Press Release

Biocon Q3FY20 Earnings
Revenue at Rs 1,784 Cr, Up 14%; EBITDA at Rs 480 Cr, Up 18%; Net Profit *(before exceptional item)* at Rs 225 Cr, Up 6%

Biologics Up 31% at Rs 588 Cr; Small Molecules Up 16% at Rs 544 Cr; Research Services Up 11% at Rs 519 Cr

Bengaluru, Karnataka, India: January 23, 2020:

Biocon Ltd (BSE code: 532523, NSE: BIOCON), an innovation-led global biopharmaceuticals company, today announced its consolidated financial results for the fiscal third quarter ended December 31, 2019.

Commenting on the highlights, ***Chairperson & Managing Director, Kiran Mazumdar-Shaw stated:*** *"We witnessed a strong revenue growth of 14% to Rs 1,784 Crore in Q3FY20, led by Biologics, Small Molecules and Research Services businesses. We continued our journey of increasing access to high quality biosimilars and commercialized our biosimilar Trastuzumab in U.S., Canada and many EU markets this quarter. Net Profit before exceptional item at Rs 225 Crore reported a 6% growth. EBITDA at Rs 480 Crore reported a growth of 18%. Core margins were strong at 33% with EBITDA margin of 27% and Net Profit margin of 11%.*

"Importantly, we have initiated value unlocking of our biosimilars business with the dilution of a minority stake to True North for a primary equity investment of ~USD 75 million, which gives a pre-money equity valuation of ~USD 3 billion for Biocon Biologics. We plan to raise further capital at an opportune time in the near future."

MANAGEMENT & BOARD UPDATES

- The Board of Directors of Biocon Limited have approved the appointment of **Kiran Mazumdar Shaw as Executive Chairperson of the Company** for a period of five years subject to shareholders approval, effective April 1, 2020.
- The Board has also approved the change in designation of **Siddharth Mittal from Joint Managing Director to Managing Director of Biocon Ltd** effective April 1, 2020.
- **M.B. Chinappa** has been appointed **Chief Financial Officer** of **Biocon Biologics India Ltd**, effective Jan. 6, 2020.

BUSINESS HIGHLIGHTS

- The board of Biocon Biologics approved a **primary equity investment** of **Rs 536.25 Crore** by **True North**, for a 2.44% equity stake valuing the entity at **Rs 21,450 Crore** or **~USD 3 billion** on a pre-money equity basis.
- Our biosimilar Trastuzumab, **Ogivri™**, co-developed by Biocon and Mylan, launched in **U.S.** in both 420 mg and 150 mg strengths; the second biosimilar from our partnered portfolio commercialized in the U.S. after Fulphila® (Pegfilgrastim) in 2018**.**
- Received **U.S. FDA** approval for **supplemental Biologics License Application (sBLA)** for **Pegfilgrastim** Drug Substance to be manufactured at new Biologics manufacturing facility in Bengaluru.
- Received **Establishment Inspection Report (EIR)** from **U.S. FDA** stating the agency has closed its inspection of our **Biologics Drug Product facility** in **Bengaluru**, which had undergone a Post-Approval Inspection in August 2019.
- **Generic Formulations** business crossed the **Rs 100 Crore** revenue milepost in Q3FY20.
- **License agreement** with Equillium for novel molecule, **Itolizumab,** was expanded to include Australia and New Zealand.

FINANCIAL HIGHLIGHTS
Q3FY20

- **Consolidated Revenue** grew **14%** to **Rs 1,784 Crore** from Rs 1,566 Crore in Q3FY19
- **Earnings before Interest, Depreciation and Amortization (EBITDA)** increased **18%** to **Rs 480 Crore** (*vs. Rs 406 Crore in Q3FY19*)
- **Profit Before Tax** *(before exceptional item)* **was up 11% at Rs 315 Crore** (*vs. Rs 283 Crore in Q3FY19*)
- **Net Profit** *(before exceptional item)* **was up 6% at Rs 225 Crore** (*vs. Rs 211 Crore in Q3FY19*). **Net Margin** (before exceptional item) **13%.**
- **Net Profit** at **Rs 203 Crore** (*vs. Rs 217 Crore in Q3FY19*) was impacted due to higher R&D expenses and tax impact of an exceptional item.
- Q3FY20 **Core margin** (*i.e., EBITDA margin net of licensing, impact of forex and R&D)* stood at **33%; EBITDA margin** at **27%; Net Profit margin** at **11%.**
- **Net R&D expenses** for the quarter at **Rs 131 Crore** was up by **71%** (*vs. Rs 77 Crore in Q3FY19*) corresponding to **11%** of our revenue ex-Syngene.
- **Gross R&D expenses** were **Rs 155 Crore**, up **46%** *(vs. Rs 106 Crore in Q3FY19)* corresponding to **13%** of our revenue ex-Syngene.

9MFY20 HIGHLIGHTS

- **Consolidated Revenue** grew **19%** to **Rs 4,885 Crore** *(vs. Rs 4,107 Crore in 9MFY19)*.
- **EBITDA** increased **25%** to **Rs 1,383 Crore** *(vs. Rs 1,107 Crore in 9MFY19)*.
- **Net Profit** *(before exceptional item)* **rose 23%** to **Rs 637 Crore** *(vs. Rs 516 Crore in 9MFY19)*.
- **Net Profit was Rs 625 Crore** *(vs. Rs 692 Crore in 9M FY19).*
- **Core margin** was **34%, EBITDA margin 28% and Net Profit margin 13%.**

CONSOLIDATED KEY FINANCIALS: Q3FY20

In Rs Crore, except growth numbers

Particulars	Q3FY20	Q3FY19	Growth
INCOME			
Small Molecules	**544**	469	**16%**
Biologics	**588**	449	**31%**
Branded Formulations	**157**	212	**(26%)**
Research Services	**519**	467	**11%**
Inter-segment	(60)	(56)	**8%**
Revenue from Operations#	**1,748**	1,541	**13%**
Other Income	**36**	25	**40%**
TOTAL REVENUE	**1,784**	1,566	**14%**
EBITDA	**480**	406	**18%**
PBT BEFORE EXCEPTIONAL ITEM	**315**	283	**11%**
PBT	**315**	289	**9%**
Net Profit	**203**	217	**(7%)**
Net Profit *(before exceptional item)*	**225**	211	**6%**
Exceptional Item *(net of tax)*	**(22)**	6	
R&D Expenses in P&L	**131**	77	**71%**
Gross R&D Spends	**155**	106	**46%**
Core Margin	**33%**	32%	
EBITDA Margin	**27%**	26%	
Net Profit Margin	**11%**	13%	
Net Profit Margin *(excluding exceptional item)*	**13%**	14%	
#includes Licensing Income	**9**	7	

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

EXECUTIVE COMMENTARY:

BUSINESS SEGMENT REVIEW: Q3FY20

SMALL MOLECULES: APIs & Generic Formulations

- Q3 FY20 **Revenue** at **Rs 544 Crore**, up 16% (YoY)
- 9M FY20 **Revenue** at **Rs 1,553 Crore**, up 19% (YoY)

The **Small Molecules** business reported a revenue growth of **16%** for the quarter at **Rs 544 Crore**, led by a strong performance by Generic Formulations and APIs businesses.

Commenting on the performance, **Siddharth Mittal, CEO & Joint MD, Biocon Ltd**, said, *"Steady API sales and a robust YoY growth in Generic Formulations led to an overall growth of 16% in our Small Molecules revenue to Rs 544 Crore. Importantly, the Generic Formulations business crossed the Rs 100 Crore revenue milepost in Q3FY20 on the back of key Formulations commercialized in U.S."*

The **Small Molecule** APIs business performance was driven by increased sales of our immunosuppressants in key geographies, as well as, stable demand for our statins and specialty APIs. We filed for approval of three of our APIs in key regulated markets.

The **Generic Formulations** business crossed the **Rs 100 Crore** revenue milepost in Q3FY20, reporting robust growth on the back of consistent client acquisitions and increased market share for all its formulations launched in the U.S.

Biocon's API Manufacturing facility at **Visakhapatnam** was recognized for **'Outstanding Achievements in Safety Management'** in the Pharmaceuticals sector during the 18th Annual Greentech Safety Award Program in New Delhi.

BIOCON BIOLOGICS: Biosimilars

- Q3 FY20 **Revenue** at **Rs 588 Crore**, up **31%** (YoY)
- 9M FY20 **Revenue at Rs 1,594 Crore**, up **50%** (YoY)
- **Patient Reach** of Biocon Biologics' Biosimilars (9M FY20): **1.29 million**

The **Biologics** segment reported a strong revenue growth of **31%** at **Rs 588 Crore** for Q3FY20, led by higher traction in sales of our key biosimilars in developed and emerging markets. **PBIT margins** for 9M FY20 were healthy at **29%.**

Commenting on the performance, **Dr Christiane Hamacher, CEO & Managing Director, Biocon Biologics India Ltd**, said, *"We are pleased with the robust performance and a profitable growth of our biosimilars business during the quarter and 9 months of FY20 led by key products*

like Trastuzumab and Pegfilgrastim. Our Insulins business continues to do well in several emerging markets.

"The commercialization of Ogivri, our biosimilar Trastuzumab, in the U.S. was a landmark achievement. The approval of the sBLA for Fulphila® expands our capacity multifold thus enabling us to enhance patient access. We have successfully balanced business performance with our mission of impacting millions of patient lives across global markets and are well prepared to cross a revenue milestone of USD 1 billion by FY22."

The commercialization of our high quality biosimilar Trastuzumab, **Ogivri™** by our partner Mylan in the U.S., in both 420 mg multi-use vials and 150 mg single-use vials provides an important new option for cancer patients and dispensing flexibility to healthcare professionals. Our biosimilar Pegfilgrastim, Fulphila®, continues to do well and the additional approval of our new manufacturing facility for Pegfilgrastim in Bengaluru will enable Biocon Biologics to scale up capacity multi-fold and address the growing market opportunities in the U.S. and other global markets. **Ogivri ™** was also commercialized in Canada and many additional EU markets.

Biocon Biologics is the only company from India to have **commercialized two biosimilars** in **the U.S.**, with the aim to offer greater value to patients, prescribers and payors in the U.S.

During the quarter our **biosimilar Trastuzumab** received approval from the **Argentinian health regulator**, ANMAT, and our partner Laboratorios Raffo S.A. (Raffo), a leading Argentinian pharmaceutical company, will commercialize the product soon. Additional approvals, market entries and tender wins for our biosimilar Trastuzumab and Insulin Glargine in Latin America and CIS will also help drive our growth in emerging markets.

Biocon Malaysia has **commenced supply of Insulin Glargine** to the Ministry of Health (MoH), Malaysia. The MoH has also **extended the contract** with Biocon Malaysia for **recombinant human insulin** (rh-Insulin) formulations for a year under the government's Off-Take Agreement (OTA) initiative.

We are **committed to take forward our '10 cents Mission'** and have started engaging with diverse stakeholders in several low and middle-income countries (LMICs). We also initiated our partnership with International Diabetes Federation and participated at the IDF Annual Congress, held in South Korea.

Regulatory Updates

The **U.S. FDA** approved Biocon Biologics and Mylan's **supplemental Biologics License Application (sBLA)** for **Pegfilgrastim Drug Substance** to be manufactured at a new Biologics

manufacturing facility. It had conducted a Pre-Approval Inspection of this new Drug Substance manufacturing facility in September 2019.

The U.S. FDA also issued an **EIR closing** its inspection of our **Biologics Drug Product facility** in Bengaluru, which had undergone a Post-Approval Inspection in August 2019.

New Monoclonal Antibodies Facility On Track

Our state-of-the-art, new 2,50,000 sq ft **Drug Substance facility for monoclonal antibodies** at Biocon Park is ready and undergoing the qualification phase. This facility once fully ready for commercialization over the next 12 to 18 months will expand our capacities significantly and will enable us to address the growing patient needs across markets.

Value Unlocking

Private equity fund, True North, **has invested USD 75 million for a 2.44% equity stake in Biocon Biologics India Ltd. (BBIL).** This values the Biologics business at pre-money equity valuation of ~USD 3 billion and an enterprise value of ~USD 3.5 billion. The funds will address BBIL's immediate investment needs for capex and R&D.

BRANDED FORMULATIONS

- Q3 FY20 **Revenue** at **Rs 157 Crore**, down 26% (YoY)
- 9M FY20 **Revenue Rs 419 Crore**, down 20% (YoY)

The **Branded Formulations** business reported a **revenue** of **Rs 157 Crore** for Q3FY20, as pricing pressure and other headwinds continued to weigh on both the India and UAE businesses. Our efforts aimed at addressing the ongoing challenges have helped improve profitability on a sequential basis.

NOVEL BIOLOGICS

For our novel, first-in-class oral prandial insulin molecule **Insulin Tregopil**, we commenced a multiple ascending dose study (phase 1b) in people with Type 1 diabetes during Q3FY20 in Germany. This study is being done in partnership with the U.S.-based JDRF, a leading global organization funding Type 1 diabetes research and advocacy worldwide.

We expanded the scope of the licensing agreement with our partner **Equillium** for our novel asset, **Itolizumab**, to include **Australia** and **New Zealand**. Equillium had originally secured exclusive rights to develop and commercialize Itolizumab, the novel first-in-class, humanized anti-CD6 monoclonal antibody for the U.S. and Canada markets in May 2017. Equillium is developing the asset for the treatment of acute graft-versus-host disease (aGVHD), severe asthma and lupus nephritis.

RESEARCH SERVICES – SYNGENE

- Q3 FY20 **Revenue** at **Rs 519 Crore**, up 11% (YoY)
- 9M FY20 **Revenue** at **Rs 1,405 Crore**, up 9% (YoY)

Revenue from the **Research Services** business this quarter stood at **Rs 519 Crore,** a growth of **11%,** driven by the Discovery Services and Development Services. As a part of its commitment to operate at the leading edge of pharmaceutical research, Syngene has extended its Biologics discovery and preclinical research capabilities in CAR-T therapy, an innovative cell based approach to treating cancer.

During the quarter, **Syngene** received approval from the **Ministry of Health of the Russian Federation** for compliance with meeting current Russian **Good Manufacturing Practices** (cGMP) standards. Syngene's Viral Testing Facility also received **Good Laboratory Practice** (GLP) certification from the **National GLP Compliance Monitoring Authority** making it India's first and only GLP certified viral clearance study service provider.

Enclosed: Fact Sheet – with Financials as per IND-AS

About Biocon Ltd:

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. Biocon 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 U.S. and Europe. It is a leading global player for APIs including statins, immunosuppressants and specialty molecules. It also has a pipeline of promising novel assets in immunotherapy under development. 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 has a large portfolio of biosimilars under global clinical development with three of these commercialized in developed markets like EU, Australia, U.S. and Japan. Biocon is committed to pursue the path of innovation to develop products that have the potential to benefit a billion lives. For more information, visit www.biocon.com Follow-us on Twitter: @bioconlimited

FOR MORE INFORMATION	
MEDIA RELATIONS **Seema Ahuja** **Sr. VP & Global Head, Corporate Communications** ☎+91 80 2808 2222 ✆ +91 99723 17792 ✉ seema.ahuja@biocon.com	**INVESTOR RELATIONS** **Saurabh Paliwal** **Head, Investor Relations** ☎ +91 80 6775 2040 ✉ investor.relations@biocon.com
Rumman Ahmed **Sr.Manager, Corporate Communications** ☎+91 80 2808 2223 ✆ +91 98451 04173 ✉ rumman.ahmed@biocon.com	

Earnings Call

The company will conduct a call at 9.00 AM IST on January 24, 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 January 31, 2020 on +91 22 7194 5757, Playback Code: 03055. Transcript of the conference call will be uploaded on the company website in due course.

Disclaimer: *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.*