Press Release

Biocon Reports Q1FY18 Revenue at Rs 988 Crore; EBITDA at Rs 246 Crore; Net Profit at Rs 81 Crore

Bengaluru, Karnataka, India: July 27, 2017:

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

Commenting on the quarterly performance and highlights, **Chairperson and Managing Director Kiran Mazumdar-Shaw stated**:

"Our Biologics business had a strong quarter led by insulins sales. Financial performance was muted largely due to a combination of factors: weakening of US$; GST impact; and inclusion of operational and fixed costs of Malaysia. Additionally, the YoY comparison was impacted by the one-time adjustment in Q1FY17 related to IndAS migration. Our core operating margins, however were healthy at 29% for Q1FY18. A major milestone this quarter was the US FDA Oncologic Drugs Advisory Committee (ODAC) recommendation for approval of our biosimilar Trastuzumab. We also received regulatory approvals from the Indian regulator for our biosimilar Bevacizumab."

"The outlook for FY18 remains cautious as much depends on regulatory approvals and tender outcomes for our biosimilars in key emerging markets. However, we will endeavour to maintain healthy core operating margins, going forward."

Highlights of Q1 FY18:

- **U.S. Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC)** recommended approval of Biocon-Mylan's proposed biosimilar Trastuzumab in all eligible indications ; **first biosimilar Trastuzumab** to be recommended by the Committee.

- **Drug Controller General of India** approved Biocon's biosimilar **Bevacizumab**, prescribed for various cancers including metastatic colorectal cancer and lung cancer.

- Biocon received **GMP compliance certification** from **France's ANSM** for its biologics Drug Substance facility for manufacturing Trastuzumab and Pegfilgrastim; Drug Product facility will require re-inspection.
- Clinical data on **Insulin Glargine** presented at the **American Diabetes Association**'s 77th Scientific Sessions in San Diego.
- **Ms. Pratima Rao** appointed as **Mission Director** & **Head** of **Biocon Foundation**, she will lead our **CSR** wing**.**
- **Biocon Foundation** won the prestigious '**Health CSR Project of the Year' Award** for strengthening primary healthcare delivery in India through its **eLAJ platform**.

FINANCIAL HIGHLIGHTS: Q1FY18

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

Particulars	**Q1FY18**	**Q1FY17**	**Growth**
INCOME			
Biocon			
Small Molecules	**363**	435	**-17%**
Biologics	**184**	161	**15%**
Branded Formulations	**130**	158	**-17%**
Research Services	**291**	275	**6%**
Inter-segment	**(34)**	(37)	
Revenue from Operations#	**934**	992	**-6%**
Other Income	**54**	41	**32%**
TOTAL REVENUE	**988**	1033	**-4%**
EBITDA	**246**	304	**-19%**
Interest & Finance charges	**16**	06	**182%**
Depreciation & Amortisation	**99**	66	**49%**
PBT	**135**	237	**-43%**
Net Profit	**81**	167	**-51%**
R&D Expenses in P&L	**58**	52	**13%**
Gross R&D Spends	**96**	92	**4%**
EBITDA Margin	**25%**	28%	
Core EBITDA Margin	**29%**	33%	
Net Profit Margin	**8%**	15%	
#includes Licensing Income	**8**	17	

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

EXECUTIVE COMMENTARY:

PERFORMANCE REVIEW: Q1FY18

Our Q1 Revenue at Rs 988 Cr reflected a decline of 4% due to the combined impact of a stronger rupee, GST and the one-time positive impact in Q1FY17 on account of the transition to IndAS.

Net R&D spends during the quarter stood at Rs. 58 Cr, an increase of 13% YoY. At a Gross level, R&D spends in Q1FY18 were Rs 96 Cr largely on account of our Biologics programs, including our Biosimilars and Novels. Staff costs rose 18% to Rs 193 Cr.

EBITDA for Q1 was Rs. 246 Cr. The decline of 19% was largely on account of inclusion of Fixed and operational costs related to Malaysia in our P&L, post capitalisation of this facility beginning this quarter, as well as, an increase in Staff costs. Adjusted for the one-time impact from the transition to Ind AS in Q1FY17, EBITDA declined 9%.

Interest and depreciation costs increased 60% to Rs. 115 Cr for the quarter, largely attributable to the Malaysia facility.

While EBITDA margin for the quarter stood at 25%, the core operating margin (i.e. EBIDTA margin, net of licensing, impact of forex and R&D) remains healthy at 29%.

Net Profit for the quarter stood at Rs 81 Cr.

SMALL MOLECULES

The Small Molecules business reported sales of Rs 363 Cr in Q1FY18. The sales were impacted due to pricing pressure, rupee appreciation and one time positive impact to this segment in Q1FY17 due to the transition to Ind AS.

Our API customers in key developed markets received regulatory approvals while we made regulatory submissions for a few in key emerging markets.

The commissioning of our manufacturing facility for complex solid oral dosage forms in FY18, will support our regulatory filings for Generic Formulations in developed and emerging markets.

BIOLOGICS

The Biologics vertical comprising Novel Biologics and Biosimilars, including rh-insulin, insulin analogs, monoclonal antibodies and recombinant proteins, reported a strong growth of 15% with sales at Rs 184 Cr. Key regulatory developments augur well for our business in emerging markets.

Biosimilars: Insulins & Analogs

The strong growth by Insulins business in Q1 was led by increased traction in NAFTA and LATAM regions, as well as, sales in Malaysia under a government contract. We further expanded our commercial footprint with the launch of Insulin Glargine in two new emerging markets in the AFMET region.

Biocon and Mylan presented new data from the Insulin Glargine clinical program, including the INSTRIDE studies, at the American Diabetes Association's 77th Scientific Sessions in San Diego. The studies confirmed the efficacy, safety and immunogenicity of our Insulin Glargine in comparison to the reference product in patients with Type 1 and Type 2 diabetes.

Our Insulins manufacturing facilities in Bangalore and Malaysia, underwent key audits that would enable regulatory approvals in few emerging markets, going forward.

Biosimilars: Monoclonal Antibodies & Recombinant Proteins

The Biocon-Mylan collaboration to co-develop a broad portfolio of biosimilar products for the global marketplace has made steady progress during the quarter.

Earlier this month, our collaboration product became the first biosimilar Trastuzumab to be recommended for approval by the US FDA Oncologic Drugs Advisory Committee (ODAC). The unanimous endorsement by the Committee confirms the quality of our

joint research and development capabilities and the biosimilar product in terms of safety, purity and potency in comparison to the reference product. Along with our

partner Mylan, we now look forward to engage with the US FDA to seek final approval which will enable us to expand access to this high-quality, affordable Trastuzumab for treating HER2-positive breast cancers in the US.

We have made regulatory submissions for our biosimilar Trastuzumab in Canada, Australia and some new emerging markets. The review process is underway.

With respect to our pending EMA Marketing Authorization Applications for proposed biosimilars of Trastuzumab and Pegfilgrastim, we have received a GMP compliance certificate from the French medicines regulator, ANSM, for our biologics Drug Substance facility that produces Trastuzumab and Pegfilgrastim. However, the biologics Drug Product facility will require a re-inspection, post implementation of the Corrective and Preventive Action (CAPA) plan submitted to the regulator. We are working to expeditiously address the concerns of the regulator and will request for a re-inspection as early as possible.

We received approval from the Indian drug regulator(DCGI) for our biosimilar Bevacizumab being developed as an affordable alternative for metastatic colorectal cancer and lung cancer patients in India.

Novel Biologics

The Clinical Trial Application for a phase 3 study with our Novel Insulin Tregopil in Type 2 diabetes, filed with the Indian regulator (DCGI) in Q4FY17 is under review. Plans for clinical trials for patients with Type 1 Diabetes are underway.

We initiated Stage 2 of the Phase I study for a subcutaneous form of our novel anti-CD6 mAb, Itolizumab, in Australia.

In Immuno-Oncology, our lead molecule FmAb2, a fusion antibody progressed in pre-clinical development during Q1 FY18.

BRANDED FORMULATIONS

The Branded Formulations business, which includes sales in India and UAE, reported Revenue of Rs 130 Cr. As anticipated, our Branded Formulations India business was impacted due to discontinuance of Abraxane® and pre-GST market dynamics. We saw

the reduction in inventory to nearly half by hospitals and stockists during June 2017. We anticipate the GST impact to roll-over into Q2FY18, however we believe the situation would normalize by end of first half of this fiscal. Most of our key brands continue to do well and 13 of our brands currently have a market share of over 20%.

Our Branded Formulations business in UAE continues to do well. A significant milestone this quarter was the launch of our biosimilar Insulin Glargine in UAE under the brand name Glaricon. This would augment our position in the anti-diabetes space, where our in-licensed products Jalra® and Jalra-M® have captured a double digit market share. During Q1FY18, we have in-licensed two more innovator brands from Novartis, Imprida® (*Amlodipine + Valsartan*) & ImpridaHCT ® (*Amlodipine + Valsartan + Hydrochlorothiazide*), which will fortify our position in the UAE cardiovascular market, where we currently rank among the Top 10 companies.

RESEARCH SERVICES – SYNGENE

Research Services through Syngene reported revenue of Rs 291 Cr registering a growth of 6%. Syngene, on a standalone basis, reported revenue of Rs. 308 Cr in Q1. Syngene Amgen Research Centre has been expanded to include a larger team, which reflects the confidence of our partner in Syngene's capabilities. A multiyear contract with a specialty pharma company of Japan, augurs well for Syngene.

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. Visit: www.biocon.com

Earnings Call

*The company will conduct a call at **9.00 AM IST on July 28, 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 223938 1081.** 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 Aug 4, 2017 on +91 22 3065 2322. Playback ID: 44711**. Transcript of the conference call will be uploaded on the company website in due course.*

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