PRESS RELEASE

Biocon Q1FY22 Revenue at Rs 1,808 Cr, Up 6%; EBITDA at Rs 437 Cr; Biosimilars Up 10 % at Rs 758 Cr; Research Services Up 41 % at Rs 595 Cr;

Bengaluru, Karnataka, India: July 22, 2021:

Biocon Ltd (BSE code: 532523, NSE: BIOCON), an innovation-led global biopharmaceuticals company, today announced its consolidated financial results for the first quarter ended June 30, 2021.

Commenting on the results, **Kiran Mazumdar-Shaw**, **Executive Chairperson**, **Biocon,** said:
"Biocon has seen a strong 41% YoY growth in Research Services and a steady growth in its Biosimilars business, reporting revenue of Rs 758 Crore, up 10% over the same period last year, and 14% over the preceding quarter. Consolidated revenues, at Rs 1,808 Crore, saw a muted growth on account of COVID-related operational challenges at Biocon's API facilities, both in Bengaluru and Hyderabad. Q1FY22 P&L was also impacted by a share of loss in its Boston-based associate start-up entity, Bicara Therapeutics Inc. Excluding this share of loss, Profit before Tax was a healthy Rs 224 Crore. Novel Biologics are investment intensive and we will explore external venture funding to support clinical development for long-term value creation. Business sentiments are favorable for Biosimilars, Generics and Research Services. Globally, we see a strong demand for biosimilars and generic drugs, given the growing emphasis on affordable drug pricing. Net Profit, excluding the share of loss from Bicara, was at Rs 142 Crore and reported Net profit was at Rs 84 Crore."

"The outlook for the rest of the year is promising with several drug approvals on the anvil, contingent to timely U.S. FDA onsite inspections in India and Malaysia, whilst Research Services continue to see rising demand."

"John Shaw has decided to step down from the Board effective the end of the Annual General Meeting this year, due to health reasons. My colleagues on the Board, join me to place on record our heartfelt appreciation for the critical and invaluable role he has played in building Biocon," she added.

PERFORMANCE REVIEW: Q1FY22

- **Q1FY22 Consolidated Revenue** grew 6**%** to **Rs 1,808 Crore** from Rs 1,712 Crore in Q1FY21.
- **Q1FY22 Earnings before Interest, Depreciation and Amortization (EBITDA)** was **Rs 437 Crore** (vs. Rs 432 Crore in Q1FY21). **Our Core EBITDA margins were at 30%**
- **Q1FY22 Profit before Tax (PBT)** was **Rs 166 Crore** (vs. Rs 249 Crore in Q1FY21). Q1FY22 PBT excluding share of loss in Bicara, stood at Rs 224 Crore
- **Q1FY22 Net Profit** was **Rs 84 Crore** (vs. Rs 149 Crore in Q1FY21). Q1FY22 Net profit excluding share of loss in Bicara, **stood at Rs 142 Crore**

FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q1FY22

In Rs Crore

Particulars	Q1FY22	Q1FY21	YoY%
INCOME			
Generics	486	621	(22%)
Biosimilars	758	692	10%
Novel Biologics	11	-	-
Research services	595	422	41%
Inter-segment	(89)	(41)	
Revenue from operations #	**1,761**	**1,694**	**4%**
Other income	47	18	158%
Total Revenue	**1,808**	**1,712**	**6%**
EBITDA	**437**	**432**	**1%**
PBT	**166**	**249**	**(33%)**
Net Profit for the Period	**84**	**149**	**(44%)**
R&D Expenses in P&L	120	107	13%
Gross R&D Spend	**136**	**142**	**(4%)**
EBITDA Margins	24%	25%	
Core EBITDA Margins	30%	31%	
Net Profit Margins	5%	9%	

 # includes Licensing income. Figures above are rounded off to the nearest Cr; % based on absolute numbers.

BIOCON LTD: BOARD ANNOUNCEMENT

John Shaw Retires from the Board of Directors

John Shaw, Vice-Chairman and Non-Executive Director, **Biocon**, will retire from Biocon's Board of Directors due to health reasons, on July 23, 2021, at the conclusion of its Annual General Meeting. As a key member of the Company's Board and the management team since 1999, John Shaw has contributed majorly to the transformation of Biocon from a small enzymes company, to a globally recognized biopharmaceutical company. Over the past 22 years, John Shaw has played an important role in building Biocon, ensuring the highest levels of corporate governance in the Company, as well as, contributing to the financial and strategic development of the Group. On behalf of the Board, we express our deep appreciation and gratitude to John Shaw, for his stewardship and guidance.

BIOCON LTD: MANAGEMENT UPDATE

Biocon appointed **Dr S Vijaya Kumar as Head of Operations**, to lead the Manufacturing, Projects and EHS (Environment, Health and Safety) functions for the Generics business. Kumar is an industry veteran with more than 30 years of extensive experience across manufacturing and engineering in global, diversified setups.

BUSINESS SEGMENT REVIEW: Q1FY22

GENERICS: APIs & Generic Formulations

Q1FY22 revenue at Rs 486 Crore, down 22% (YoY) from Rs 621 Crore in Q1FY21.

Commenting on the Generics segment performance, **Siddharth Mittal, CEO & Managing Director, Biocon Limited**, said,

"The Generics business delivered a subdued performance as the second wave of the pandemic resulted in operational and supply chain challenges that impacted our API manufacturing. With the number of COVID-19 cases starting to decline, we expect operational and supply chain challenges to normalise in the coming quarter. Additionally, the comparable period in the previous fiscal benefited from customers stockpiling APIs on account of Covid-related uncertainties.

We also continued to face pricing pressures in our US formulations business. However, I am pleased to report the launch of two new formulations in the US during the quarter - Labetalol Hydrochloride tablets and Esomeprazole Magnesium Delayed-Release capsules, which will further expand our global presence.

Increasing operational efficiencies through digitisation, cost optimisation and capacity enhancement, continue to remain a key focus area for us, as we bring high quality, affordable products to market. I welcome Dr Vijaya Kumar to the organisation and am confident that his appointment will bolster our efforts on these fronts."

Our statin formulations portfolio in the US, comprising Atorvastatin, Simvastatin and Rosuvastatin, held on to its market share for the quarter, even as we continue to see increasing pricing pressure.

Tacrolimus capsules, launched in the US in Q3FY20, has started to see a gradual ramp up in market share during the quarter.

We also strengthened our US formulations portfolio with the launch of Labetalol Hydrochloride tablets and Esomeprazole Magnesium Delayed-Release capsules. Labetalol Hydrochloride is used to treat high blood pressure and helps in prevention of cardiovascular complications such as heart attack and stroke, while Esomeprazole Magnesium, a proton pump inhibitor, is indicated for treatment of gastroesophageal reflux diseases. The market size of these products in the US, as per IQVIA, is estimated to be $63 million and $230 million respectively.

Travel restrictions delayed inspection of our facilities and consequently, launches, as well as expansion into some key markets.

Following the expanded use of the Mutual Recognition Agreement in May 2021, by which the US FDA began accepting and classifying inspections by EMA and MHRA for some countries, including India, we have requested the agency to consider the recently inspected and certified Biocon Pharma Ltd facility by the MHRA, for product approval. We await the agency's feedback.

We remain on track to commission our greenfield Immunosuppressants API manufacturing facility in Visakhapatnam, in FY22, followed by qualification and validation in the next fiscal.

NOVEL BIOLOGICS

Equillium, our US-based partner, had an End-of-Phase 1 meeting with the US FDA, which confirmed a path to advance Itolizumab into a single Phase 3 pivotal study for aGVHD to support their Biologics License Application (BLA). The study is expected to commence in Q4 of CY 2021.

Biocon owns the European rights for Itolizumab. An important milestone was reached this quarter wherein The Committee for Orphan Medicinal Products gave an orphan designation to Itolizumab for the treatment of acute and chronic GVHD.

BIOSIMILARS: Biocon Biologics

- Q1FY22 **Revenue** at **Rs 758 Crore**, up **10%** YoY
- Q1FY22 **EBITDA** at **Rs 215 Crore**, up **10%** YoY
- Q1FY22 **EBITDA** margin at **28%**
- Q1FY22 **Core EBITDA** at **Rs 271 Cr;** Core EBITDA margins at **36%**
- Q1FY22 **PBT** at **Rs 101 Crore**
- Q1FY22 **Net R&D Expenses at Rs 59 Crore,** representing 8% of revenue
- Patients reached through our biosimilars: **3.4 million** (MAT June 2021)**#**

Highlights:

- **Expanded global footprint** with entry into seven new markets
- Received **marketing authorization approval** for **bBevacizumab** (***Abevmy****) from **TGA, Australia** and **MHRA, UK**
- **U.S. FDA schedules pre-approval inspection** of our Malaysia facility in Q3 of CY2021 in support of the BLA for bAspart*
- **Over 50,000 patients benefited** from our comprehensive COVID-19 portfolio, cumulatively, by end of Q1FY22
- **Commissioned rooftop solar power generation** at some of our manufacturing facilities, potentially reducing carbon emissions by 400 tons annually.

Commenting on the performance, **Dr. Arun Chandavarkar, Managing Director, Biocon Biologics Ltd,** said,

"The real highlight of this quarter was our ability to pull out all stops to make available our Covid-care portfolio, anchored by Alzumab-L, our novel antibody Itolizumab, to many thousand patients in critical need. Whilst we certainly hope that the surge in infections does not manifest as severely in future, we are now fully geared to address future patient demand."

"We reported revenues of Rs 758 Crore, representing a YoY growth of 10%. This was driven by strong growth in India, led by our Covid- care portfolio and continued growth in other markets for biosimilars. Core EBITDA margins were a healthy 36% and after accounting for R&D, our EBITDA was at Rs 215 Crore, representing a 28% margin. This translated to a Profit before Tax of Rs 101 Crore." he added.

Q1FY22 Business Performance:

Q1FY22 revenue grew 10% YoY to **Rs 758 Crore**, driven by a strong performance from Branded Formulations India and steady sales of our insulins and monoclonal antibodies (mAbs) across developed and emerging markets. Through our comprehensive COVID-19 portfolio, we addressed the needs of thousands of patients in India, which has also contributed to the topline performance for the quarter.

We expanded our footprint in emerging markets with the launch of key products, bTrastuzumab, bGlargine and rh-Insulin in additional markets. Our bTrastuzumab recorded a strong uptake in key emerging markets like Brazil, where it retained its leadership position with a 39% market share in the retail segment.

Through our partner Viatris, we saw a steady increase in market share for bTrastuzumab (Ogivri*), bPegfilgrastim (Fulphila*) and bGlargine (Semglee*) in the U.S. despite increased competition. Sales in Europe improved on the back of new market entries and steady market share in key countries. Sales in emerging markets also picked up this quarter.

Supporting the fight against COVID-19 in India

Itolizumab, our novel anti-CD6 monoclonal antibody repurposed for COVID-19, is playing a crucial role in the fight against the novel coronavirus, in India. We had stepped up production of Itolizumab to address the rise in demand in the second wave of the pandemic, benefiting over 27,000 COVID-19 patients cumulatively by end of Q1FY22.

In addition to our own brand ALZUMAb-L, Sun Pharma also markets our Itolizumab under the brand name, Itolizac. While we hope that the COVID-19 situation in India improves without another wave of infections, we are fully geared to meet patient needs, if there is a surge in demand.

Through our comprehensive COVID-19 portfolio, including Remdesivir for mild to moderate patients, Itolizumab for moderate to severe patients and CytoSorb for critical patients, we **benefited more than 50,000 patients** cumulatively by end of Q1FY22.

Our 24x7 COVID Care Helpline continues to respond to queries from thousands of caregivers seeking Biocon products prescribed in the management of COVID-19.

Itolizumab: Promising Therapy for COVID-19

Doctors have used Itolizumab extensively across the country during the second wave of the pandemic. Dosing the right patient at the right time, is extremely critical for favorable outcomes with Itolizumab. The results from the 300-patient, multi-centric, Phase 4 study of Itolizumab in COVID-19, are expected to be available for publishing in the near future.

Regulatory Progress

We **received marketing authorization approval** from TGA, Australia and MHRA, UK for our co-developed **bBevacizumab** (Abevmy*) during the quarter. On **bAspart**, there are currently no pending

technical or clinical queries on the BLA submitted to the U.S. FDA. A **pre-approval inspection** of our bAspart manufacturing facility in Malaysia is scheduled in Q3 of calendar year 2021.

The regulatory process for the **grant of 'interchangeability'** designation to our bGlargine (Semglee*) is progressing under the 351(k) pathway in the U.S. with the goal date of end July 2021.

Captive Solar Power Generation
Biocon Biologics has successfully commissioned **rooftop solar power generation**, spread over 2,000 sq. m., at some of our manufacturing facilities in Bengaluru. This green energy initiative will generate up to 300 KW of power, **potentially reducing carbon emissions by 400 tons annually**.

**Partnered with Viatris*
#Moving 12-month patient population (July 2020 to June 2021)

RESEARCH SERVICES: Syngene

- **Q1FY22 revenue at Rs 595 Crore, up 41% (YoY) from Rs 422 Crore in Q1FY21**

Highlights from the quarter:

- Syngene signed a **five-year agreement with IAVI**, a US-based non-profit scientific research organization, for **manufacturing of three anti-HIV monoclonal antibodies** for use in phase I and II clinical trials. Syngene will provide an integrated solution including clone selection, analytical methods development, manufacturing process development, scale-up and cGMP manufacturing of drug substance, viral clearance studies, cGMP manufacturing of drug product and stability studies.
- The **Mangalore API facility** successfully **completed ISO 9001-2015** certification **audit**.

Commenting on the performance, **Jonathan Hunt, CEO & Managing Director, Syngene** said:

"We made a strong start to the financial year. In line with our expectations, progress continued across all our business divisions. Growth for the quarter was strongly boosted by the manufacturing of COVID-19 treatment, Remdesivir, as we increased production to meet the needs of the second wave of COVID-19 in India. We also made headway with the expansion of our dedicated R&D center for Bristol Myers Squibb following the contract extension announced last quarter. Our safety protocols during the second wave continued to provide a sustainable work environment to operate at normal levels and keep client projects on track."

Other Updates:

- As India battled with the second wave of COVID-19, we reinforced compliance to safety protocols at all our facilities and continued with our vaccination drive for employees and their family members. Over 20,000 people were vaccinated till end of Q1FY22.

Biocon Foundation:
The Biocon Foundation organized a **vaccination drive** for the **neighbouring community,** where 2,200 people from the underserved and socially disadvantaged groups were vaccinated at the eLAJ Smart Clinic, in Huskur, Bengaluru.

The Foundation also **strengthened the infrastructure at the Government General Hospital**, Anekal, to facilitate treatment of COVID-19 patients. It provided oxygen concentrators, ICU monitors, pulse oximeters and glucometers, besides installing a digital X-ray machine, ultrasound machine and a defibrillator. We are also in the process of setting up a liquid medical oxygen storage plant of upto 3,000 litre capacity at the hospital.

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 a fully integrated global biosimilars organization. It 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, and other non- communicable diseases. Five molecules from Biocon Biologics' portfolio have been taken from lab to market, in developed markets like United States, EU, Australia, Canada and Japan. With a team of ~ 4,800 people, Biocon Biologics is committed to transforming healthcare and transforming lives by enabling affordable access to millions of patients' worldwide. Website: www.biocon.com/businesses/biosimilars/**; Follow us on Twitter:** @BioconBiologics

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Earnings Call

The management of the Company will host an ***Earnings Call*** *on* ***23rd July, 2021 at 9:00 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 are given below as well as on the on the company website www.biocon.com under Investors>>Financial Calendar>>Earnings Call for period ended June 30, 2021. Transcript of the conference call will be uploaded on the company website in due course.*

Zoom Webinar Details	
Date	23rd July 2021
Time	9:00hrs -10:30hrs, IST
Join Zoom Webinar	Click here to attend earnings call

Or Copy this URL in your browser: https://biocon-biologics.zoom.us/webinar/register/WN_uCjvlS2aRraF2wAW5pTfIQ

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.