Press Release

Biocon Q3FY18 Revenue at Rs 1092 Crore; EBITDA at Rs 256 Crore; Net Profit at Rs 92 Crore

Bengaluru, Karnataka, India: January 24, 2018:

Biocon Ltd (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, today announced its consolidated financial results for the fiscal third quarter ended on December 31st, 2017.

Commenting on the highlights, **Chairperson & Managing Director, Kiran Mazumdar-Shaw stated**: ***"This has been a significant quarter for Biocon as we crossed a major milestone of obtaining USFDA approval for biosimilar Trastuzumab partnered with Mylan. Another highlight was the announcement of a new strategic partnership with Sandoz to develop, manufacture and commercialize a portfolio of next wave of biosimilars for global markets.***

Our Branded Formulations and Research Services segments reported a healthy double-digit growth during this quarter. We expect growth in other segments to revive from early next fiscal."

Highlights:

- **Biocon** becomes **the first Company from India** to get **its biosimilar approved** by the **USFDA;** Ogivri™, co-developed by Biocon and **Mylan,** is also the first biosimilar Trastuzumab to be approved in the US.

- **Biocon** collaborates with **Sandoz** for a **global partnership** to develop, manufacture and commercialize a number of next generation biosimilars to enhance patient access to complex bio-therapeutics in the area of immunology and oncology.

- **Biocon** also receives **approval** from **ANVISA,** the Brazilian regulatory agency, for **biosimilar Trastuzumab**, the first biosimilar Trastuzumab to be approved in Brazil.

- **Biocon** launches **KRABEVA®**, a biosimilar Bevacizumab in India, for the treatment of patients with metastatic colorectal cancer and other types of lung, kidney, cervical, ovarian and brain cancers.

- **EMA accepts** the resubmission of Marketing Authorization Applications for Biocon and Mylan's proposed biosimilars of Trastuzumab and Pegfilgrastim.

FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q3FY18

As per IND-AS *In Rs Crore, except growth numbers*

Particulars	Q3FY18	Q3FY17	Growth
INCOME			
Small Molecules	**369**	407	**-9%**
Biologics	**190**	222	**-15%**
Branded Formulations	**156**	123	**27%**
Research Services	**388**	332	**17%**
Inter-segment	(45)	(40)	10%
Revenue from Operations[#]	**1058**	1044	**1%**
Other Income	**34**	48	**-28%**
TOTAL REVENUE	**1092**	**1092**	**0%**
EBITDA	**256**	324	**-21%**
Interest & Finance charges	**15**	9	**67%**
Depreciation & Amortisation	**97**	71	**39%**
PBT	**150**	245	**-39%**
Net Profit	**92**	**171**	**-46%**
R&D Expenses in P&L	**53**	85	**-37%**
Gross R&D Spends	**94**	100	**-6%**
EBITDA Margin	**23%**	30%	
Core EBITDA Margin	**27%**	32%	
Net Profit Margin	**8%**	16%	
[#]includes Licensing Income	**12**	79	

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

EXECUTIVE COMMENTARY:

PERFORMANCE REVIEW: Q3FY18

Biocon's **Total Revenue** for Q3FY18 stood at Rs 1092 Crore with **Revenue from Operations** at Rs 1058 Crore. **Licensing Income** for the quarter fell to Rs 12 Crore from Rs 79 Crore and **Other Income** declined to Rs 34 Crore thus impacting reported financial results this quarter.

Gross R&D expenses stood at Rs 94 Crore for this quarter, while **Net R&D expenses** reflected on the P&L were Rs 53 Crore, corresponding to 8% of our revenues (excluding Syngene).

EBITDA stood at Rs 256 Crore, with an **EBITDA margin** of 23% for Q3FY18. Operating margins declined on account of lower Licensing Income, compounded by fixed and operating costs related to Malaysia operations.

Core EBITDA margins for Q3FY18 (net of licensing, impact of forex and R&D) stood at **27%.**

Reported Net Profit for the quarter was Rs 92 Crore, which represents a **Net Profit margin** of 8%. The bottomline for the quarter was impacted by a 42% increase in **Interest and Depreciation** costs to Rs 112 Crore largely attributable to Malaysia.

While the financial performance this quarter has been soft, the regulatory advancement in our Biologics business made during this period augurs well for the future.

BUSINESS SEGMENT REVIEW

SMALL MOLECULES: APIs & Generic Formulations

The **Small Molecules** business, which reported revenue of Rs 369 Crore, continues to face headwinds arising from pricing pressures and channel consolidation in the US impacting our statins business. However, continued demand for our immunosuppressants offset some of the pressure.

Rosuvastatin calcium, our first Generic Formulation launch in the competitive US market, has garnered about 10% market share. Our partner also launched this product on Day-1, in Western Europe.

BIOLOGICS: Biosimilars & Novels

Revenues from the **Biologics** vertical, comprising Novel Biologics and Biosimilars, were at Rs 190 Crore. Adjusted for licensing income, product sales grew 16% year on year with growth seen in both insulins and biosimilar antibodies portfolio.

The plant requalification activities undertaken at our fill-finish plant led to production disruption and supply constraints for some products thereby impacting sales. The plant has resumed commercial production, since then.

Biosimilars

Biocon & Sandoz Pact

Biocon recently announced a partnership with Sandoz, a Novartis division and a global leader in biosimilars, for an exclusive portfolio of next-generation biosimilars in the area of immunology and oncology. This is an endorsement of Biocon's expertise in developing and manufacturing biosimilars for global markets. This synergistic partnership will leverage the capabilities of both partners for an 'end to end' play encompassing development, manufacturing, regulatory approval and commercialization globally.

This collaboration addresses some of the long term biosimilars opportunities beyond the near term opportunities being addressed by our existing and continuing successful global partnership with Mylan. This new partnership is a significant milestone in Biocon's journey of developing high quality, affordable biologics that have the potential to benefit patients globally.

Regulatory Updates

Insulins & Analogs

We received regulatory approvals from **ANVISA**, Brazil for our Recombinant Human Insulin (rh-Insulin) drug product under the new non-originator biologicals pathway enabling us to target a larger share of the over US$ 100 million rh-insulins market. Our Malaysia facility has also received GMP approval from ANVISA for both Drug Substance and Drug Product.

Our Insulin Glargine approval in Russia, one of the Top 3 emerging markets, will pave the way for the drug product launch by our partner later this year.

We also made progress in our biosimilar Insulin Aspart program, initiating a global Phase I clinical study for the molecule.

Monoclonal Antibodies & Recombinant Proteins

A major highlight of Q3FY18 was the US Food and Drug Administration's (**USFDA**) approval for Ogivri™, a biosimilar Trastuzumab co-developed by Biocon and Mylan. It is the first biosimilar Trastuzumab and the first biosimilar from Mylan and Biocon's joint portfolio to be approved in the US. It has earned Biocon the distinction of being the first company from India to secure a biosimilar approval in the US. This FDA approval endorses our biosimilars development and manufacturing capability and augurs well for obtaining regulatory approvals in several markets worldwide.

Our biosimilar Trastuzumab also received regulatory approval from **ANVISA** through our partner Libbs Farmaceutica. This is the first biosimilar Trastuzumab to be approved in Brazil.

The European Medicines Agency (**EMA**) has accepted for review our partner Mylan's resubmitted Marketing Authorization Applications (MAA) for proposed biosimilars of Trastuzumab and Pegfilgrastim.

Novel Biologics

Insulin Tregopil Program

We have commenced a pivotal Phase II/III clinical study with **Insulin Tregopil,** our novel, fast-acting oral insulin candidate, in people with Type 2 diabetes in India, post approval from the Drugs Controller General of India (DCGI).

BRANDED FORMULATIONS

The **Branded Formulations** business, which includes sales in India and UAE, reported a revenue of Rs 156 Crore, a YoY growth of 27%.

Revenue from the Branded Formulations (India) business was driven by Oncotherapeutics and Comprehensive Care divisions and strong sales reported by key brands such as **CANMAb™, BIOMAb EGFR®, Basalog® , Ivnex™** and others**.**

Initial sales from **KRABEVA®** (biosimlar Bevacizumab)**,** our second oncology biosimilar launched in India, this quarter have been very encouraging. Developed for the treatment of metastatic colorectal cancer and other types of lung, kidney, cervical, ovarian and brain cancers, it is an important addition to our current Oncology portfolio in India.

The **Branded Formulations** business in **UAE** reported a strong revenue growth driven by metabolics portfolio comprising novel in-licensed products like **Jalra®** and **Imprida®** and our brand of biosimilar Insulin Glargine, **Glaricon™**. Sales momentum of our other branded generic products also boosted revenue during the quarter.

RESEARCH SERVICES – SYNGENE

The Research Services business through Syngene registered a growth of 17% at Rs 387 Crore,

on the back of a strong performance by the Chemical Development vertical and good traction in Discovery Services. Syngene has extended its agreement with Bristol-Myers Squibb (BMS) through 2026 and expanded the scope of its current collaboration.

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 India's largest and fully-integrated, innovation-led biopharmaceutical company. As an emerging global biopharmaceutical enterprise serving customers in over 120 countries, it is committed to reduce therapy costs of chronic diseases like diabetes, cancer and autoimmune. Through innovative products and research services it is enabling access to affordable healthcare for patients, partners and healthcare systems across the globe. It has successfully developed and taken a range of Novel Biologics, Biosimilars, differentiated Small Molecules and affordable Recombinant Human Insulin and Analogs from 'Lab to Market'. Some of its key brands are INSUGEN® (rh-insulin), BASALOG® (Glargine), CANMAb™ (Trastuzumab), BIOMAb-EGFR™ (Nimotuzumab), KRABEVA® (Bevacizumab) and ALZUMAb™ (Itolizumab), a 'first in class' anti-CD6 monoclonal antibody. The Company has a rich pipeline of Biosimilars and Novel Biologics at various stages of development including Insulin Tregopil, a high potential oral insulin. www.biocon.com , follow-us on Twitter: @bioconlimited

Earnings Call

*The company will conduct a call at **9.00 AM IST on January 25, 2018** 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 3938 1081 or +91 70456 71221.** 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 February 1, 2019 (23:50 IST) on +91 22 3065 2322 Playback code: 17384#**. Transcript of the conference call will be uploaded on the company website in due course.*

FOR MORE INFORMATION	
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