

Biocon Earnings
Q4FY20 Revenue Up 6% at Rs 1,644 Cr;
EBITDA Down 11% at Rs 382 Cr; Net Profit Down 42% at Rs 123 Cr

FY20 Revenue Up 15% at Rs 6,529 Cr; EBITDA Up 15% at Rs 1,765 Cr;
Net Profit (before exceptional item) Up 4% at Rs 760 Cr

Bengaluru, Karnataka, India: May 14, 2020:

Biocon Ltd (BSE code: 532523, NSE: BIOCON), an innovation-led global biopharmaceuticals company, today announced its consolidated financial results for the fourth quarter and fiscal year ended on March 31st, 2020.

Commenting on the results, **Kiran Mazumdar-Shaw, Executive Chairperson, stated: “Q4FY20 witnessed a muted growth of 6% with revenues at Rs 1,644 Crore due to operational challenges including one-time COVID-19 related impact on our Biologics business. Small Molecules and Research Services businesses, however, delivered robust growth of 15% and 14%, respectively. On a full-year basis, we reported a revenue growth of 15% led by a strong performance by Biologics which grew by 29%, Small Molecules by 18% and Research Services by 10%. We believe that the Biologics business will recover in Q1FY21 and fully normalise from Q2FY21. For FY20, EBITDA at Rs 1,765 Crore reported a growth of 15%. Net Profit, before exceptional item, at Rs 760 Crore reported a 4% growth. Core margins were strong at 33% with EBITDA margin of 27% and Net Profit margin of 11%.”**

“We are dealing with unprecedented challenges related to COVID-19 and as a science-led company we are engaged in several initiatives spanning diagnostic tests, vaccines and therapies towards combating COVID-19. We have also implemented several workplace safety measures in accordance with Government guidelines, including temperature checks, wearing of masks, sanitising, zoning and physical distancing. We are confident that together with our teams and partners we will assure safe and uninterrupted manufacturing and enable access to our life-saving medicines despite the current challenges,” she added.

BUSINESS HIGHLIGHTS: Q4FY20 & FY20

SMALL MOLECULES:

- Crossed an **annual revenue** milestone of **Rs 2,000 Crore** for the first time.
- Revenue from **Generic Formulations** more than doubled during the quarter.
- Received **EIR** with VAI classification from **U.S. FDA** for **two distinct Small Molecules** API manufacturing facilities in Bengaluru; inspections stand closed.
- Closed **U.S. FDA** inspection for **Oral Solid Dosage facility** located in Bengaluru with zero observations.

BIOCON BIOLOGICS:

- Our biosimilar **Pegfilgrastim, Fulphila®**, co-developed with Mylan, commercialized in **Australia** and **Canada**.
- **U.S. FDA** accepted the **Biologics License Application** for our proposed biosimilar **Bevacizumab**, co-developed with Mylan, for review under the 351(k) pathway.

- **Won patent litigation** asserted by Sanofi for **Insulin Glargine** device patent in U.S.
- **Insulin manufacturing** facility in **Malaysia** received **EIR** from **U.S. FDA**, denoting closure of inspections.
- Received **EIR** from **U.S. FDA** for **two Biologics manufacturing** facilities in Bengaluru; inspection stands closed.
- **Biologics Drug Substance manufacturing facilities** in Bengaluru receive **EU GMP** certification.
- **Received permission** from Indian regulator **DCGI** for conducting **clinical trials** to study **Itolizumab** in treating moderate to severe patients with **COVID-19** complications in India.

RESEARCH SERVICES: Syngene

- Commissioned a **new research facility** at Biocon Park in Bengaluru.
- Repurposed one of its **high-end laboratories to conduct RT-PCR tests** for COVID-19, helping scale up testing capacity in Bengaluru, offering free testing services to city hospitals.
- **Partnered** with Pune-based Mylab Discovery Solutions **to supply reagents** (primers and probes) for use in its COVID-19 **RT-PCR testing diagnostic kits**.

Biocon Group of Companies are contributing in several ways to the fight against COVID-19 through their expertise in scientific innovation and as a compassionate corporate group.

FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q4 & FULL YEAR FY20

As per IND-AS

In Rs Crore, except growth numbers

Particulars	Q4FY20	Q4FY19	Growth	FY20	FY19	Growth
INCOME						
Small Molecules	541	472	15%	2,094	1,773	18%
Biologics	357	451	(21%)	1,951	1,517	29%
Branded Formulations	117	133	(12%)	536	656	(18%)
Research Services	607	534	14%	2,012	1,826	10%
Inter-segment	(42)	(61)	(32%)	(226)	(257)	(12%)
Revenue from Operations[#]	1,581	1,529	3%	6,367	5,514	15%
Other Income	63	28	124%	161	144	12%
TOTAL REVENUE	1,644	1,557	6%	6,529	5,659	15%
EBITDA	382	431	(11%)	1,765	1,538	15%
PBT (Before exceptional items)	204	284	(28%)	1,119	1,020	10%
PBT	204	284	(28%)	1,186	1,215	(2%)
Net Profit	123	214	(42%)	748	905	(17%)
Net Profit (before exceptional items)	123	214	(42%)	760	729	4%
R&D Expenses in P&L	125	92	36%	439	290	52%
Gross R&D Spends	139	166	(16%)	527	480	10%
EBITDA Margin	23%	28%		27%	27%	
Core EBITDA Margin	29%	34%		33%	32%	
Net Profit Margin (before exceptional income)	8%	14%		12%	13%	
Net Profit Margin	8%	14%		11%	16%	
[#] includes Licensing Income net of tax	8	7		31	25	

Notes: Figures above are rounded off to the nearest Cr; % based on absolute numbers.

EXECUTIVE COMMENTARY:

PERFORMANCE REVIEW: Q4 & Full Year FY20

- **FY20 Consolidated Revenue** grew 15% to Rs 6,529 Crore from Rs 5,659 Crore in FY19.
 - **Q4FY20 Consolidated Revenue** grew 6% to Rs 1,644 Crore from Rs 1,557 Crore in Q4FY19.
- **FY20 Earnings before Interest, Depreciation and Amortization (EBITDA)** increased 15% to Rs 1,765 Crore (vs. Rs 1,538 Crore in FY19).
 - **Q4FY20 EBITDA** decreased 11% to Rs 382 Crore (vs. Rs 431 Crore in Q4FY19).
- **FY20 Net Profit** at Rs 748 Crore (vs. Rs 905 Crore in FY19).
 - **Q4FY20 Net Profit** at Rs 123 Crore (vs. Rs 214 Crore in Q4FY19).
- **FY20 Net Profit** (before exceptional item) at Rs 760 Crore (vs. Rs 729 Crore in FY19).

BUSINESS SEGMENT REVIEW: Q4FY20

SMALL MOLECULES: APIs & Generic Formulations

- Q4FY20 Revenue at Rs 541 Crore, rose 15% (YoY) from Rs 472 Crore in Q4FY19

The **Small Molecules** business reported a revenue growth of 15% for the quarter at Rs 541 Crore led by steady API sales and strong growth in Generic Formulations. While the API business faced challenges in the Latin America region it continued to do well in India, APAC and EU driven by our statins and immunosuppressants portfolio.

Commenting on the performance, **Siddharth Mittal, CEO & Managing Director, Biocon Ltd**, said, *“Steady API sales and a robust YoY growth in Generic Formulations led to a 15% increase in Small Molecules revenue for the fourth quarter, helping us close FY20 with a 18% rise in revenue to Rs 2,094 Crore. For the first time ever, the Small Molecules business crossed an annual revenue milestone of Rs 2,000 Crore. The new financial year comes with a new set of challenges in the midst of the ongoing COVID-19 pandemic. However, we are confident of emerging from the current situation stronger and more determined than ever to deliver on our commitment to provide the highest quality biopharmaceuticals to our patients and partners.”*

Our Small Molecules **APIs manufacturing facility** at Biocon Park, Bengaluru received an EIR (*Establishment Inspection Report*) from the U.S. FDA for the pre-approval and GMP inspection held in January 2020 with a VAI (*Voluntary Action Indicated*) status for the five observations. We are addressing these observations as per the CAPA submitted with the U.S. FDA. The receipt of EIR indicates the closure of this inspection.

Additionally, we received an EIR from the U.S. FDA for our Small Molecules **API Manufacturing Facility** at 20th KM, Biocon Campus, Bengaluru, for the post-approval and GMP inspection conducted in February 2020 with a VAI classification for the observations, which indicates closure of the inspection.

Our **Oral Solid Dosage manufacturing facility** in Bengaluru also successfully concluded the U.S. FDA's pre-approval inspection conducted in January 2020 with zero observations.

BIOCON BIOLOGICS: Biosimilars

- Q4FY20 Revenue at Rs 357 Crore, down 21% (YoY) from Rs 451 Crore in Q4FY19

After reporting **three consecutive quarters of robust performance**, the **Biologics** segment reported a de-growth of 21% to Rs 357 Crore in Q4FY20 due to operational challenges related to COVID-19 and less than expected contribution from our partners.

We expect the business to normalize by Q2FY21 as we continue to pursue growth through our strong biosimilars portfolio in many markets across the globe.

Commenting on the performance, **Dr Christiane Hamacher, CEO & Managing Director, Biocon Biologics India Ltd**, said, *"We had excellent growth for three consecutive quarters in FY20 until the COVID-19 pandemic impacted our Q4 earnings. However, we expect the biosimilars business to recover Q1FY21 onwards on the back of growth opportunities of our key biosimilars supplemented by the expected U.S. launch of Insulin Glargine in mid-CY20. Despite the Q4 FY20 setback, we have recorded a strong revenue growth of 29% at Rs 1,951 Crore in FY20. Our scientific expertise in developing and manufacturing complex biosimilars together with the commercialization strengths of our partners, position us well to be a global leader in the biosimilars space over the long term. As we move ahead, we are confident to capitalize on the new global opportunities. We remain committed to impact 5 million patient lives and attain a revenue milestone of USD 1 billion in FY22."*

During the quarter, we extended our footprint in **Australia** and **Canada** with the commercialization of **Fulphila®**, our biosimilar Pegfilgrastim. Early sales of Fulphila, the third biosimilar from our collaboration with Mylan in **Australia**, have been encouraging. Ogivri and Semglee (Insulin Glargine) were commercialized in Australia earlier this financial year.

In Q4FY20, the U.S. FDA accepted the **Biologics License Application (BLA)** for our proposed biosimilar **Bevacizumab** filed under the 351(k) pathway. The FDA goal date set under the Biosimilar User Fee Act (BsUFA) is Dec. 27, 2020

Similarly, in case of our insulins portfolio, we are on track with the development of **Insulin Aspart** for the global markets. We also continue to work with the **U.S. FDA** on the development of **rh-Insulin** for the U.S., taking into account the draft guidance for insulin biosimilars under the 351(k) pathway.

During the quarter, our **Insulins manufacturing facility in Malaysia** received an **EIR (Establishment Inspection Report)** from the U.S. FDA, denoting the closure of its inspection of the facility in February 2020. This along with positive developments on a patent litigation for **Insulin Glargine device** in the U.S. bring us closer to the anticipated launch of **Semglee®**, our biosimilar Insulin Glargine, in the U.S. in mid-CY20.

In the month of April, we also received an **EIR** from the **U.S. FDA** for the pre-approval inspections of **two** of our **biologics manufacturing facilities** in Bengaluru held in September 2019. The receipt of the EIR indicates a successful closure of these inspections.

We also received the **Certificate of GMP compliance from EMA for our Biologics Drug Substances** facilities at 20th KM, Hosur Road, Bengaluru. These facilities are used for the manufacture of Drug Substances of **Pegfilgrastim** and **Recombinant Human Insulin** and manufacturing related activities for **Insulin Glargine** and **Insulin Aspart** and were inspected by the agency in January 2020.

Key business developments during the quarter augur well for us as we progress in FY21. We have a strong portfolio of in- market and in- development biosimilars, which will enable us to pursue the path of growth in the years ahead.

BRANDED FORMULATIONS

- Q4FY20 Revenue at Rs 117 Crore, down 12% (YoY) from Rs 133 Crore in Q4FY19

Branded Formulations business continues to face challenges and COVID-19 has compounded these challenges further. For Q4FY20, business revenue at Rs 117 Crore reported a de-growth of 12%. Both supply side and demand side challenges on account of the nationwide lockdown in India impacted business across our divisions in Branded Formulations. On the positive side, **CANMAb®** sales commenced in **Sri Lanka** during the quarter.

Our Branded Formulations business in the **UAE** through our JV entity, **Neo Biocon**, faced significant business challenges in the last fiscal resulting from a price reduction mandated by the Ministry of Health, UAE.

Whilst this challenge was being addressed, our JV partner has come under investigation for governance issues which is likely to have a reputational impact on the JV. As a Company committed to the highest standards of governance, we have decided to wind up the JV entity.

NOVEL BIOLOGICS

In our **Novel Biologics** business, the Phase 1b clinical trial for our novel, first-in-class oral insulin molecule Insulin Tregopil in people with Type 1 diabetes is progressing in Germany. There has been no impact yet on patient enrolment for the study due to COVID-19 pandemic.

RESEARCH SERVICES: SYNGENE

- Q4FY20 Revenue at Rs 607 Crore, up 14% (YoY) from Rs 534 Crore in Q4FY19

Research Services reported a growth of 14% YoY with revenue at Rs 607 Crore for Q4FY20, driven by strong performances in **Discovery Services** and **Development Services**. During the quarter, the Company commissioned a new 152,000 sq. ft. multi-disciplinary research facility at Biocon Park in Bengaluru that will support discovery biology, QC microbiology and other research domains. Its Mangalore API manufacturing facility is undergoing qualification in preparation for commencement of GMP commercial manufacturing. Additionally, Syngene

successfully underwent a U.S. FDA inspection of its small molecule bioanalytical laboratory within Clinical Development services.

Jonathan Hunt, CEO & Managing Director, Syngene International Limited, said: *“The fourth quarter saw strong performances from our two main divisions, Discovery Services and Development Services delivering improved profitability for the quarter. We are proud to play an active role in addressing the pandemic by opening a dedicated COVID-19 testing centre to deliver antibody-based tests to support the local community and hospitals in the Bangalore region. Additionally, we have diverted resources to supply reagents for use in the development and manufacture of COVID-19 testing kits. Our scientists are also actively involved in research projects with our clients and partners to find vaccines that could make a significant contribution to combatting the COVID 19 virus.”*

Leveraging its scientific expertise and commitment to help the nation tide over the COVID-19 challenge, **Syngene has started COVID-19 testing** at its NABL-accredited and ICMR-certified laboratory using **RT-PCR technology** to support government hospitals in Bengaluru ramp up testing. All tests are being offered free of charge. It has also entered into a partnership with Pune-based **Mylab Discovery Solutions** to supply reagents for use in its indigenously developed COVID-19 testing kits. Syngene scientists are also actively involved in research projects to find vaccines against the COVID-19 virus.

BUSINESS SEGMENT REVIEW: FULL YEAR FY20

SMALL MOLECULES: APIs & Generic Formulations

- FY20 Revenue at Rs 2,094 Crore, up 18% (YoY) from Rs 1,773 Crore in FY19

In FY20, the **Small Molecules** business recorded robust revenues with annual revenue crossing the Rs 2,000 crore milestone for the first time ever.

The performance of the **Small Molecules** business was driven by a better product mix and increased demand for our APIs in global markets. Our **Generic Formulations** business continues to report robust growth every quarter and has attained a critical mass in FY20. All our products have reported an increase in market share in FY20.

We have also entered **China**, the **world’s 2nd largest pharma market**, by forging a strong partnership with China Medical System Holdings for commercializing three of our Generic Formulations products.

To be future ready, we initiated a **greenfield project** in FY20 for a **fermentation-based manufacturing facility** in **Visakhapatnam, Andhra Pradesh**, to cater to the anticipated strong volume growth in the Small Molecules APIs business.

BIOCON BIOLOGICS: Biosimilars

- FY20 Revenue at Rs 1,951 Crore, up 29% (YoY) from Rs 1,517 Crore in FY19
- FY20 PBIT Margin at 25% vs 26% in FY19

- Patient Reach of Biocon Biologics' Biosimilars (FY20): **2.1 million**

The **Biologics business** reported a **strong revenue growth of 29%** at **Rs 1,951 Crore**, for **FY20**. We expanded our global footprint with commercialization of some of our key biosimilars coupled with regulatory approvals in developed and most of the world (MoW) markets. We also started the value unlocking process for Biocon Biologics, with the aim of investing, competing and winning in the large and growing opportunity for biosimilars. We launched the '10 Cents Mission' to enable universal access to rh-Insulin by reducing prices to less than 10 US cents / day for low- and middle-income countries, which account for 80% of the global diabetes burden, and dialogues with various governments are ongoing.

Biocon Biologics launched its **second biosimilar**, Ogivri[®], **Trastuzumab** co-developed with Mylan, in the U.S. in December 2019 and became the **first company from India** to have **commercialized two biosimilars in the U.S.** Fulphila[®] (Pegfilgrastim) was the first biosimilar to be commercialized by us in the U.S. in FY19. We look forward to the major near term milestone of approval and launch of Semglee in the U.S.

Our biosimilars business continues to do well in many of the most of the world (MoW) markets. In **Latin America**, we hold registrations for our biosimilar **Trastuzumab** in over 10 countries and during the year we commercialized it in many of these markets.

As our **biosimilars** start making inroads in most of the developed markets around the world, as well as, emerging markets, we are accordingly **expanding production capacity** to cater to the expected demand. During FY20, we augmented manufacturing capacity for two of our key biosimilar products, Trastuzumab and Pegfilgrastim.

As a patient-centric organization, we continue to enhance affordable access to critical biologics therapy for diabetes and cancer patients through our five commercialized biosimilars. During the year, we served 2.1 million patients.

A **key milestone** during **FY20** was the **private equity investment of USD 75 million** by Activ Pine LLP, an affiliate of True North Fund, in Biocon Biologics. This was a primary equity infusion for a 2.44% stake at an **equity valuation of USD 3 billion** and an **enterprise valuation of USD 3.5 billion on a pre-money basis.**

BRANDED FORMULATIONS

- FY20 Revenue Rs 536 Crore, down 18% (YoY) from Rs 656 Crore in FY19

In FY20, the **Branded Formulations** business reported a revenue of Rs 536 Crore.

In terms of annual performance, the positive performance of the Nephrology, Immunotherapy and Critical Care divisions of the **India** business was offset by pressure in Metabolics, Oncology and Market Access divisions.

The **UAE** branded business has been impacted by steep price cuts announced by the Ministry of Health. However, our biosimilars portfolio in UAE continues to do well with our brand

Canhera capturing ~**30% volume** share (IMS MAT Feb 20) of the biosimilar Trastuzumab market in UAE.

RESEARCH SERVICES: SYNGENE

- FY20 Revenue at Rs 2,012 Crore, up 10% (YoY) from Rs 1,826 Crore in FY19

Our **Research Services** segment reported a **revenue growth of 10%** at **Rs. 2,012 Crore** in FY20, driven by a strong performance in the **Discovery Research** division.

During the year, Syngene continued to build on its capabilities in both Discovery and Development Services. It expanded its research capabilities into **CAR-T therapy**, strengthened its biologics manufacturing capacities by adding new bioreactors as well as strengthened its leadership team.

IMPACT OF COVID-19

The COVID-19 pandemic since March 2020 and the consequent lockdowns in India and various other countries have had a ripple effect on businesses worldwide. However, in order to minimise impact to patients, Biocon activated business continuity plans to run essential and critical manufacturing and quality operations with minimal staffing. Still, supply chain disruptions, impaired mobility and industry-wide dislocation as a fallout of the pandemic affected parts of our business.

We are monitoring the situation and are gradually ramping up our operations to provide life-saving medicines to patients and partners. At the same time, we are prioritizing the health and safety of our employees and implementing additional safety measures.

CONTRIBUTING TO THE FIGHT AGAINST COVID-19

As a globally recognized biopharmaceuticals company engaged in innovative science to develop new drugs and manufacture life-saving therapies, Biocon is playing a key role in the global efforts to tackle the COVID-19 crisis. In this time of national and global crisis, Biocon Group of companies has taken up several relief initiatives working closely with the government at the state and national levels, as well as, other social bodies. We are also contributing towards the nation's well-being by supporting our communities and the underprivileged who need our help.

1. Monetary Donation: Each employee of Biocon Group of Companies has donated a minimum of one day's salary in addition to contributions made by the companies. The total contribution will go to the PM Fund to support the underprivileged who need humanitarian aid during this crisis.

2. Feeding the Underprivileged: Biocon Foundation collaborated with the Akshaya Patra Foundation to ensure better access to food and nutrition for the underprivileged who are currently facing hunger due to the economic fallout of the COVID-19 crisis. The Foundation has provided 20,000 'COVID-19 Relief Care Package Food Kits' to daily wage earners and migrant laborers in Bengaluru, Hyderabad and Visakhapatnam.

3. Contributing to Research:

- **Biocon** is repurposing its biological therapy **ALZUMAb (Itolizumab)** for COVID-19.
- We have received **DCGI approval** for a **clinical trial of Itolizumab**, an anti-CD-6 IgG1 monoclonal antibody, in moderate to severe patients with COVID-19 complications. Itolizumab binds to CD6 receptor and inhibits T-cell activation, thereby inhibiting production of pro-inflammatory cytokines. We believe that ‘cytokine storm,’ which is a complication of COVID-19, can thus be treated with Itolizumab. Itolizumab, a novel biologic developed by Biocon was commercialized in India for Plaque Psoriasis in 2013.
- The clinical trial has been initiated at multiple hospitals in Mumbai and Delhi and we plan to carefully study early safety and efficacy in COVID-19 patients.
- **Syngene** has repurposed one of its **high –end laboratories** to conduct **RT-PCR tests** for COVID-19 and is offering its scientific expertise to scale up testing. A dedicated team of scientists has been trained to perform these tests as per national and international regulatory guidelines. These services are being offered free to the city hospitals.
- Syngene is also working to **supply reagents** (primers and probes) for COVID-19 diagnostic testing to clients.
- Syngene is also working on **research projects related to vaccine development**, which could represent a longer-term solution for fighting the coronavirus pandemic.

4. Offering life-saving therapies on priority to state governments: Biocon Biologics has reached out to various state governments in India, offering them support during this crisis through our life-saving medicines, including insulin and cancer therapies, at affordable price to enable them to look after the growing needs of patients during COVID-19.

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 and Europe. It also has a pipeline of promising novel assets in immunotherapy under development. www.biocon.com Follow-us on Twitter: @bioconlimited

Biocon Biologics is a subsidiary of Biocon Ltd. It is uniquely positioned as a fully integrated ‘pure play’ biosimilars organization in the world and aspires to transform patient lives through innovative and inclusive healthcare solutions. The Company’s portfolio of biosimilar molecules comprises a rich pipeline of approved and in-development biosimilars, which are an outcome of its high end R&D and global scale manufacturing expertise. The Company has commercialized three of its biosimilars in the developed markets like EU, U.S., Japan and Australia. It is a leading global insulins player with over 15 years of experience in addressing the needs of patients with diabetes, having provided over 2 billion doses of human insulin worldwide, thus far. Follow-us on Twitter: @BioconBiologics

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Earnings Call

The company will conduct a call at 5.00 PM IST on May 15, 2020 where the senior management will discuss the company's performance and answer questions from participants. To participate in this conference call, please dial the numbers provided below ten minutes ahead of the scheduled start time. The dial-in number for this call is +91 22 6280 1151. Other toll numbers are listed in the conference call invite which is posted on the company website www.biocon.com. The operator will provide instructions on asking questions before the start of the call. A replay of this call will also be available from the conclusion of the call till May 22, 2020 on +91 22 7194 5757, Playback Code: 87721. Transcript of the conference call will be uploaded on the company website in due course.

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.