PRESS RELEASE

Biocon Q2FY25 Revenue at Rs 3,623 Cr, EBITDA at Rs 718 Cr

Segmental Revenue Contribution

Biosimilars at 59%; Research Services 24%; Generics 17%

Bengaluru, Karnataka, India: October 30, 2024:

Biocon Limited (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, 2024.

Q2FY25 | Financial Highlights

Rs 3,623 Crore
CONSOLIDATED REVENUE

Rs 718 Crore
EBITDA

20%
EBITDA MARGIN

Rs 200 Crore
NET R&D INVESTMENT

7% of Revenue

Rs 3,590 Crore
OPERATING REVENUE[&]

Rs 992 Crore
CORE EBITDA

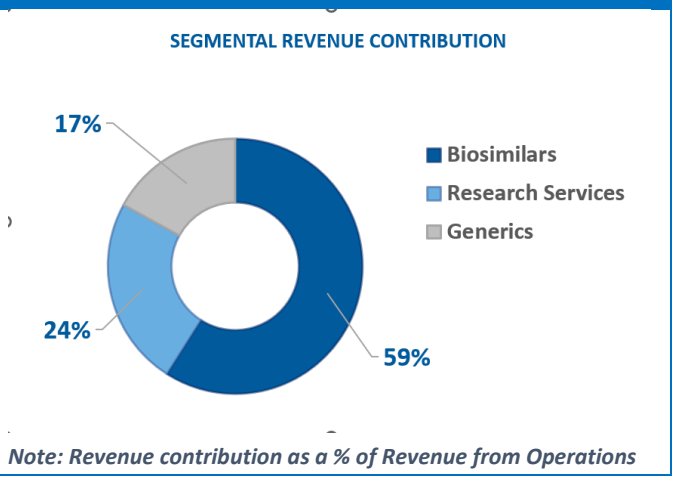
28%
CORE EBITDA MARGIN

Q2FY25 | Business Segments Revenue

Rs 2,182 Crore
BIOSIMILARS: Biocon Biologics Limited

Rs 891 Crore
RESEARCH SERVICES: Syngene

Rs 624 Crore
GENERICS: APIs & Generic Formulations



Note: Revenue contribution as a % of Revenue from Operations

Note: [&]: Revenue from Operations at Rs 3,590 crore, was Up 8% YoY after adjusting Q2FY24 revenue for Branded Formulations, India business.

Leadership Comments

BIOCON GROUP

"Biocon Group's overall Q2FY25 financial and operational performance provides a foundation for improved performance as we move into the second half of the fiscal. Reported Operating Revenues of Rs 3,590 Cr reflect YoY growth of 8% on a like for like basis and core EBITDA and EBITDA margins of 28% and 20% respectively remain healthy. We had a robust performance in the Biosimilars business, up 19% on a like for like revenue basis, driven by strong market share gains in our US Oncology and Insulins franchises. Syngene has returned to sequential growth and has good visibility of a pickup in momentum in the coming quarters led by its Discovery Services and Biomanufacturing CMO business. Generics has continued to face price and demand pressures that have supressed performance, but key new formulation launches in Q3 and Q4 provide the basis of a turnaround before the year end. All three businesses are tracking towards a better performance in the second half of the year, on the back of product approvals and unfolding market opportunities.

"Biocon Biologics' successful refinancing of its long-term debt of US$ 1.1 billion through a combination an $800 million USD bond listed on the Singapore Stock Exchange and a new $300 million syndicated loan facility was a credible success. This was Biocon Group's debut bond issue and to be 3x oversubscribed speaks to strong investor confidence in our Biosimilars growth potential."

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

"With like for like Operating Revenue growth of 8%, Biocon Group's consolidated performance in Q2FY25 was balanced and in line with our expectations. Healthy double-digit growth in Biosimilars more than offset a relatively muted performance in the Generics business and a marginal decline in Syngene's revenues. Reported Net Loss for the quarter was Rs 16 Cr on account of higher tax, based on geographical split of profits and minority interest. Adjusting for exceptional items, the loss stands at Rs 13 Cr.

"We maintain our outlook for a transition to accelerating growth in the second half of the year with Syngene returning to growth, building momentum in our Biosimilars business and a recovery in Generics in the latter part of H2 driven by the launch of our first GLP-1 generic in the UK. The highly successful Biocon Biologics bond issue was a standout achievement and has significantly strengthened its mid-term financial foundation."
*-- **Peter Bains, Group CEO, Biocon Limited.***

BIOCON GENERICS

"The Generics business continues to face pricing pressure and demand contraction. This quarter we also carried out a planned shut-down of one of our API facilities, which further

impacted revenues. We received a few drug product approvals in the U.S., UK, EU and MoW markets, which will support our near-term sales. The licensing agreements signed with two leading pharmaceutical companies in the Middle East and Brazil, for the commercialization of our GLP-1 products will enable mid and long-term growth in these regions.
"As stated earlier, we expect a transition to growth in the second half of this fiscal on the back of new product launches, including Liraglutide in the UK, as well as other injectable products, such as Micafungin and Daptomycin."

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

BIOCON BIOLOGICS

"The strategic refinancing of our long-term debt through a US$800 million USD bond issuance and a new syndicated loan facility was the highlight this quarter. This provides greater financial liquidity and allows us to re-deploy investments into the business to fuel growth. It is an important milestone for Biocon Group as well as the industry, as it is the first USD bond issuance by any biopharmaceutical company in Asia.

"The business delivered a robust 19% year-on-year growth on a like for like basis, underpinned by an increase in market shares in North America, expansion in Europe, and 15 new launches in Emerging Markets. On the regulatory front, EMA has validated our filing for bDenosumab. We also signed a settlement and license agreement for Yesintek, our bUstekinumab, with the originator that paves the way for launch in Europe, UK, Canada, and Japan."

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

SYNGENE

"Syngene's performance in the second quarter was broadly flat, in line with our expectations, the operating EBITDA margin stood at 27%. We are witnessing early positive signs of recovery in Discovery Services, largely driven by collaborations on pilot projects with large and mid-sized biopharma clients who are looking for alternatives to China. With recent investments in the research and CDMO businesses, we are in a good position to leverage opportunities to drive medium to long-term growth. We remain on track to deliver within our guidance range for the full year."

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

FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q2FY25

In Rs Crore

Particulars	Q2FY25	Q2FY24	YoY (%)
INCOME			
Generics	**624**	676	(8)
Biosimilars^	**2,182**	1,969	11
Research Services	**891**	910	(2)
Inter-segment	**(107)**	(93)	
Revenue from Operations	**3,590**	3,462	4
Other Income*	**33**	158	(79)
Total Revenue	**3,623**	3,620	0%
Net R&D Expenses	**200**	264	(24)
Gross R&D Spend	**200**	278	
EBITDA	**718**	900	(20)
EBITDA Margins	**20%**	25%	
Core EBITDA**	**992**	1,100	(10)
Core EBITDA Margins	**28%**	32%	
PBT *(before exceptional items^)*	**72**	238	(70)
PBT	**98**	214	(54)
Net Profit *(before exceptional items^^)*	**(13)**	142	
Net Profit***	**(16)**	126	

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

Notes to financials above:

** Q2 FY24 includes dilution gain in Bicara for ₹75 Crore*

***Core EBITDA excludes R&D, Forex, Licensing income, Bicara dilution gain and derivative MTM loss/ gain*

^ Exceptional Items - Q2FY25: Inventory provision reversal gain; Q2 FY24 - Pertained to Product Linked Incentive accrual reversal for FY23 consequent to cap on annual claim allocation, and transaction costs on the acquisition of Stelis unit by Syngene

^^ Deferred tax charge on withdrawal of indexation benefit on long term capital asset

**** Reported Net Loss for the Quarter was Rs 16 Cr on account of higher tax based on geographical split of profits and minority interest. Adjusting for exceptional items, the loss stands at Rs 13 Cr.*

Financial Commentary: Q2FY25

- **Total Consolidated Revenue** for Q2FY25 was flat year-on-year (YoY) at **Rs 3,623 crore**.
- **Revenue from Operations** was up **4% YoY** at **Rs 3,590 crore,** (**Up 8% YoY** after adjusting Q2FY24 revenue for Branded Formulations, India business)
- **Core EBITDA** at **Rs 992 crore**, represents **core operating margins** of **28%.**
- **Net R&D investments** for the quarter were **Rs 200 crore**, representing 7% of revenue ex-Syngene.
- **EBITDA** for the quarter stood at **Rs 718 crore**, representing an **EBITDA margin of 20%.**
- **Profit Before Tax** and exceptional items stood at **Rs 72 crore.**

- ***Reported Net Loss for the Quarter*** *was Rs 16 Cr on account of higher tax based on geographical split of profits and minority interest.* ***Adjusting for exceptional items****, the loss stands at* ***Rs 13 Cr.***

CORPORATE HIGHLIGHTS

Awards & Recognitions

HR

- Biocon (including Biocon Biologics) has been ranked **No. 9** on U.S.-based *Science* magazine's list of **Top 20 Global Employers** in the biotech, pharma and biopharma sector for 2024.

ESG

- Biocon (including Biocon Biologics) ranked among **Top 5 India's Most Sustainable Companies (IMSC) in the Pharma & Healthcare sector** at the BW Businessworld IMSC Awards 2024**.**
- Biocon Biologics won the **Company of the Year (Biotechnology Manufacturing) Trophy** at the **Sustainability & CSR** Malaysia Awards 2024.
- Biocon Biologics won the **2024 Workplace Occupational Health & Safety and Environment (OHS&E) Excellence Award** from the World Safety Organization.
- Biocon Group won the **Gold Medal** for **Oral Cancer Care Program**, which was adjudged **Best Health CSR Campaign** at PRmoment India Health Comms Award 2024.

Quality & Operational Excellence

- Biocon (including Biocon Biologics) won over 20 awards for best industry practices for quality and operational excellence in local and national level competitions.

Management Updates

Biocon Biologics Limited

Anuj Goel has been appointed as **Chief Development Officer.** He is a Biocon veteran with over 28 years of experience spanning enzymes, small molecules, insulins and monoclonal antibodies (mABs). Anuj and has been instrumental in building the Company's R&D capabilities and infrastructure from the ground-up and has a deep understanding of science, regulatory expectations and the business.

Ankur Bhatnagar takes on the role of **Global Head, R&D – CMC** from Anuj. During his 23 years with the Company, he has held a wide range of technical and leadership roles in R&D. He has played a critical role in securing product approvals for global markets and leading several scientific development initiatives.

Kathleen Blanchard has been appointed as **Global General Counsel**. She has over 25 years of experience in various Legal, Compliance, and IP roles both as an attorney at marquee law firms in the U.S. as well as in-house counsel at leading global pharma companies. She has a proven track record of leading high performing global teams and being a strategic partner to the business.

Business Highlights

GENERICS: APIs & Generic Formulations

- **Q2FY25 Revenue at Rs 624 Crore, down 8% YoY**

Business Performance

During the quarter, the Company obtained approvals in the U.S. for Sacubitril + Valsartan tablets used in the treatment of chronic heart failure, and for Daptomycin for injection to treat bacterial infections. Approvals were also received for Micafungin 50mg an 100mg powder in the UK and EU, for Posaconazole DR tablets in the UAE and for Tacrolimus capsules in India.

The business secured a tender for Everolimus tablets in a MoW market, with supplies expected to commence in Q3FY25. Continuing its regional expansion strategy, the business entered into two new partnerships.
A licensing and supply agreement was signed with Tabuk Pharmaceutical for commercializing its GLP-1 products for both diabetes and chronic weight management in select countries within the Middle East. Biocon will develop and manufacture the products, while Tabuk will hold the marketing authorization rights and be responsible to register, import and promote them in the region.

Subsequently, in October, Biocon entered into an exclusive distribution and supply agreement with a leading speciality pharmaceutical company in Brazil for the commercialization of its vertically integrated drug product, Liraglutide (gVictoza® and gSaxenda®). Biocon will be responsible for regulatory approval, manufacturing and supply of the product, while the partner will commercialize it in Brazil.

Regulatory Inspections

Two separate U.S. FDA surveillance inspections of Biocon's API facilities in Bengaluru (Sites 1 & 2) concluded in September with a few observations. The Company has submitted individual Corrective and Preventive Action (CAPA) plans to the agency and is confident of addressing these expeditiously. During the quarter, Biocon has received Establishment Inspection Reports (EIRs) for both its API sites in Visakhapatnam (Sites 5 and 6) from the U.S. FDA, following inspections conducted in June 2024.

BIOSIMILARS: Biocon Biologics

- **Q2FY25 Revenue at Rs 2,182 Crore, Up 19% YoY** on a Like-for-Like^ Basis
- **Served 5+ million patients** *(MAT September 2024 basis)*[##]

^After adjusting Q2FY24 revenue for Branded Formulations, India business
[##]12-month moving annual patient population (October 2023 to September 2024)

Business Performance

Q2FY25

Biocon Biologics' Q2FY25 **revenue** at **Rs 2,182 crore** reported a YoY **growth** of **19%** on a like-for-like basis after adjusting Q2FY24 revenue** for Branded Formulations, India business.

Core EBITDA stood at **Rs 691 crore**, with **Core EBITDA margin** at **32%. It reported EBITDA** of **Rs 469 crore,** representing **EBITDA** margins of **21%**. Adjusting for the forex impact of the appreciation of the

Japanese yen versus the U.S. dollar, EBITDA was **Rs 550 crore** with a margin of **25%**, reflecting the strong underlying profitability of the core business.

Notes: ***Q2FY24 Revenue included Branded Formulations India sales which is not a part of Q2FY25 revenue.*

Strategic Refinancing

Biocon Biologics successfully refinanced its long-term debt of US$1.1 billion through a combination of US$800 million U.S. dollar-denominated bonds and a new syndicated loan facility. This strategic re-financing will help improve the Company's liquidity profile, provide enhanced financial flexibility, strengthen its capital structure and allow it to re-deploy investments into the business to fuel long-term growth. The bonds have been listed on the Singapore Stock Exchange, and it is the first U.S. dollar-denominated bond issuance by any biopharmaceutical company in Asia-Pacific, as well as the largest high yield debut bond issuance from India in the past 10 years.

Advanced Markets

North America[@]

Biocon Biologics has positioned itself as a strategic player among customers, payors, and patients in North America.

Its Oncology franchise, comprising **Ogivri®** (bTrastuzumab) and **Fulphila®** (bPegfilgrastim), is witnessing robust demand with a marked YoY increase in market share. The market share for Ogivri® increased to 18% from 11%, while Fulphila® rose to 21% from 15% (YoY). Market share for unbranded bGlargine and **Semglee®** surpassed 15%, which includes share from closed-door pharmacy networks and government business, on the back of a steady demand.

In July, the Company moved into its new North America headquarters in Bridgewater, New Jersey, and marked its first anniversary as an independent commercial organization in the United States and Canada.

Europe[@] and JANZ

Biocon Biologics reported steady market shares in Europe at a regional level with Germany and France continuing to drive value. Strong growth across key markets and products has allowed the Company to expand patient access. Hulio® (bAdalimumab) retained its market-leading position in Germany with an 18% market share and 11% in France. The Company has made significant progress in expanding its footprint, with strong market growth in the UK and the Mediterranean cluster, including Italy and Spain.

The Company obtained approvals for bAspart and bEtanercept in New Zealand during the quarter.

[@]Market shares based on IQVIA Q2 CY2024 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 patient reach, securing market leading shares in several key countries such as 74% for bTrastuzumab and 86% for bBevacizumab in South Africa. The Company continues to witness strong demand for its portfolio especially for insulins in Mexico and for bAdalimumab and bEtanercept in Saudi Arabia. Biocon Biologics has also seen an uptick in market shares across its self-led markets, which are a strategic priority for the Company.

During the second quarter, 15 launches of key commercialized products were accomplished across AFMET and LATAM regions such as bBevacizumab and bPegfilgrastim in Saudi Arabia. These new launches will be the key growth drivers, going forward.

The Company received regulatory approvals for five of its products, *viz.,* bBevacizumab, bEtanercept, bAdalimumab, bAspart and rh-Insulin in several countries in the AFMET and LATAM regions.

To strengthen the business further, the Company is working on localization in multiple countries in the AFMET region and exploring new partnerships in the APAC region.

Regulatory Inspections

In terms of facility inspections, the U.S.FDA has classified Biocon Biologics' Drug Substance facility at Biocon Campus, Bengaluru as Voluntary Action Initiated (VAI). This inspection was held in February 2024 and pertains to the supply of rh-insulin drug substance to the United States.

The Company has submitted a comprehensive Corrective and Preventive Action (CAPA) plan to the U.S. FDA following the cGMP inspection at its insulins manufacturing facility in Malaysia in September 2024. Another CAPA plan has been submitted to the agency related to the inspection of its manufacturing facility at Biocon Park, Bengaluru in July 2024.

The Company is confident of addressing all the observations expeditiously and does not expect the outcome of these inspections to impact the supply of its commercialized products. Furthermore, these sites are cGMP certified by several other leading global regulators including the Europe Medicines Agency (EMA), and Health Canada.

Progress in Pipeline

The European Medicines Agency (EMA) has validated Biocon Biologics' regulatory filling for **bDenosumab** and the Company is on track to complete filings in several other markets later this year.

To strengthen its immunology franchise, the Company has signed a settlement and license agreement with Janssen and J&J, clearing the way for the commercialization of **Yesintek** (bUstekinumab), a proposed biosimilar to Stelara®, in Europe, the UK, Canada, and Japan upon regulatory approval.

Scientific Publications & Presentations

At the **European Academy of Dermatology and Venereology (EADV) 2024 Congress** in Amsterdam, the Company presented results from two separate pivotal Phase 3 clinical studies in patients with chronic plaque psoriasis supporting interchangeability between biosimilar **Adalimumab-fkjp** *(low concentration)* and the Adalimumab reference product *(high concentration)*; and between **Bmab 1200** (**Yesintek**) and the Ustekinumab reference product, establishing bio-equivalence, efficacy and comparable safety.

Biocon Biologics has released a report in collaboration with Clarivate that highlights pathways to increase adoption of biosimilars in low- and middle-income countries (LMICs). A peer-reviewed article based on this study titled **"Increasing Adoption of Quality-Assured Biosimilars to Address Access Challenges in Low- and Middle-Income Countries"** has been published in the prestigious *Generics and Biosimilars Initiative (GaBI) Journal*.

RESEARCH SERVICES: Syngene

- **Q2FY25 Revenue at Rs 891 Crore, down 2% YoY**

Business Performance

Syngene reported positive signs of recovery reflected in the QoQ growth of 13% in revenue. On a YoY basis, Revenue as well as EBITDA were marginally down. Recovery in Discovery Services was largely driven by pilot projects from large and mid-sized biopharma clients seeking alternatives to China. To meet increased demand in the long term, Syngene continues to add to its capacities and capabilities for antibody-drug conjugates, peptides, and oligonucleotides.

Development and Manufacturing Services revenue was led by sustained delivery in biologics manufacturing and an increase in process development projects in small molecules compared to last year. Syngene progressed with repurposing the biologics manufacturing facility acquired in December last year. The facility remains on track to commence operations in the second half of this financial year.

NOVEL BIOLOGICS

Bicara Therapeutics Inc., a U.S. based clinical-stage biotechnology company in which Biocon has a minority shareholding**,** successfully closed its initial public offering (IPO) and its shares began trading on the Nasdaq on September 13, 2024, under the ticker symbol "BCAX." Bicara raised USD 362 million in gross proceeds from its IPO. Biocon's shareholding in Bicara now stands at 10.7%.

Biocon's U.S.-based partner **Equillium** is making progress in developing Itolizumab, the novel molecule licensed from Biocon. In a Phase 3 clinical study for acute graft-versus-host disease (aGVHD), 145 patients have been dosed across 116 active sites in 13 countries. Additionally, enrolment for a Phase 2 clinical trial for Ulcerative Colitis in India has been completed.

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

Earnings Call

The management of the Company will host an Earnings Call on October 30, 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 *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	October 30, 2024
Time	18:30 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, 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.