PRESS RELEASE

Biocon Q3FY22 Revenue at Rs 2,223 Cr, Up 18%; EBITDA at Rs 537 Cr, Up 25%; Biosimilars Up 28% at Rs 981 Cr; Research Services Up 10% at Rs 641 Cr; Generics Up 7% at Rs 607 Cr

Bengaluru, Karnataka, India: January 20, 2022:

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

Commenting on the results, **Kiran Mazumdar-Shaw**, **Executive Chairperson**, **Biocon,** said, *"Biocon's consolidated Q3FY22 revenues grew by 18% YoY to Rs 2,223 Crore, driven by a strong performance across all business segments. Biosimilars grew by 28% to Rs 981 Crore, Research Services was up 10% at Rs 641 Crore and Generics delivered a 7% growth at Rs 607 Crore.*

"EBITDA at Rs 537 Crore grew by 25%, which was impacted by mark- to- market loss attributed to Biocon Biologics' equity investment in Adagio. Core EBITDA stood at Rs 715 Crore with a healthy margin of 33%. PBT for the quarter stood at Rs 269 Crore. Adjusted for Adagio related loss, PBT was higher at Rs 346 Crore, indicating a healthy operating profitability."

"Biocon Biologics achieved a key milestone with the commercialization of the world's first interchangeable biosimilar, our Insulin Glargine, in the U.S.. Approvals for several of our generics and biosimilars in global markets, and renewal of key long-term research service agreements at Syngene, position us for a strong close to this fiscal," **she added.**

PERFORMANCE REVIEW: Q3FY22

- **Consolidated Revenue** grew **18%** to **Rs 2,223 Crore** from Rs 1,885 Crore in Q3FY21
- **Earnings before Interest, Tax, Depreciation and Amortization (EBITDA)** was **Rs 537 Crore** (vs. Rs 428 Crore in Q3FY21)
- **Core EBITDA* margins** were at **33%**
- **Profit before Tax (PBT)** was **Rs 269 Crore** (vs. Rs 236 Crore in Q3FY21)
- **Net Profit** was **Rs 187 Crore** (vs. Rs 169 Crore in Q3FY21)

FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q3FY22

In Rs Crore

Particulars	Q3FY22	Q3FY21	YoY%
INCOME			
Generics	607	567	7%
Biosimilars	981	769	28%
Novel Biologics	16	-	100%
Research services	641	585	10%
Inter-segment	(72)	(63)	13%
Revenue from operations #	**2,174**	**1,857**	**17%**
Other income	48	28	73%
Total Revenue	**2,223**	**1,885**	**18%**
EBITDA	**537**	**428**	**25%**
PBT	**269**	**236**	**14%**
Net Profit for the Period	**187**	**169**	**11%**
R&D Expenses in P&L	138	171	-19%
Gross R&D Spend	**178**	**183**	**-3%**
EBITDA Margins	24%	23%	1%
Core EBITDA* Margins	**33%**	**31%**	**2%**
Net Profit Margins	8%	9%	-1%

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

**Core EBITDA is EBITDA net of licensing, forex, mark- to- market loss related to investment in Adagio Therapeutics and R&D expense.*

KEY UPDATES: Q3FY22

- Our **Environment, Sustainability & Governance (ESG)** efforts and initiatives were recognized with the induction of Biocon into the **Dow Jones Sustainability Index (DJSI)** for Emerging Markets with a 93-percentile for the industry sector, placing us amongst the top 15 companies to feature in the 2021 listing. We also secured an improved Carbon Disclosure Project (CDP) rating of 'B' from 'C' earlier as per the 2021 CDP report.

- Biocon has been selected to participate in the **Production Linked Incentive (PLI)** scheme announced by the Government of India, which will provide financial incentives linked to investments in manufacturing infrastructure and corresponding revenue growth. Biocon is amongst one of 55 companies selected for the scheme.

BUSINESS SEGMENT REVIEW: Q3FY22

GENERICS: APIs & Generic Formulations

- **Q3FY22 Revenue** at **Rs 607 Crore,** up **7%** YoY**, 15%** QoQ

Commenting on the Generics segment performance, **Siddharth Mittal, CEO & Managing Director, Biocon Limited**, said, *"I am pleased with our robust sequential growth in the third quarter, that was driven by our day-one U.S. launch of Everolimus 10mg tablet, a vertically integrated formulation, as well as a ramp-up of demand in our API business. The Everolimus launch also contributed to our YoY revenue growth. The quarter saw a return to normalized operations, which had been impacted due to COVID related challenges in previous quarters.*

"During the quarter, we continued to make progress on our product pipeline, with three new approvals – one in the U.S. and two in Europe.

"Our partnership with Tabuk Pharmaceuticals paves the way for expansion into the Middle East and North Africa and underscores our commitment to make medicines available to patients who need them around the world.

"Looking ahead, our efforts will focus around further capacity expansion, cost improvement projects and accelerating our pipeline to bring our products to market expeditiously."

Business Performance

Our Generics business witnessed a healthy 15% sequential revenue growth in Q3FY22, that was supported by the U.S. launch of **Everolimus tablets**, the generic version of Afinitor®, as well as a pick-up in demand in our API business. The YoY growth of 7% was driven mainly by the Everolimus launch, and we expect this product to continue to contribute to the growth of our generic formulation portfolio.

COVID related disruptions that had impacted our operations earlier in the fiscal began to abate during this quarter as we saw a return to normalcy.

The business continues to face headwinds due to pricing pressure in various markets, increase in solvent and other raw material prices and higher logistic costs.

During the quarter, we received approval for our ANDA for **Mycophenolic Acid** from the U.S. FDA. This product is indicated for the prophylaxis of organ rejection in adult patients receiving kidney transplants and is available in 180mg and 360mg strengths.

In Europe, we received approvals for **Everolimus tablets** of 2.5mg, 5mg and 10mg strengths and **Fingolimod capsule** of 0.5 mg strength.

Our greenfield Immunosuppressants API manufacturing facility in Visakhapatnam continues to remain on track to be commissioned by the end of FY22, with qualification and validation in FY23.

BIOSIMILARS: Biocon Biologics Limited

Q3FY22

- **Revenue** at **Rs 981 Crore**, up **28%** YoY**, 32%** QoQ
- **Core EBITDA*** at **Rs 363 Crore**, up **27%** YoY
- **Core EBITDA* margins** at **38%**
- **EBITDA** at **Rs 236 Crore**, up **12%** YoY
- **EBITDA margin** at **24%**
- **PBT** at **Rs 124 Crore**
- **PBT**, excluding the mark- to- market loss related to Adagio investment, stood at **Rs 201 Crore**, up **82%** YoY
- **Net R&D Expenses at Rs 64 Crore,** representing 7% of revenue

9MFY22

- **Revenue** at **Rs 2,482 Crore**, up **16%** YoY
- **Core EBITDA** at **Rs 938 Crore**
- **Core EBITDA margins** at **38%**

Highlights:

- Our interchangeable **bGlargine (Semglee**)** has been launched in the U.S. by our partner Viatris.
- The interchangeable **bGlargine** has received preferred status in the national formularies of two leading U.S. Pharmacy Benefit Managers (PBMs), **Prime Therapeutics** and **Express Scripts**, and will also be offered through **Walgreens Prescription Savings Club.**
- The **U.S. Court of Appeals for the Federal Circuit (USCAFC)** has ruled in favour of our partner Viatris on all the five Sanofi Lantus® SoloSTAR® device patents.
- We received approval for our **bBevacizumab** from Health Canada.
- **Patients reached**: **3.6 million** (MAT December 2021)[##]

Commenting on the performance, **Dr Arun Chandavarkar, Managing Director, Biocon Biologics Ltd.**, said, *"Following the landmark approval of our interchangeable bGlargine, the first-ever such biosimilar approval, by the U.S. FDA, we recorded another milestone this quarter with the commercialization of this product by our partner Viatris in the U.S.*

"Biocon Biologics reported a revenue growth of 28% YoY and 32% QoQ at Rs 981 Crore. Core EBITDA rose 27% to Rs 363 Crore with healthy Core EBITDA margins at 38%. The strong growth in revenue is on the back of robust demand for our products across geographies and the commencement of supplies of interchangeable bGlargine to the U.S.

"Encouraged by the demand for our insulins globally and considering the new opportunities, we have initiated investments for the expansion of our insulin manufacturing facility in Malaysia. We have seen good progress on our R&D pipeline with a few molecules expected to enter the clinic in Q4FY22.

"I am proud of our team who have confronted the challenges brought on by the pandemic with resilience and resourcefulness in order to address patient needs across the world."

Management Update

Biocon Biologics has appointed **Matthew Erick** as the **Chief Commercial Officer - Advanced Markets**. Matthew's appointment reflects our strategic intent to build commercial capabilities in the advanced markets of North America, Europe, Australia and New Zealand. He has over two decades of experience in the pharmaceuticals and healthcare industry in the U.S., with a demonstrated track record of driving business growth, managing large teams and developing a collaborative work culture.

Dr Mandar Ghatnekar has joined as **Chief Digital Transformation Officer** to lead all IT & Digital Solutions initiatives at Biocon Biologics. He has over two decades of IT Advisory and Consulting experience across the life sciences industry.

Ajit Pal Singh has joined as **Head of Branded Formulations, India** business. He brings rich experience in sales and marketing having worked in leading Indian and global pharmaceutical companies during his 26-year career.

Business Performance

Revenue for the quarter stood at **Rs 981 Crore,** reporting a growth of **28%** YoY, driven by steady sales of our biosimilars portfolio including insulins, monoclonal antibodies (mAbs) and recombinant proteins across developed and emerging markets and a strong performance from our Branded Formulations business in India.

EBITDA, at **Rs 236 Crore**, was **up 12%**. This includes mark -to- market loss of Rs 77 Crore, related to investment in Adagio.

Core EBITDA, excluding R&D, forex, licensing income and mark - to- market loss related to Adagio, stood at **Rs 363 Crore**, up **27%** year-on-year. **Core EBITDA margin** was at a healthy **38%** for the quarter.

Profit Before Tax, excluding the mark- to- market loss related to Adagio, stood at **Rs 201 Crore**, up **82%** year-on-year.

Developed Markets

Biocon Biologics reported significant growth in revenues from developed markets led by supplies of our **interchangeable bGlargine** to our partner Viatris in the U.S., as well as **bTrastuzumab** (Ogivri**) gaining volume market share in some of the European markets.

Through our partner Viatris, we launched the world's first interchangeable biosimilar Glargine, **Semglee**** injection, a branded product, and biosimilar Insulin Glargine injection, an unbranded product, in the U.S. in November 2021. Both biosimilar products are available in vial and prefilled pen

presentations and are interchangeable for the reference brand, LANTUS® (Insulin Glargine), allowing for substitution at the pharmacy counter.

Our **interchangeable bGlargine** has been listed as the preferred bGlargine brand on the national formularies of two major pharmacy benefit managers in the U.S., **Express Scripts** & **Prime Therapeutics**. It is also available through the Prescription Savings Club of **Walgreens**, the second largest pharmacy chain in the U.S. These developments augur well for the future growth of our business.

We continued to maintain a steady market share for **bTrastuzumab** (Ogivri*) in the U.S. and **bPegfilgrastim** (Fulphila**) in the U.S. and key EU countries.

We also received approval for our **bBevacizumab** from **Health Canada** during the quarter.

Emerging Markets

During the quarter, Biocon Biologics-led business in emerging markets, including India, recorded a strong, double-digit growth driven by our existing portfolio of bTrastuzumab and Insulins across all regions AFMET, APAC and LATAM.

We continued to strengthen our presence in existing markets with the launch of new products and renewing business for our existing products. We are progressing well with our **bBevacizumab** since its EU approval in April 2021 and have signed partnership agreements in 20 emerging markets during FY22 and continue to file for approval in several other countries.

Our oncology portfolio led by **bTrastuzumab** has shown strong growth in many markets. It is the leading biosimilar product in several key countries and has captured close to half the market share in Brazil, Indonesia and Algeria.

Insulins, including **bGlargine,** continue to hold steady market share in the Middle East, Egypt, Pakistan, Morocco and have recorded improved market share in some of the LATAM countries like Mexico.

Our **Branded Formulations - India** business reported double-digit growth for the quarter, and the 9MFY22 revenue exceeded the revenue recorded for the full year in FY21, on the back of a good performance across all the divisions. We continue to strengthen our patient-centric programs and Healthcare Professionals (HCPs) engagement initiatives.

During the quarter, we expanded our insulins access program to address the needs of young people with Type 1 diabetes in India in collaboration with the Research Society for the Study of Diabetes in India (RSSDI).

Serum Institute Alliance on Track

Our strategic alliance with Serum Institute Life Sciences (SILS), which involves a merger of Covishield Technologies Private Ltd (CTPL) into Biocon Biologics, is on track.

Clinical Updates

The development of our next wave of biosimilars continues to progress well, with some of them poised to enter the clinic this quarter.

Biocon Biologics has completed a PK-PD (RHINE-1) study for its biosimilar recombinant human Insulin R with the U.S. licensed Humulin R formulation in healthy subjects and its results have been published in the *Diabetes Obesity and Metabolism* scientific journal.

We expect these trial results to allow us to seek approval with the U.S. FDA under the 351(k) biosimilar pathway.

***Partnered with Viatris*
^ MAT December 21
[##]Moving 12-month patient population (October 2020 to December 2021)

NOVEL BIOLOGICS

Equillium, our U.S.-based partner, is on track to initiate a Pivotal Study in early CY22 for use of **Itolizumab** in the First-Line treatment of Acute Graft Versus Host Disease (aGVHD). Equillium is also conducting a Proof of Concept study for its use in systemic lupus erythematosus (SLE) / lupus nephritis (LN) and has expanded its EQUALISE phase 1b study to clinical centres in India.

Our Boston-based associate, **Bicara Therapeutics**, completed enrolment for the dose finding part of the Phase 1 trial for its lead program, **BCA101**, as a single agent and in combination with a PD1 inhibitor. Bicara established all doses tested to be safe and tolerable for both monotherapy and in combination and is on track to open three expansion cohorts in early CY22.

RESEARCH SERVICES: Syngene

Q3FY22

- **Q3FY22 revenue** at **Rs 641 Crore, up 10%** YoY
- **Q3FY22 PBT** at **Rs 128 Crore, up 10%** YoY

9MFY22

- **9MFY22 revenue** at **Rs 1,846 Crore, up 21%** YoY

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

"Syngene's performance across all divisions has been positive through the year, and we expect a busy fourth quarter. As a result, we have raised our revenue growth guidance for the full year to high teens.

"A highlight for the quarter was the extension of our long-standing collaboration with Amgen Inc. until 2026. This partnership will also add a new state-of-the-art dedicated laboratory to accelerate the advancement of Amgen's R&D projects.

"The 5-year renewal of the long-standing contract with Amgen, coming on the heels of the 10-year contract extension signed with BMS last year, confirms the stability of both relationships and provides a clear perspective on the future of our Dedicated Centers.

"I believe that Syngene is well-positioned to meet our clients' evolving requirements and capture market opportunities as they arise."

Business Performance

Discovery Services and the Dedicated Centers were key growth drivers, while Development Services and Manufacturing Services delivered sustained performances.

Syngene extended and expanded its long-standing, multi-disciplinary research collaboration with **Amgen Inc.** until the end of 2026. The Company will also build and operate a dedicated laboratory to accelerate the scale-up of small molecule projects.

BIOCON FOUNDATION

During the quarter, our **eLAJ clinics** continued to support the Government's efforts in fighting the pandemic. Lab technicians and data entry operators appointed by the Foundation are providing services for RT-PCR reporting, phone monitoring of quarantined patients and vaccination data entry, in 20 Government Primary Health Care Centers.

The **Oral Cancer mHealth program** developed by the Foundation to address a critical need for cancer screening in India through a mobile based management platform that enables the early detection of Oral Cancer, has been recognized as the **Top CSR initiative** by the CSR Journal.

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* ***21st January, 2022 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 company website www.biocon.com under Investors>>Financial Calendar>>Earnings Call for period ended December 31, 2021. Transcript of the conference call will be uploaded on the company website in due course.*

Zoom Webinar Details	
Date	21st January, 2022
Time	9:00hrs -10:30hrs IST
Join Zoom Webinar	Click here to attend earnings call

Or Copy this URL in your browser: https://biocon.zoom.us/meeting/register/tJcpd-6vrD0vHNM0L8Jo0Jn5q8q2w7QLIgBR

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.