PRESS RELEASE

Biocon Q2FY22 Revenue up 10% at Rs 1,945 Cr; EBITDA up 35% at Rs 551 Cr; Net Profit (before exceptional items) up 11% at Rs 188 Cr;

Biosimilars Up 10% at Rs 743 Cr; Research Services Up 17% at Rs 610 Cr.

Bengaluru, Karnataka, India: October 21, 2021:

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

Commenting on the results, Kiran Mazumdar-Shaw, **Executive Chairperson**, **Biocon and Biocon Biologics,** *said "Biocon reported Q2FY22 revenue growth of 10% at Rs 1,945 Crore, primarily driven by good performance of the Research Services and Biosimilars business segments, which reported a growth of 17% and 10%, respectively. EBITDA at Rs 551 Crore was up by 35% and PBT (before exceptional items) at Rs 276 Crore went up by 27%. The exceptional item relates to modification of the optionally convertible debentures of a PE investment in Biocon Biologics and reversal of SEIS claims relating to a prior period. Net Profit for Q2FY22, before such exceptional items, was Rs 188 Crore, up 11%. Our Core EBITDA margins for the quarter were at a healthy 33%.*

"Biocon Biologics made strategic moves this quarter which will drive future growth of our Biosimilars business and deliver long term value for our shareholders. The U.S. FDA's approval of Semglee® as the first interchangeable biosimilar product under the 351(k) regulatory pathway, is a historic milestone for both Biocon and Viatris, and will enable us to expand patient access to our Insulin Glargine. This has led to Semglee's inclusion as a preferred Insulin Glargine brand on the National Preferred Formulary® of Express Scripts, a leading Pharmacy Benefit Manager (PBM). We expect the formulary coverage to begin in January 2022 and believe Semglee has the potential to bring significant cost savings for patients, employers and PBMs.

"The quarter also marked Biocon Biologics' strategic entry into vaccines & the infectious diseases segment through key partnerships with Serum Institute Life Sciences and Adagio Therapeutics.

"With the waning pandemic and improvements in supply chain conditions, I believe all three business segments, Generics, Biosimilars and Research Services, are well positioned for sustained growth in H2FY22," **she added.**

PERFORMANCE REVIEW: Q2FY22

- **Q2FY22 Consolidated Revenue up 10%** at **Rs 1,945 Crore** YoY.
- **Q2FY22 Earnings before Interest, Depreciation and Amortization (EBITDA) up 35%** at **Rs 551 Crore** YoY. **Core EBITDA margins at 33%.**
- **Q2FY22 Profit before Tax (PBT)** before exceptional items, at **Rs 276 Crore**.
- **Q2FY22 Net Profit** (before exceptional items) at **Rs 188 Crore.**
- **Q2FY22 Net Profit** (after exceptional items) at **Rs 138 Crore.**

FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q2FY22

In Rs Crore

Particulars	Q2FY22	Q2FY21	YoY%
INCOME			
Generics	530	604	(12%)
Biosimilars	743	676	10%
Novel Biologics	12	-	-
Research services	610	520	17%
Inter-segment	(54)	50)	
Revenue from operations #	**1,840**	**1,750**	**5%**
Other income	105	16	577%
Total Revenue	**1,945**	**1,765**	**10%**
EBITDA	**551**	**407**	**35%**
PBT (before exceptional items)	**276**	**218**	**27%**
Net Profit for the Period (before exceptional items)	**188**	**169**	**11%**
Exceptional Item, net of taxes	**(50)**	**-**	**-**
Net Profit for the period (after exceptional items)	**138**	**169**	**(18%)**
R&D Expenses in P&L	146	148	
Gross R&D Spend	**165**	**165**	
EBITDA Margins	28%	23%	
Core EBITDA Margins	33%	32%	
Net Profit Margins (before exceptional items)	10%	10%	
Net Profit Margins	7%	10%	

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

BIOCON LIMITED: BOARD ANNOUNCEMENT

Pursuant to the vacancy created by the retirement of Mr. John Shaw from the Board of Biocon Limited, **Dr. Eric Mazumdar** has been appointed as a **Non-Executive Director** to the Board, with effect from November 1, 2021. Dr. Mazumdar is an Assistant Professor of Computing and Mathematical Sciences, and Economics at the California Institute of Technology. His research is at the intersection of engineering, machine learning and economics, at reputed institutions such as the University of California, Berkeley, the MIT Computer Science and Artificial Intelligence Laboratory, and the MIT Koch Institute for Cancer Research.

Dr. Mazumdar holds a PhD in Electrical Engineering and Computer Sciences from the University of California, Berkeley and a Bachelor of Science in Electrical Engineering and Computer Science from the Massachusetts Institute of Technology.

BUSINESS SEGMENT REVIEW: Q2FY22

GENERICS: APIs & Generic Formulations

- **Q2FY22 Revenue at Rs 530 Crore, down 12%** YoY
- **H1FY22 Revenue at Rs 1,016 Crore, down 17%** YoY

Commenting on the Generics segment performance, **Siddharth Mittal, CEO & Managing Director, Biocon Limited**, **said** *"The Generics business witnessed a muted performance for the quarter as we encountered continuing pricing pressure in the US for our formulations portfolio, and a slower than expected ramp up of demand for some of our key APIs. Operational and supply challenges in the earlier part of the quarter also impacted the performance of the API business. There was advance buying by customers in the corresponding period of the previous fiscal, apprehending COVID related disruptions and is reflected in the year-on-year decrease in revenues.*

We continue to make progress on expanding our formulations portfolio with the launch of Everolimus tablets in the US in October, which reaffirms our commitment to establish a strong global footprint of complex formulations to treat chronic conditions.

Looking ahead, we will stay focused on our capacity enhancement projects along with several other strategic initiatives to increase operational efficiencies, which will help us deliver on our mission to make affordable healthcare accessible."

Following the launches of Labetalol Hydrochloride tablets and Esomeprazole Magnesium Delayed-Release capsules earlier in the quarter, we launched Everolimus tablets, a generic version of Afinitor®, in the US in October 2021. Everolimus was introduced in four strengths of 2.5mg, 5mg, 7.5mg and 10mg, with the 10 mg tablet being a 'day-1' generic launch. Everolimus is a prescription medication that is used to treat certain types of cancers and tumours.

In September, the US FDA conducted a Remote Interactive Evaluation for our oral solid dosage manufacturing facility in Bengaluru, as part of a pre-approval review for previously filed ANDAs. The final close-out report from the agency is awaited.

Our greenfield Immunosuppressants API manufacturing facility in Visakhapatnam, remains on track to be commissioned in the latter part of FY22, with qualification and validation in FY23.

NOVEL BIOLOGICS

Equillium, our US based partner, has announced plans to initiate a Phase-3 Pivotal Study for use of Itolizumab in First-Line treatment of Acute Graft Versus Host Disease (aGVHD), following regulatory feedback from the US FDA, and is on track to initiate the study in Q4 of CY21.

During Q2FY22, our Boston-based associate Bicara Therapeutics continued to make progress in the dose finding part of the Phase 1 trial for its lead program, BCA101, as single agent and in combination with a PD1 inhibitor. On the basis of the current progress, Bicara anticipates declaring the recommended dose for expansion by the end of CY 2021.

BIOSIMILARS: Biocon Biologics Limited (BBL)

Q2FY22

- Q2FY22 **Revenue** at **Rs 743 Crore**, **up 10 %** YoY
- Q2FY22 **EBITDA** at **Rs 303 Crore**, **up 72%** YoY
- Q2FY22 **EBITDA margin** at **38%**[**]
- Q2FY22 **Core EBITDA**[^^] at **Rs 304 Cr; Core EBITDA**[^^] **margins** at **42%**
- Q2FY22 **PBT** (before exceptional items) at **Rs 174 Crore**
- Q2FY22 **Net R&D Expenses at Rs 76 Crore,** representing **10% of revenue**

H1FY22

- H1FY22 **Revenue** at **Rs 1,501 Crore**, **up 10%** YoY
- H1FY22 **Core EBITDA**[^^] at **Rs 575 Cr; Core EBITDA margins** at **39%**

Highlights:

- Received **world's first interchangeable biosimilar approval** from **U.S. FDA** for our bGlargine (**Semglee*)**
- Interchangeable **bGlargine** to be listed as a **preferred insulin brand** on **National Preferred Formulary®** of Express Scripts, a leading U.S. pharmacy benefit management organization.
- Commercialized **bBevacizumab** in several **EU markets**, and **Malaysia.**
- Received approval for **bAspart** from **Health Canada**.
- Entered into a strategic alliance with **Serum Institute Life Sciences (SILS)** for a foray into **vaccines**; will get committed access to **100 million doses** of SILS' vaccines annually for 15 years in exchange for **~15% stake** at a post-money valuation of **~USD 4.9 billion**.
- Partnered with **Adagio Therapeutics** to manufacture and commercialize a **broadly neutralizing antibody**, **ADG20**, for the prevention and treatment of **COVID-19,** for select markets across GCC & Asia, including India.
- **Patients reached through our biosimilars**: **3.4 million** (MAT September 2021)[##]

Commenting on the performance, Dr Arun Chandavarkar, Managing Director, Biocon Biologics Ltd. said: *"The key highlight this quarter was the USFDA approval of our bGlargine as the world's first interchangeable biosimilar paving the way for a robust growth of this product. The preferred formulary status for our bGlargine at Express Scripts, USA, which covers 28 million lives, is an outcome of this interchangeable designation.*

"Biocon Biologics' revenue from operations grew 10% to Rs 743 Crore this quarter, supported by continued market share gains in developed markets and strong growth in India & emerging markets. This business performance coupled with a focus on costs, is reflected in our highest reported Core EBITDA of Rs 304 Crore at a healthy 42% margin.

"We also took a strategic decision to leverage our biologics capabilities to make a meaningful impact in infectious diseases. We partnered with Adagio Therapeutics for a novel antibody for treatment and prevention of COVID-19. Thereafter, we entered into a strategic alliance with Serum Institute Life Sciences which gives us access to a 100 million doses vaccine capacity (with assured revenues and related margins) and their portfolio of vaccines.

"Our vertically integrated strengths in biosimilars and expansion into the infectious disease segment, provides a strong impetus for a robust and sustainable growth over the next few years," ***he added.***

Q2FY22 Business Performance: Biocon Biologics

Revenue for the quarter stood at **Rs 743 Crore,** reporting a growth of **10%**, driven by a strong performance of our biosimilars portfolio including insulins, monoclonal antibodies (mAbs) and recombinant proteins across developed and emerging markets. **EBITDA** at **Rs 303** Crore, was **up 72%** and **EBITDA margin** stood at a healthy **38%****. **Profit before Tax** (before exceptional items) stood at **Rs 174** Crore, for the quarter.

Developed Markets

During the quarter, we have commercialized our **bBevacizumab** (Abevmy*) in several EU markets, including Germany, Croatia, Czech Republic and Slovakia, through our partner Viatris. Market shares of our **bPegfilgrastim** and **bTrastuzumab** continue to grow in Europe, with our **bTrastuzumab** being the leading biosimilar in some EU markets where our partner Viatris is present. Our **bGlargine** continues to benefit patients in over 7 EU countries.

In U.S., our **bTrastuzumab** (Ogivri*) and **bPegfilgrastim** (Fulphila*) maintained a high single-digit market share while bGlargine (Semglee®) continues to report a steady increase in market share. **bTrastuzumab** also continues to be a leading biosimilar in Canada and Australia. During the quarter, we received approval for our **bAspart** from **Health Canada**.

bGlargine: Approved as World's First Interchangeable Biosimilar & Listed on a leading US National Formulary

In July 2021, our **bGlargine** (Semglee*) received a historic U.S. approval as the first interchangeable biosimilar under the 351(k) regulatory pathway. It is the first biosimilar to receive such an approval.

Launch preparations are on track and our partner Viatris will introduce the **interchangeable bGlargine** product in the U.S. by end of this calendar year. Our **bGlargine** is poised for a strong growth in U.S. on the back of the interchangeability designation.

More recently, **Express Scripts**, a leading pharmacy benefit management organization in the US has announced that it will list our interchangeable biosimilar **Insulin Glargine** (Semglee®), co developed with our commercial partner Viatris, as a **preferred Glargine brand** on its **National Preferred Formulary® (NPF)**, which covers more than 28 million lives. Broad coverage of **Semglee®** by Express Scripts will help ensure that many patients on its network who need **Insulin Glargine** may receive the full benefits of and access to treatment with lower or maintained out- of pocket- costs. We expect the formulary coverage to begin in January 2022. Our **bGlargine** has the potential to bring significant cost savings for patients, employers and PBMs.

The inclusion on the formulary is an important milestone for Biocon Biologics as it furthers our mission to expand affordable access to patients. We believe adoption of biosimilars through PBMs like Express Scripts, will drive down the high costs of biologics therapy in the US and expand patient access.

Emerging Markets

Biocon Biologics-led business in emerging markets, including India, recorded a strong growth during the quarter, driven by the launch of key biosimilars in new markets and expansion of our existing business. We launched **bBevacizumab** in Malaysia and also won a two-year tender for **bGlargine.** This furthers our commitment to enable affordable access to high quality biosimilars, to patients in Malaysia.

In the **AFMET** region, we made good progress with the launch of **bGlargine**, **bPegfilgrastim** and **bTrastuzumab** in some new markets like Tunisia, Belarus, Israel etc.

In **LATAM**, our **bTrastuzumab** (Zedora®) continued to retain its leadership position in **Brazil** with a strong double-digit market share, while in **Argentina** we made further inroads with our **bTrastuzumab,** which will expand our business in the region. We also made significant progress in laying the foundation for market entry in a few new countries in the region.

We are making a significant impact to patients through our branded formulations business in India, which reported strong sales across diabetes, oncology, immunology and critical care segments. During the quarter, we also introduced Insulin initiation kits for rh-Insulin (**Insugen®**) and bGlargine (**Basalog ®**) to enable a smooth transition from oral antidiabetic drugs to insulins for people with diabetes.

ALZUMAb-L (Itolizumab), our novel anti-CD6 monoclonal antibody repurposed for COVID-19, continues to play a crucial role in the fight against the novel coronavirus in India. ALZUMAb-L has benefited over 42,000^ COVID-19 patients so far.

Our strategic entry into vaccines and novel antibodies for infectious diseases, which are a natural adjacency to our biosimilars business, will be a future growth driver for Biocon Biologics.

Foraying into Vaccines through Strategic Alliance

Biocon Biologics and Serum Institute Life Sciences (SILS) have entered into a strategic alliance that provides Biocon Biologics an asset light and accelerated entry into the vaccines segment. The near term focus would be on COVID-19 vaccines. Additionally, the partnership will have access to SILS' current development pipeline to address unmet needs in other communicable diseases like mosquito-borne infections.

The alliance provides Biocon Biologics a committed access to 100 million doses of vaccines annually for a period of 15 years and commercialization rights to SILS vaccine portfolio leading to a committed revenue stream and related margins in exchange for ~15% stake at a post money valuation of ~USD 4.9 billion.

Partnering for Novel Antibody Against COVID-19

Biocon Biologics has also entered into a manufacturing and commercialization partnership with Boston-based Adagio Therapeutics Inc. for ADG20, a novel antibody therapy for COVID-19. This collaboration enables us to expand our therapeutic focus into infectious diseases. ADG20 is being developed for the treatment and prevention of COVID-19. With Adagio planning to seek Emergency Use Authorization (EUA) in the U.S. early next year, Biocon Biologics will be able to seek approvals in the emerging markets utilizing the clinical and non-clinical data from Adagio's EUA submission.

Other Regulatory Developments

Biocon Biologics has submitted a **Corrective and Preventive Action Plan** (CAPA) to the U.S. FDA, in response to the pre-approval inspection of our manufacturing facility in Malaysia, for **bAspart,** held in September. We believe this will not impact the commercialization plans for **bAspart** in the U.S.

During the quarter, we also made regulatory filings for some of our key biosimilars in emerging markets in the LATAM and AFMET regions, which will fuel our future growth.

**Partnered with Viatris*
*** EBITDA margin calculated based on revenue of ₹807 cr which includes forex, Adagio revaluation gains and other income*
##Moving 12-month patient population (August 2020 to September 2021)
^ MAT September 21
^^ Core EBITDA for Q2FY22 is EBITDA net of licensing, forex, Adagio revaluation gains and R&D expense

RESEARCH SERVICES: Syngene

- **Q2FY22 Revenue** at **Rs 610 Crore, up 17%** YoY
- **H1FY22 Revenue** at **1,205 Crore, up 28%** YoY

Highlights:

- Q2FY22 was characterized by strong performances in all divisions. In Discovery Services, there was a positive demand for new services like Protein Degradation Technology (PROTACS) and Peptide Synthesis.

- Expanded the client base in Biologics powered by expansion of microbial manufacturing and capacity building in mammalian manufacturing.
- Syngene also continued to expand relationships with existing clients and long-term partners in the dedicated research centres.
- Strong performance delivered in the first half of the year and Syngene is on track to deliver as per guidance for the full year.

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

"The second quarter was characterized by positive performances in all divisions. In Discovery Services, we saw excellent client demand, particularly within the emerging biopharma segment, as well as further expansion of our relationships with existing clients and our long-term partners in the dedicated research centers.

"During the quarter, we continued to manufacture Remdesivir for COVID-19, under a voluntary licensing agreement from Gilead. The quarter also saw continued investment in new technologies and the successful implementation of several digitization and automation projects across our operations. These investments play an important role in enhancing productivity, reducing the impact of human error and improving quality systems across our business.

"We are pleased to have delivered a strong performance in the first half of the year. Careful management of costs, coupled with a robust business continuity plan, enabled us to continue to build capability and capacity to meet the growing requirements of our clients. Notwithstanding the continuing uncertainty of the pandemic, we believe that we are well positioned to deliver our guidance of mid-teens revenue growth for the full year," ***he added.***

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* ***22nd October, 2021 at 9:00 hrs****, over a Zoom call, where the senior management will discuss the company's performance and answer questions from participants. Details of the Zoom call are given below as well as on the on the company website www.biocon.com under Investors>>Financial Calendar>>Earnings Call for period ended September 30, 2021. Transcript of the conference call will be uploaded on the company website in due course.*

Zoom Call Details	
Date	22nd October, 2021
Time	9:00hrs -10:30hrs, IST
Join Zoom Call	Click here to attend earnings call

Or Copy this URL in your browser: https://bit.ly/Q2FY22EC

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.