Press Release

Biocon Q2FY18 Revenues at Rs 1019 Crore; EBITDA at Rs 233 Crore; Net Profit at Rs 69 Crore

Bengaluru, Karnataka, India: October 26, 2017:

Biocon Ltd (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, today announced its consolidated financial results for the fiscal second quarter ended on September 30th, 2017.

Commenting on the quarterly performance and highlights, **Chairperson and Managing Director Kiran Mazumdar-Shaw stated**: *"Whilst we are pleased with the growth recovery of our research services (Syngene) and branded formulations business segments in the July – September quarter, our overall earnings performance was muted on account of several specific factors. In particular, plant modifications undertaken to comply with regulatory requirements led to production disruptions. Additionally, we experienced regulatory and tender delays in some emerging markets for our biosimilars business. Malaysia facility costs and pricing pressures in our APIs business continue to weigh on our P&L. We expect these headwinds to ease by the end of this fiscal."*

She added: *"A significant development this quarter is the submission of our Insulin Glargine dossier with the USFDA under 505 (b)(2) pathway."*

EXECUTIVE COMMENTARY:

PERFORMANCE REVIEW: Q2FY18

Biocon's **Total Revenues** for Q2FY18 stood at Rs 1019 Crore, up 3% YoY. **Revenues from Operations** grew 2% YoY to Rs 969 Crore, despite a drop in licensing income this quarter. The **Licensing Income** for the quarter stood at Rs 1 Cr as compared to Rs 33 Crore in the comparable period last year. **Other Income** in Q2FY18 stood at Rs 50 Crore. **Net R&D Expenses** at Rs 54 Crore corresponds to 9% of our revenue (ex-Syngene). **Gross R&D Spends** for Q2FY18 stood at Rs 93 Crore, which is line with our commitment to R&D.

We reported an **EBITDA** of Rs 233 Crore, with an **EBITDA margin** of 23% for Q2FY18. The operating margins were largely impacted due to inclusion of fixed and operating costs related to the Malaysia facility and reduced gross margins due to pricing pressure in key markets. **Core EBITDA margins** for Q2FY18 (Net of Licensing, Forex impact and R&D) stood at 27%. **Interest and depreciation costs** increased 43% to Rs 107 Crore for the quarter, attributable to our Malaysia facility. **Reported Net Profit** for the quarter was Rs 69 Crore, which represents a **Net Profit margin** of 7%.

FINANCIAL HIGHLIGHTS (CONSOLIDATED) : Q2FY18

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

Particulars	Q2FY18	Q2FY17	Growth
INCOME			
BIOCON			
Small Molecules	**351**	403	**-13 %**
Biologics	**156**	156	**0 %**
Branded Formulations	**176**	137	**29%**
Research Services	**335**	303	**11%**
Inter-segment	**(49)**	(44)	**10%**
Revenue from Operations#	**969**	955	**2%**
Other Income	**50**	38	**32%**
TOTAL REVENUE	**1019**	**993**	**3%**
EBITDA	**233**	278	**-16%**
Interest & Finance charges	**14**	7	**112%**
Depreciation & Amortisation	**93**	68	**37%**
PBT	**132**	208	**-37 %**
Net Profit	**69**	**147**	**-53%**
R&D Expenses in P&L	**54**	65	**-17%**
Gross R&D Spends	**93**	113	**-17%**
EBITDA Margin	**23%**	28%	
Core EBITDA Margin	**27%**	32%	
Net Profit Margin	**7%**	15%	
#includes Licensing Income	**1**	33	

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

BUSINESS SEGMENT REVIEW

SMALL MOLECULES: APIs & Generic Formulations

The **Small Molecules** business reported a revenue of Rs 351 Crore. The business was impacted by a lower offtake of certain products as a result of pricing pressure faced by some of our clients. However, we were able to increase market share for some of our specialty APIs in key markets. During the quarter, we made regulatory submissions for key APIs in both regulated and emerging markets.

Biocon's **Active Pharmaceutical Ingredients (API) manufacturing facility** in Vishakhapatnam, Andhra Pradesh successfully **completed a US FDA audit** without any observations.

The **Generic Formulations** business made its debut in the US with the launch of Rosuvastatin Calcium tablets in Q2FY18. We also **commissioned our first solid oral dosage forms manufacturing facility** during the quarter. The commissioning of the facility and the completion of full cycle development for new products will enable us to ramp up our regulatory filings for Generic Formulations in developed and emerging markets.

BIOLOGICS : Novels & Biosimilars

Revenues from the **Biologics** vertical, comprising Novel Biologics and Biosimilars, were flat at Rs 156 Crore as plant modifications undertaken to comply with regulatory requirements led to production disruptions. Additionally, we continued to witness regulatory and tender delays in some emerging markets which impacted revenue growth.

Biosimilars: Insulins & Analogs

The **Insulins** business maintained its robust year-on-year growth momentum in Q2FY18 led by increased uptake in key emerging markets. Insulin sales in Malaysia and Mexico added to the revenues for this business in the quarter.

Regulatory Update

During the quarter, our partner Mylan has made a regulatory submission for our *Insulin Glargine* under the 505 (b) (2) pathway with the **USFDA**. Our dossier for this product is also under advanced stages of review in some of the other developed markets.

Our **Insulin manufacturing sites in both India and Malaysia received GMP certifications** from regulators representing key markets. The **Malaysia** facility received **EU GMP Certification** for *Insulin Glargine* Drug Substance and Drug Product.

Additionally, our **Bangalore site** received **GMP Certification** for *Insulin Glargine* Drug Substance and Drug Product from **NPRA, Malaysia** and **MFDS, South Korea**.

We have also made **new regulatory submissions** for *Insulin Glargine* in some of the emerging markets, during this quarter.

Biosimilars: Monoclonal Antibodies & Recombinant Proteins

The biosimilar dossiers submitted by Biocon and Mylan in several developed and emerging markets across the globe are currently under review.

Regulatory Update: US FDA

The US FDA has issued a Complete Response Letter (CRL) for biosimilar *Pegfilgrastim* jointly developed by Biocon and Mylan. The application for *Pegfilgrastim* will be resubmitted after it has been updated with data from ongoing facility requalification activities. **The CRL did not raise any questions on biosimilarity, pharmacokinetic/ pharmacodynamic data, clinical data or immunogenicity.** We do **not expect this CRL to impact the commercial launch timing** of biosimilar *Pegfilgrastim* in the US. We are committed to working with the agency to expeditiously resolve the issues stated in the CRL.

The FDA also extended the target action date for the biosimilar *Trastuzumab* application to Dec 3, 2017 to review some of the clarificatory information submitted to them as a part of the application review process. This three-month extension is **not expected to impact the anticipated timeline for commercialization** of this product in the US.

Regulatory Update- EMA

With respect to our **EMA** audits and Marketing Authorization Applications (**MAAs**) for proposed biosimilars of *Trastuzumab* and *Pegfilgrastim*, the EMA's **CHMP** (Committee for Medicinal Products for Human Use) has considered and accepted our request for withdrawal of the **MAAs** as part of the process linked to the re-inspection of our Drug Product facility in Bangalore.

We have **implemented the Corrective and Preventive Actions (CAPAs)** in accordance with the plans submitted earlier during the year to EMA for our Drug Product facility and are engaged with the regulator on next steps for re-inspection of this facility and early resubmission of our dossiers.

Novel Biologics

We have progressed further with **our novel fast acting, orally delivered *Insulin Tregopil*** this quarter by collaborating with **JDRF**, the world's leading organization supporting Type 1 diabetes research, which has extended its support to **Biocon's study of novel** *Insulin Tregopil* to treat Type 1 diabetes. The primary objective of this study will be to evaluate the safety and tolerability of multiple ascending doses of *Insulin Tregopil* in individuals with Type 1 diabetes.

BRANDED FORMULATIONS

The **Branded Formulations** business, which includes sales in India and UAE, reported a revenue of Rs 176 Crore, a YoY growth of 29%.

Revenues for the Branded Formulations (India) business were **driven by** strong sales of key brands such as **Insugen®, Basalog®, BIOMAb EGFR®** and **CANMAb™.** Channel

restocking post GST related disruption reflected a strong business traction across Metabolics, Oncology, Comprehensive Care and Institutional Business divisions.

BIOMAb EGFR® retained its **No. 1** position* while **CANMAb™**, which ranks as the **No. 2** brand* of *Trastuzumab* in the country, garnered a volume market share of over 30% this quarter. Our rh-Insulin brand **Insugen®** also reported a growth of over 20%* in Q2FY18. *(*Source: IMS data)*

Our efforts to facilitate early adoption of **CytoSorb®** saved the lives of seven critically ill H1N1 patients, this quarter.

During Q2, we also commenced a 40-patient, multi-center, pan-India study to identify potential biomarkers for treating subgroups of chronic plaque psoriasis patients with **ALZUMAb™**. Scientific presentations related to key products such as **BIOMAb EGFR®** (*Nimotuzumab*) and **Basalog®** (*Insulin Glargine*) made at key international forums will help build additional confidence in our products among the medical fraternity in India.

Our **Branded Formulations** business in **UAE** reported a strong revenue growth of 42% driven by our metabolics portfolio comprising novel products like **Jalra®**and **Imprida®** and contribution from the newly launched **Glaricon™,** our brand of biosimilar *Insulin Glargine***.** A pickup in the sales momentum of our other branded generic products also boosted revenue during the quarter.

RESEARCH SERVICES – SYNGENE

Research Services through **Syngene** reported revenues of Rs 335 Crore registering a growth of 11%. The performance was led by sustained growth in the Dedicated R&D Centers and strong performance by Chemical Development vertical with some catch-up seen from the delayed projects in Q1.

Biocon: Ranked Among Top 10 Global Pharma & Biotech Employers for 2017

Biocon has featured as the only Asian Company in the prestigious US-based *Science* Magazine's Annual '**Science Careers Top 20 Employer'** list for 2017. **Ranked at No. 9** amongst global pharma and biotech companies, Biocon is recognized for 'being innovative', 'having a clear vision' and 'being socially responsible'. Biocon has been in this exclusive list of **Global Top 20 Best Employers** since 2012.

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 autoimmune, diabetes, and cancer. 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), BIOMAb-EGFR™ (Nimotuzumab), CANMAb™ (Trastuzumab), Evertor® (Everolimus) and ALZUMAb™ (Itolizumab), a 'first in class' anti-CD6 monoclonal antibody. It has a rich pipeline of Biosimilars and Novel Biologics at various stages of development including Insulin Tregopil, a high potential oral insulin. Visit: www.biocon.com Follow us on Twitter @bioconlimited

Earnings Call

*The company will conduct a call at **9.00 AM IST on October 27, 2017** 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 3300 1500 PIN: 800345#.** 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 Nov 3, 2017 on +91 22 3300 2300. PIN: 255147#**. Transcript of the conference call will be uploaded on the company website in due course.*

For More Information Contact:	
Media Relations	
Seema Ahuja **VP & Global Head, Corporate Communications** ☎+91 80 2808 2222 ✆ +91 99723 17792 ✉ seema.ahuja@biocon.com	**Rumman Ahmed** **Sr.Manager, Corporate Communications** ☎+91 80 2808 2223 ✆ +91 98451 04173 ✉ rumman.ahmed@biocon.com
Investor Relations	
Saurabh Paliwal **Head, Investor Relations** ☎ +91 80 6775 2040 ✆ +91 95383 80801 ✉ saurabh.paliwal@biocon.com	

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