



PRESS RELEASE

Biocon Q3FY25 Revenue at Rs 3,856 Cr, Up 7%[#] EBITDA at Rs 787 Cr, Up 16%[#]; Net Profit at Rs 25 Cr

Biosimilars[^] Up 14%; Research Services Up 11%

Bengaluru, Karnataka, India: January 30, 2025:

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

Q3FY25 | Financial Highlights (Growth on a like-for-like basis*)

Rs 3,856 Crore
CONSOLIDATED REVENUE

Up 7%

(like-for-like basis)

Rs 3,821 Crore
OPERATING REVENUE
Up 10%

(like-for-like basis)

(#Adjusting for BFI revenues, income from BFI part divestment; and Bicara gain in Q3FY24) Rs 787 Crore

EBITDA

Up 16%

(like-for-like basis)

20%

EBITDA MARGIN

Rs 1,007 Crore

CORE EBITDA

Up 4%

(like-for-like basis)

26%

CORE EBITDA MARGIN

Rs 199 Crore

NET R&D INVESTMENT

7% of Revenue

(ex Syngene)

Q3FY25 | Business Segments Revenue

Rs 2,289 Crore, Up 14% YoY

(like-for like basis^)

BIOSIMILARS: Biocon Biologics

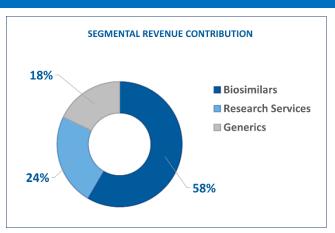
(^Adjusting for BFI revenues & income from BFI part divestment in Q3FY24)

Rs 944 Crore, Up 11% YoY

RESEARCH SERVICES: Syngene

Rs 686 Crore, Down 2% YoY

GENERICS: APIs & Generic Formulations



Note: Revenue contribution as a % of Operating Revenue





Leadership Comments

BIOCON GROUP

"The Biocon Group reported Q3FY25 Operating Revenue of Rs 3,821 crore, with performance driven by a sustained double-digit growth of 14% on a like-for-like basis in Biosimilars and a return to growth in Research services, which grew by 11%. The growth trajectory is clearly visible with sequential growth across all the three business segments this quarter. EBITDA at Rs 787 crore, reported a growth of 16% while Profit before Tax and Exceptional Items at Rs 138 crore, improved significantly from a marginal loss last year, on a like-for-like basis.

"Syngene's return to growth, combined with global approvals for bUstekinumab and European approval for gLiraglutide, will pave the way for launches and drive growth in Q4 and beyond. These developments will strategically position the Biocon Group for enhanced long-term growth."

-- Kiran Mazumdar-Shaw, Chairperson, Biocon Group.

"Biocon Group's Q3FY25 financial performance was led by 10% like-for-like growth in Operating Revenue. The strengthening of operational building blocks has improved growth visibility across all three businesses, reinforcing our confidence in continued growth for the rest of this fiscal year and beyond.

"The Biosimilars business sustained its growth momentum in this quarter and now has clear line of sight for multiple new product launches beginning in Q4FY25. Syngene's growth rebound this quarter sets a positive trajectory for the remainder of the year. Recovery in the Generics business in the fourth quarter will be driven by the launch of our first GLP-1 generic in the UK and EU, coupled with new speciality product launches in the U.S."

-- Peter Bains, Group CEO, Biocon Limited.

BIOCON GENERICS

"The 10% sequential revenue growth in the Generics business was primarily driven by API sales, supported by an improved performance from generic formulations.

"We crossed important milestones in the quarter with the European Union (EU) DCP approval for Liraglutide and the successful regulatory outcomes of the U.S. FDA inspections of both our Bengaluru API sites.

"We expect to see an improved performance in the quarters ahead, on the back of the launch of our GLP-1 product Liraglutide in the UK and EU, as well as new product launches in the U.S."

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

BIOCON BIOLOGICS

"This quarter marked the completion of one year since the successful integration of the acquired business. The business delivered a robust 14% year-on-year growth on a like-for-like basis, underpinned by an increase in market shares in North America demonstrating strong customer confidence and geographic expansion in Europe, and 14 launches in Emerging Markets. During the quarter we received several regulatory approvals for our bUstekinumab, YESINTEK, including from the U.S. FDA, Japan and a positive recommendation for approval by the CHMP to EMA. The U.S. FDA classified our manufacturing facilities in India, and Malaysia, as VAI, thereby paving the way for new product approvals in the United States. Several key milestones that we achieved this quarter will consolidate the business and drive growth in the coming quarters."

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





SYNGENE

"Syngene's third quarter performance saw a return to growth across all business divisions that sets us up well for the next quarter. Our revenue from operations was up by 11% and reported profit after tax (before exceptional items) grew by 14%.

"Our Discovery Services division saw the initial "China+1" pilot projects, with large and midsize pharma companies, starting to convert into longer term contracts. This underscores Syngene's ability to build strong partnerships through a combination of great science and high operating and quality standards. The quarter also saw positive momentum in our CDMO division led by biologics. Growth in the quarter suggests that market dynamics, particularly in U.S. biotech, are stabilising, albeit later than expected."

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

Financial Commentary: Q3FY25

- Consolidated Total Revenue for Q3FY25 was at Rs 3,856 crore. Reported 7% YoY growth on a like-for-like basis, after adjusting for Branded Formulations India (BFI) revenues & income from BFI part divestment in Q3FY24 and gain from Biocon's stake dilution in Bicara Therapeutics.
- Revenue from Operations at Rs 3,821 crore was up 10% YoY on a like-for-like basis.
- Core EBITDA at Rs 1,007 crore, Up 4% on a like-for-like basis, with core operating margins of 26%.
- Net R&D investments for the quarter were Rs 199 crore, representing 7% of revenue ex-Syngene.
- **EBITDA** for the quarter stood at **Rs 787 crore**, **Up 16%** on a like for like basis, an **EBITDA margin** of **20%**.
- **Profit Before Tax** (before exceptional items) stood at **Rs 138 crore, improved significantly** from a marginal loss last year, on a like-for-like basis.
- Reported Net Profit for the Quarter was Rs 25 crore. Adjusting for exceptional items, Net Profit stands at Rs 13 crore. (Last year, Profit benefited from Bicara gain & income from part divestment of BFI business by Biocon Biologics.)

Business Highlights

GENERICS: APIs & Generic Formulations

- Q3FY25 Revenue from Operations at Rs 686 Crore, down 2% YoY; Up 10% QoQ
- Q3FY25 EBITDA was Rs 39 crore

Business Performance

During the quarter, the Company and its European Union (EU) partner, Zentiva, obtained EU Decentralized Procedure (DCP) approval for Liraglutide (Saxenda® and Victoza®). The approval marks another step forward in accelerating the availability of these innovative GLP-1 therapies across the EU, positioning the Company for strategic growth in the region.





Approval was received for Tacrolimus capsule in 0.5mg, 1mg and 5mg strengths in China, making this the second key drug product approval for Biocon in this important market.

The oral solid dosage facility in Cranbury, New Jersey, U.S., which was acquired to strengthen the Company's manufacturing infrastructure and foothold in the U.S., has now been qualified by the U.S. Food and Drug Administration (FDA) for three vertically integrated statin products, with supply having commenced in the quarter. The business also secured a 5-year national contract for one of these products.

The Company launched two new injectable products in the U.S. - Daptomycin for injection in 500mg vials, used to treat bacterial infections, and Nitrofurantoin oral suspension liquid 25mg/5ml strength, used in the treatment of urinary tract infections in adults and paediatric patients over one month of age.

Regulatory Inspections

During the quarter, Biocon received Establishment Inspection Reports (EIRs) with a Voluntary Action Indicated (VAI) for both its API sites in Bengaluru (Sites 1 & 2) from the U.S. FDA, following inspections conducted in September 2024.

BIOSIMILARS: Biocon Biologics

- Q3FY25 Revenue from Operations at Rs 2,289 Crore,
 Up 14% YoY on a like-for-like^ basis; Up 5% QoQ
- Q3FY25 EBITDA was Rs 487 crore; Up 44% YoY on a like-for-like^ basis
- Q3FY25 R&D Investments was Rs 135 crore, accounting for 6% of Revenue
- Served 5+ million patients (MAT December 2024 basis)##

Marking 1st Anniversary as an Integrated Global Biosimilars Company

Biocon Biologics marked the one-year milestone of completing the integration of the acquired business. Supported by a diverse, multicultural workforce spanning more than 25 nationalities, the Company has emerged as a fully integrated, global biosimilars company operating in over 120 countries.

Having successfully transformed from a two-country operation focused on Development and Manufacturing to an end-to-end biosimilars company with a strong Commercial engine. With this consolidation of business operations during 2024, Biocon Biologics has laid a strong foundation for accelerated business growth that will unlock value for the company and all its stakeholders.

Business Performance

Q3FY25

Biocon Biologics' Q3FY25 **Revenue from Operations** at **Rs 2,289 crore** reported a YoY **growth** of **14%** on a like-for-like basis after adjusting Q3FY24 revenue** for the Branded Formulations, India (BFI) revenue and income from part divestment of BFI business by the Company.

[^]After adjusting Q3FY24 revenue for Branded Formulations India (BFI) revenue and income from part divestment of BFI business

^{##12-}month moving annual patient population (January 2024 to December 2024)





Reported EBITDA for Q3FY25 was **Rs 487 crore**, including a non-cash forex translation loss of Rs 20 crore. Excluding the forex impact, **EBITDA margin** for the quarter was **22%**. On a like-for-like basis, **EBITDA grew 44% YoY** after adjusting for a Rs 350 crore gain in Q3FY24 from part divestment of the Branded Formulations (India) business, and BFI revenue.

Notes: **Q3FY24 Revenue included Branded Formulations India revenue and income from part divestment of Branded Formulations India business which are not a part of Q3FY25 revenue.

Final Remittances for Acquisition Completed

Biocon Biologics has fulfilled its obligations towards all deferred milestones under the acquisition agreement, which marks the full and final remittance of considerations from the Company towards Viatris for the acquisition.

Biocon Biologics' balance sheet is reconfigured and its financials this quarter reflect a revised debt maturity profile after the completion of the strategic refinancing announced in October 2024.

Advanced Markets

North America@

Biocon Biologics continued to deliver a strong performance across its product portfolio in the U.S. The oncology franchise, comprising **Ogivri®** (**bTrastuzumab**) and **Fulphila®** (**bPegfilgrastim**), witnessed a significant increase in demand, with the market share for Ogivri® doubling to **22%** from 11% last year, while the share for Fulphila® rose to **23%** from 19% a year ago. The shares of the insulin franchise, which includes **Semglee®** and unbranded Insulin Glargine, continued to be in the mid-to-high teens, including all channels.

The Company received **U.S. Food and Drug Administration** (FDA) approval for **YESINTEK™** (Ustekinumab-kfce), a biosimilar to the reference product, Stelara® (Ustekinumab) and is preparing for a February 2025 launch, which will strengthen its immunology portfolio in the U.S.

The U.S. FDA validated the Company's Biologics License Application (BLA) filing for **Denosumab**, a biosimilar to the reference products Prolia® and XGEVA®, which has also been filed in several other geographies.

At the American Academy of Ophthalmology (AAO) 2024 Annual Meeting, the Company presented results of an extension of the pivotal Phase III study evaluating switching with MYL-1701P, a proposed biosimilar to Aflibercept. MYL-1701P showed promising results, demonstrating comparable safety, efficacy, and immunogenicity between patients continuing on MYL-1701P and those who switched from Aflibercept to MYL-1701P.

Europe and JANZ

In Europe, Biocon Biologics maintained stable market shares at a regional level with strong uptake in key markets such as Germany and France, where the Company holds double-digit shares for products such as Hulio® (bAdalimumab).

The Company received a Positive Opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP), which recommended the approval of YESINTEK®





(bUstekinumab) for the treatment of adults and children with plaque psoriasis, as well as adults with psoriatic arthritis or Crohn's disease.

The Company is beginning to see the results of its focus on both geographic and product expansion with sustained growth in the Mediterranean and UK-Nordics clusters. Biocon Biologics is also experiencing positive traction in the Japanese and Australian markets through its commercial partner.

In January, the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan approved Ustekinumab BS subcutaneous injection [YD] through its partner. The biosimilar Ustekinumab has been developed and manufactured by Biocon Biologics and will be commercialized and marketed in Japan by the Company's exclusive commercial partner, Yoshindo Inc.

[®]Market shares based on Biocon Biologics' analysis of IQVIA Q3CY2024 data.

The data presented hereunder inter alia volumes, projections, market share, is based solely on our study, interpretation and conclusion derived through analysis of different data sets from varied sources inter alia IQVIA.

Emerging Markets

The Emerging Markets (EMs) business continues to expand the depth and breadth of its offering for patients through its portfolio of commercialized biosimilars. The Company further strengthened its Insulins franchise and witnessed strong demand for its key products, leading to market share expansion in both self-led and partner-led markets.

During the third quarter, 14 launches of key commercialized products were accomplished across regions, including bAdalimumab, bEtanercept, bAspart, bGlargine, bBevacizumab, and bPegfilgrastim in key countries of AFMET, LATAM and APAC regions. The Company won several tenders for its products, received 8 product approvals and continues to file new product applications across regions, which will pave the way for future growth.

Regulatory Inspections

Biocon Biologics' multi-product manufacturing facilities in Bengaluru, India and insulins facilities in Johor, Malaysia have received Voluntary Action Indicated (VAI) classifications from the U.S. FDA in response to the inspections held earlier in July 2024 and September 2024, respectively. These critical U.S. FDA decisions will pave the way for new product approvals from these facilities and will enable the Company's business further in the U.S.

Note: All trademarks, registered or unregistered, are the property of their respective owners.

RESEARCH SERVICES: Syngene

- Q3FY25 Revenue from Operations at Rs 944 Crore, Up 11% YoY; Up 6% QoQ
- Q3FY25 EBITDA was Rs 302 crore; Up 16% YoY

Business Performance

Syngene reported **11%** YoY growth in its Q3FY25 **Revenue from Operations**, driven by improved performance in Research Services, as well as the CDMO business, with increased traction in biologics. Reported **EBITDA** at Rs 302 crore was up **16%** YoY with a healthy margin of **31%**.





Development and **Manufacturing Services** delivered steady performance driven by biologics with repeat orders from existing customers and new collaborations on integrated projects that cover the scope from drug development to clinical stage manufacturing. **Discovery Services** converted initial pilot projects into full-fledged contracts, which should contribute to growth into next year. This indicates increased confidence in Syngene's capabilities and quality of delivery.

Sustainability

In the 2024 S&P Corporate Sustainability Assessment, **Biocon** has improved its S&P Global ESG Score to **69** from 63 the previous year. **Biocon Biologics**, which independently applied for the assessment for the first time in 2024, has secured a score of **53**.

Additionally, **Biocon** Limited has won the **'Excellence in Sustainability'** Award at the CPHI India Pharma Awards 2024, and **Biocon Biologics'** subsidiary in **Malaysia**, Biocon Sdn. Bhd., was presented with the **'Life at Work'** Award 2024 in the **'Environmental Practices'** category by Talent Corporation Malaysia Bhd.

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 **X** (formerly Twitter) @bioconlimited and **LinkedIn**: @BioconLimited for company updates. For latest Integrated Report of Biocon click here

Biocon Biologics Limited, a subsidiary of Biocon Limited, is a unique, fully integrated, global biosimilars company committed to transforming healthcare and transforming lives. It is capitalizing on its 'lab to market' capabilities to serve millions of patients across 120+ countries by enabling affordable access to high quality biosimilars. The Company 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 commercialized eight biosimilars in key emerging markets and advanced markets like U.S., Europe, Australia, Canada, and Japan. It has a pipeline of 20 biosimilar assets across diabetology, oncology, immunology, ophthalmology, and other non-communicable diseases. The Company has many 'firsts' to its credit in the biosimilars industry. As part of its environmental, social and governance (ESG) commitment, it 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 X (formerly Twitter): @BioconBiologics and LinkedIn: Biocon Biologics for company updates. For latest Integrated Report of Biocon Biologics click here

Syngene International Ltd. (BSE: 539268, NSE: SYNGENE, ISIN: INE 398R01022) is an integrated research, development, and manufacturing services company serving the global pharmaceutical, biotechnology, nutrition, animal health, consumer goods, and specialty chemical sectors. Syngene's more than 5600 scientists offer both skills and the capacity to deliver great science, robust data security, and world class manufacturing, at speed, to improve time-to-market and lower the cost of innovation. With a combination of dedicated research facilities for Amgen, Baxter, and Bristol-Myers Squibb as well as 2.2 Mn sq. ft of specialist discovery, development, and manufacturing facilities, Syngene works with biotech companies pursuing leading-edge science as well as multinationals, including GSK, Zoetis and Merck KGaA. For more details, visit www.syngeneintl.com For the Company's latest Environmental, Social, and Governance (ESG) report, visit https://esgreport.syngeneintl.com/





FOR MORE INFORMATION		
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Earnings Call

The management of the Company will host an Earnings Call on 31st January 2025 at 9:00 AM IST, 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 www.biocon.com under Investors >> Financial Calendar >> Earnings Call for the period ended September 30, 2024. Transcript of the conference call will be uploaded on the Company website in due course.

Zoom Webinar Details	
Date	31 January 2025
Time	9:00 AM IST
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, 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.