PRESS RELEASE

Biocon Q4FY21 Revenue at Rs 2,044 Cr, Up 26%; EBITDA at Rs 641 Cr; Up 68%

Net Profit *(before exceptional item & discontinuing operations)* at Rs 257 Cr;

Biosimilars Up 53% at Rs 664Cr; Research Services Up 8% at Rs 659 Cr; Generics Up 3% at Rs 578 Cr.

FY21 Revenue Up 14% at Rs 7,360 Cr; EBITDA Up 8% at Rs 1,907 Cr; Net Profit *(before exceptional item & discontinuing operations)* at Rs 754 Cr.

Bengaluru, Karnataka, India: April 28, 2021:

Biocon Ltd (BSE code: 532523, NSE: BIOCON), an innovation-led global biopharmaceuticals company, today announced its consolidated financial results for the fourth quarter and the fiscal year ended March 31, 2021.

Commenting on the results, **Kiran Mazumdar-Shaw**, **Executive Chairperson**, **Biocon,** said: "*In Q4FY21 our revenues grew 26% YoY to Rs 2,044 Crore driven by our Biosimilars, Research Services and Generics businesses. On a full-year basis, we reported a revenue growth of 14% led by Biosimilars which grew by 21%, Research Services by 9% and Generics by 6%. For FY21, EBITDA was at Rs 1,907 Crore and core EBITDA margins at 33%. Our determination to keep investing in science to stay a step ahead of the pandemic is reflected in the 19% rise in our Gross R&D spends in the year.*"

"As a science-led company we are contributing to the national fight against the pandemic, through several initiatives spanning diagnostic tests, vaccination and therapies towards combating COVID-19. The Biocon Group is catering to the countrywide demand for Remdesivir, Itolizumab and CytoSorb®. Syngene through its vaccination Centre is offering immunization services for Biocon Group employees as well to others operating in Electronic City, Bengaluru. Despite the challenges posed by the second COVID-19 wave in India, we will endeavor to have safe and uninterrupted operations and enable access to life-saving medicines for our patients and customers," **she added.**

PERFORMANCE REVIEW: Q4FY21

- **Q4FY21 Consolidated Revenue** grew **26%** to **Rs 2,044 Crore** from Rs 1,621 Crore in Q4FY20.
- **Q4FY21 Earnings before Interest, Depreciation and Amortization (EBITDA)** was **Rs 641 Crore** (vs. Rs 382 Crore in Q4FY20)
- **Q4FY21 Net Profit** (before exceptional item and discontinuing operations) at **Rs 257 Crore** (vs. Rs 132 Crore in Q4FY20) was up **95%**.
- Gain of **Rs 160 Crore** arising on the fair valuation of Bicara Therapeutics Inc. (Bicara) due to loss of control from Subsidiary to Associate is reported under “Other income” for the quarter.

- Adjusting for the Bicara valuation gain:
  - EBITDA for Q4FY21 stood at **Rs 481 Crore** reflecting EBITDA margins of **26%.**
  - **Net profit from Continuing operations** stood at **Rs 97 Crore** for Q4FY21.
  - **Core EBITDA margins** (i.e., EBIDTA margins, net of licensing, forex, and R&D) were at **32%.**
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PERFORMANCE REVIEW: FY21

- **FY21 Consolidated Revenue** grew **14%** to **Rs 7,360 Crore** from Rs 6,462 Crore in FY20.
- **FY21 Earnings before Interest, Depreciation and Amortization (EBITDA)** was **Rs 1,907 Crore** (vs. Rs 1,765 Crore in FY20).
- **FY21 Net Profit** (before exceptional item and discontinuing operations) at **Rs 754 Crore** (vs. Rs 789 Crore in FY20) was down **4%**.
- Adjusting for Bicara Valuation gain:
  - **FY21 EBITDA** stood at **Rs 1,747 Crore** reflecting EBITDA margins of **24%.**
  - **Net profit from Continuing operations** stood at **Rs 594 Crore** for FY21, reflecting a margin of **8%.**
  - **Core EBITDA margins** (i.e., EBIDTA margins, net of licensing, forex, and R&D) were at **32%.**

FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q4 and Full Year FY21

In Rs Crore

Particulars	Q4FY21	Q4FY20	Change	FY21	FY20	Change
INCOME						
Generics	578	562	3%	2,336	2,207	6%
Biosimilars	664	433	53%	2,800	2,315	21%
Novel Biologics	-	-	-	-	-	-
Research services	659	607	8%	2,184	2,012	9%
Inter-segment	(61)	(45)	35%	(215)	(234)	(8%)
Revenue from operations #	**1,839**	**1,558**	**18%**	**7,106**	**6,301**	**13%**
Other income	205	63	226%	255	161	58%
Total Revenue	**2,044**	**1,621**	**26%**	**7,360**	**6,462**	**14%**
EBITDA	**641**	**382**	**68%**	**1,907**	**1,765**	**8%**
PBT Before Exceptional Items	354	213	66%	1,065	1,147	(7%)
PBT from Continuing Operations	366	213	72%	1,077	1,215	(11%)
Net Profit from Continuing Operations	254	132	92%	750	777	(3%)
Net Profit for the Period	**254**	**123**	**105%**	**740**	**748**	**(1%)**
R&D Expenses in P&L	127	125	2%	553	439	26%
Gross R&D Spend	**136**	**139**	**(2%)**	**627**	**527**	**19%**
EBITDA Margins excluding Bicara Valuation Gain	26%	24%		24%	27%	
Core EBITDA Margins excluding Bicara Valuation Gain	**32%**	**29%**		**32%**	**33%**	
Net Profit Margins excluding Bicara Valuation Gain	5%	8%		8%	12%	

#includes Licensing Income. All Figures above are rounded off to the nearest Crore; % based on absolute numbers

CORPORATE UPDATE

Bicara Therapeutics to operate as a standalone company with an independent management team

During the current quarter, Biocon ceded control over the Board of Directors and Operations of Bicara to enable it to operate independently under the U.S. - based leadership team and raise funds to advance its development programs. As a result of this change, Bicara was classified as an Associate from a Subsidiary under IND-AS. Consequently, the investment in Bicara was fair valued resulting in a gain of **Rs 160 Crore,** which is reported under "Other income" for the quarter.

Dividend for FY 21

On account of the uncertainty created by an unprecedented second wave of the COVID-19 pandemic and the continued investments in R&D and Capex, the Board of Directors has decided it would not be appropriate to declare a dividend for FY21.

Kiran Mazumdar-Shaw appointed to the Board of Trustees of Memorial Sloan Kettering Cancer Center

Biocon Executive Chairperson Kiran Mazumdar-Shaw has been appointed to the Board of Trustees of Memorial Sloan Kettering Cancer Center (MSK), a world leader in cancer treatment and research, based in New York, U.S. She is among the 52 members on the board and will serve for a term of three years w.e.f. April 14, 2021.

MANAGEMENT UPDATE

BIOCON BIOLOGICS LTD:

Shreehas Tambe, former Chief Operating Officer at Biocon Biologics, has been appointed the Deputy Chief Executive Officer, effective March 1, 2021. A Biocon veteran of over 20 years, Shreehas has held various operational & strategic leadership roles here and led large, diverse teams across the Manufacturing, Quality, R&D and Projects & Engineering functions.

Biocon Biologics also appointed **Susheel Umesh** as Chief Commercial Officer – Emerging Markets. Susheel has over 30 years of experience in the pharmaceutical industry. He has worked with leading global pharmaceutical companies in India, France and Sub-Saharan Africa.

BIOCON LTD:

The Board has appointed **Indranil Sen** as the CFO in place of **Anupam Jindal** who resigned as the Chief Financial Officer (CFO) of Biocon Limited due to personal reasons. Indranil was earlier the Vice-President of Finance at Biocon Ltd and has held various key leadership roles in the finance function since joining Biocon in 2014.

BUSINESS SEGMENT REVIEW: Q4FY21 & FY21

GENERICS: APIs & Generic Formulations

Q4FY21 revenue at Rs 578 Crore, up 3% YoY from Rs 562 Crore in Q4FY20
FY21 revenue at Rs 2,336 Crore, up 6% YoY from Rs 2,207 Crore in FY20Highlights from the quarter:

- Received U.S.FDA approval for Everolimus (the generic version to Afinitor®), an immunosuppressant used in cancer treatment, in a significant boost to our efforts to vertically integrate our APIs into generic formulations for niche therapeutics. We expect to launch the product in the U.S. in FY22
- Received a certificate of Good Manufacturing Practice (GMP) compliance from the Medicines & Healthcare products Regulatory Agency (MHRA), UK, for our formulations manufacturing facility located at Biocon Park, Bengaluru.
- Partnered with Libbs Farmaceutica, a leading pharmaceuticals company in Brazil, to develop and commercialize our portfolio of generic drugs in Brazil, the world's sixth most populous country.

Commenting on the Generics segment performance, **Siddharth Mittal, CEO & Managing Director, Biocon Limited**, said, *"The FY21 performance was in line with our expectations. Revenues grew by 6% over the previous year, with a Profit Before Tax of 13%, supported by double digit growth in generic formulations and a modest single digit growth in APIs. I am pleased that we were able to ensure continuity of our business operations and serve patients and partners through a challenging year.*

Our Q4 performance delivered a moderate 3% growth over the previous year. This was mainly on account of headwinds we encountered by way of pricing pressure on both APIs and formulations, particularly in the U.S., and travel restrictions that delayed regulatory approvals, and consequently new product launches. Our API revenues were also relatively subdued, as compared to the first half of the fiscal, due to our customers stockpiling during this period, anticipating pandemic-related disruptions in supply chain.

Despite these challenges, we continue to progress on strengthening our product portfolio and expanding our global footprint. We received U.S. FDA approval for Everolimus (the generic to Afinitor®), an immunosuppressant used to treat cancer. We received a GMP compliance certificate from MHRA, UK, which boosts our efforts to establish a strong global formulations portfolio. We also partnered with Libbs Farmaceutica, a leading pharmaceuticals company in Brazil, to develop and market our generic drugs in Brazil.

We remain committed to invest in building new capabilities and capacities across functions, including R&D, manufacturing and quality, as well as strengthen our product portfolio. We are confident that focus on our strategic priorities and execution excellence will ensure that we deliver long-term, sustainable growth."

Other developments

- Our portfolio of statin formulations continue to hold mid- to high-teens market share in the U.S., while our first immunosuppressant formulation, Tacrolimus, launched in Q3 this year, has started gaining market share.
- We continue to build on our generic formulations portfolio. In the U.S., we filed an Abbreviated New Drug Application (ANDA) for our vertically integrated products, in addition to Market Authorisation Applications (MAAs), and dossiers in Europe, and Most of World (MoW) markets. In APIs, we filed 10 Drug Master Files (DMFs) in MoW markets and received four DMF approvals in the U.S., the European Union (EU) and MoW markets.
- After some initial Covid related delays, the construction of our greenfield immunosuppressant plant at Visakhapatnam had begun to return to normalcy. While we expect the facility to be commissioned in CY 2022, potential disruptions from the second wave of the pandemic may once again impact its progress.
- There are several initiatives, including cost improvement measures and a digitization drive, currently underway across the organisation, to optimise our systems and processes and drive efficiencies. These initiatives are expected to improve our cost structure, which will in turn enable us to be more competitive in the future.

Novels

Equillium, our U.S.-based partner, reported encouraging developments on the clinical advancement of Itolizumab, a first-in-class anti-CD6 monoclonal antibody. We are optimistic about Itolizumab's therapeutic use in acute graft-versus-host disease, lupus and lupus nephritis, and uncontrolled asthma. We are expecting clinical data from all studies in CY 2021.

BIOSIMILARS: Biocon Biologics

Financial Highlights:

- **Q4FY21 revenue at Rs 664 Crore, up 53% YoY.**
- **Q4FY21 EBITDA stood at Rs 164 Crore; Q4FY21 EBITDA margin was 25%.**
- **FY21 revenue at Rs2,800 Crore, up 21% YoY.**
- **FY21 EBITDA stood at Rs 747 Crore; FY21 EBITDA margin was 27%.**
- **R&D costs increased to Rs 284 Crore in FY21 from Rs 178 Crore in FY20 as we continued to progress our early-stage product pipeline. Core EBITDA margins were at 36% in FY21.**
- **3.1 million patients benefited from our biosimilars in FY21**.

Q4FY21 Regulatory & Others

- Received **marketing authorization approvals** for ***Abevmy****, **biosimilar Bevacizumab**, (in April 2021) and ***Kixelle****, **biosimilar Insulin Aspart,** from the **European Commission**.
- Received **pre-qualification approval** from **WHO** for our **biosimilar Trastuzumab 150 mg and 420 mg** presentations, opening opportunities in 46 LMIC countries.

- The **300-patients, multi-centric Phase 4** clinical study of our novel anti-CD6 monoclonal antibody, **Itolizumab**, in **COVID-19** is completed. Study results to be published soon.
- As India contends with the second wave of the COVID-19 pandemic, we have **served over 6,500 patients** with **ALZUMAb-L (Itolizumab)** so far in April 2021.

Commenting on the performance, **Dr. Arun Chandavarkar, Managing Director, Biocon Biologics Ltd,** said, *"We have reported a revenue growth of 53% YoY at Rs 664 Crore for Q4FY21 led by a strong growth of our emerging markets business supported by market share gains for Pegfilgrastim and Trastuzumab biosimilars in the developed markets and contributions from Insulin Glargine introduced in the U.S. earlier this fiscal. The marketing authorization approvals for our biosimilar Insulin Aspart and biosimilar Bevacizumab in the EU augur well for our future business prospects."*

"For the full year, our revenues have grown 21% to Rs 2,800 Crore despite a challenging business environment aggravated in part by the pandemic. However, we are confident that our strong business fundamentals as a vertically integrated company with global scale will see us expanding our reach to patients globally. With five biosimilars approved in developed markets, we will continue to invest prudently in our product portfolio thereby enabling affordable access to high quality biosimilars," ***he added.***

Q4FY21: Strong Topline Performance

Q4FY21 revenue grew **53%** YoY to **Rs 664 Crore**, driven primarily by strong sales of our biosimilar insulins and monoclonal antibodies in key emerging markets in Latin America and APAC along with improved performance in developed markets.

Two of our co-developed biosimilars, **Insulin Aspart** *(Kixelle*)* and **Bevacizumab** *(Abevmy*)* received marketing authorization approval from **the European Commission,** paving the way for their commercialization. Our biosimilar Bevacizumab, available in India as Krabeva® since 2017, has addressed the needs of many cancer patients.

Enabling Access to Itolizumab for Treating COVID-19

Responding to the second wave of COVID-19 in India, Biocon Biologics stepped up its efforts to provide its anti-CD6 novel biologic Itolizumab (ALZUMAb-L) to patients. ALZUMAb-L has approval from the Drug Controller General of India for restricted emergency use in treating CRS (cytokine release syndrome) in patients experiencing moderate to severe ARDS (acute respiratory distress syndrome) due to COVID-19. Over 6,500 patients have been treated with Itolizumab so far in April 2021 alone. We remain committed to enabling physicians in saving patients' lives.

Itolizumab Scientific Publication

Also during this quarter, the *Expert Opinion on Biological Therapy* published the results from Biocon's two-arm, randomized, controlled, multi-centre, open-label Phase 2 study to evaluate the efficacy and safety of Itolizumab in moderate to severe ARDS patients due to COVID-19. The results showed

Itolizumab is a promising, safe and effective immunomodulatory therapy for treatment of ARDS due to cytokine release in COVID-19 patients, with survival and recovery-benefit.

FY21: Steady Patient Reach

For FY21, we recorded revenue of **Rs 2,800 Crore,** representing year-on-year growth of **21%,** driven by sales of our insulins and monoclonal antibodies across developed and key emerging markets. **During the year, we served 3.1 million patients through our portfolio**.

Despite the shift in focus and resources of healthcare systems towards COVID-related therapeutics, we continued to see increase in demand for our biosimilars. We have garnered leading market share for our products in many key emerging markets, e.g., Algeria, Brazil & Malaysia. With a high double-digit market share, bTrastuzumab (*Zedora*) is the leader in the private market in Brazil.

Similarly, biosimilar Trastuzumab *(Ogivri*)* continued to improve market share across several European countries. It is also the leading[#] bTrastuzumab in Australia and Canada. Biosimilar Pegfilgrastim *(Fulphila*)* saw good sales traction[#] in EU.

In the U.S, we witnessed a modest uptake of biosimilar Insulin Glargine *(Semglee*)* following its launch in FY21 on account of the timing of approval impacting formulary contracting cycles for CY21. bPegfilgrastim and bTrastuzumab maintained a steady market share.

We believe that we are well-positioned to grow our biosimilars business globally on the back of our robust business fundamentals, scientific knowhow, global scale manufacturing and a broad product portfolio.

Regulatory Progress

We continued to secure regulatory approvals for our key products, bPegfilgrastim, bTrastuzumab, bBevacizumab, rh-Insulin, bGlargine and bAspart in several Most of the World (MoW) markets.

We embraced the 'new normal' by leveraging technology for stakeholder engagement implementing various digital solutions and undergoing virtual inspections for regulatory approvals during the year.

**Partnered with Viatris [#]Source: IQVIA data for quarter ended December 2020*

RESEARCH SERVICES: Syngene

- **Q4FY21 revenue at Rs 659 Crore, up 8% YoY from Rs 607 Crore in Q4FY20**
- **FY21 revenue at Rs 2,184 Crore, up 9% YoY from Rs 2,012 Crore in FY20**

Highlights from the quarter:

- Steady performance across discovery and manufacturing services, and the dedicated centres.Extended engagement with Bristol Myers-Squibb on dedicated R&D centre until 2030; new agreement includes an expansion in the breadth of drug discovery research, a 40%

increase in the number of scientists and an additional 50,000 sq. ft. of dedicated laboratory space.

- Syngene's API manufacturing facility in Mangalore has been audited by the Indian regulatory authority and is now GMP-certified.
- Commissioned a new HPAPI laboratory that will support scaling up of manufacturing capability.

Highlights from the full year:

- Syngene continued to build on its integrated drug discovery and development portfolio by signing a five-year collaboration with 3DC, the drug discovery and development subsidiary of Deerfield Management Company.
- Syngene is proud of its partnership with Albireo Pharma. The work completed in its laboratories of advancing odevixibat from pre-clinical supplies to regulatory filings in Europe and the US has put the compound on track to become the first approved drug for PFIC3 patients.
- Syngene expanded its research facility in Hyderabad by adding capacity for an additional 90 scientists. It also commissioned a new microbial manufacturing facility during the year to reduce its dependency on external service providers.

Commenting on the performance, **Jonathan Hunt, CEO & Managing Director, Syngene** said: *"Syngene's Q4 revenue growth was driven by a steady performance across Discovery and Manufacturing services and the dedicated R&D centres. The key highlight of this quarter was the extension of the collaboration with Bristol Myers Squibb until 2030, which underlines the value we deliver to this strategic collaboration. On a full-year basis, we have demonstrated remarkable resilience in the face of a very volatile situation, to end the year on guidance. We will continue to support the fight against the COVID-19 pandemic while continuing to deliver science that makes a difference."*

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. **Website: www.biocon.com; Follow-us on Twitter: @bioconlimited**

Biocon Biologics Limited, a subsidiary of Biocon Limited is uniquely positioned as a fully integrated 'pure play' biosimilars organization in the world. Building on the four pillars of Patients, People, Partners and Business, Biocon Biologics is committed to transforming healthcare and transforming lives. Biocon Biologics is leveraging cutting-edge science, innovative tech platforms and advanced research & development capabilities to lower treatment costs while improving healthcare outcomes. It has a strong research pipeline of biosimilar molecules across diabetes, oncology, immunology, dermatology, ophthalmology, neurology, rheumatology and inflammatory diseases. Five molecules from Biocon Biologics' portfolio have been taken from lab to market, of which three have been commercialized in developed markets

like United States, EU, Australia, Canada and Japan. With a team of over 4,800 people Biocon Biologics aspires to transform healthcare through affordable innovative solutions as well as impact millions of patients' lives. **Biocon Biologics on the Web ; Follow-us on Twitter: @BioconBiologics**

Important Update: Change in Biocon earnings call on 29th April 2021 at 9:00hrs from Voice Audio Bridge to a Zoom Meeting

*The management of the Company will host an **Earnings Call** on **29th April at 9:00 hrs**. This call was earlier planned to be conducted over a voice audio bridge. However, the management will now address the investors and the analysts over a zoom meeting at the same time.*

Conference Call Details	
Date	29th April 2021
Time	9:00hrs -10:30hrs, IST
Meeting ID	996 7147 4755
Password	174664
Join Zoom Meeting	Click here to attend earnings call

Or Copy this URL in your browser: https://zoom.us/j/99671474755?pwd=Zi81Zk1BRjNqdHRqbVQ4V21WT0RzZz09

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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.