U.S. biotech stemming from a difficult funding environment. The company continued to manage costs proactively to deliver consistent operating leverage and maintain EBITDA margin around the expected level. During the quarter, it operationalized a new capability for purifying and separating chiral compounds and HPAPIs (Highly Potent Active Pharmaceutical Ingredients) as part of its Development Services.

The recent step up in new funding into U.S. biotech is expected to drive a recovery in demand for research and development services.

During the year, Syngene continued to add capabilities that strengthen its position as a leading integrated provider of research, development and manufacturing services, resulting in full-year **revenue** growth of **9%** to **Rs 3,489 crore**, **EBITDA** growth of **10%** at **Rs 1,105 crore** with stable **EBITDA margins** of **31%**.





#### 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 U.S., 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 Limited**, a subsidiary of Biocon Limited, 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. Biocon Biologics has integrated the acquired 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, the Company is advancing the health of patients, people, and the planet to achieve key UN Sustainable Development Goals (SDGs). Website: <u>www.bioconbiologics.com</u>; Follow us on Twitter: @BioconBiologics and LinkedIn: <u>Biocon Biologics</u> for company updates.

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#### **Earnings Call**

The management of the Company will host an Earnings Call on May 16, 2024 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 the period ended December 31, 2023. Transcript of the conference call will be uploaded on the Company website in due course.

Zoom Webinar Details		
Date	May 16, 2024	
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 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.