Press Release

Biocon Q4FY18 Revenue Rs 1,237 Cr, Up 27%; EBITDA Up 30% at Rs 300 Cr; Net Profit Up 2% at Rs 130 Cr

FY18 Revenue Rs 4,336 Cr; EBITDA at Rs 1,035 Cr; Net Profit at Rs 372 Cr

Bengaluru, Karnataka, India: April 26, 2018:

Biocon Ltd (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, today announced its consolidated financial results for the fourth quarter and fiscal year ended March 31st, 2018.

Commenting on the highlights, ***Chairperson & Managing Director, Kiran Mazumdar-Shaw stated:***

"We concluded the year with a strong revenue growth of 27% in Q4FY18 led by Biologics and Research Services businesses, which grew 47% and 45%, respectively. Our traditional Small Molecules and Branded Formulations businesses also turned in a positive performance this quarter. We crossed a key milestone in Q4 when our Insulin Glargine, received regulatory approvals in the developed markets of Europe and Australia. Our biosimilar Trastuzumab also got approval in Turkey.

"The muted FY18 performance was on account of continued pricing challenges in the generics business coupled with a planned plant shut down for requalification and lower licensing income in the biologics business. In addition, operational expenses related to our Malaysia facility impacted the bottom line. However, a positive Q4 is indicative of a normalized business trend. Recent approvals of our biosimilars along with the strong performance of Syngene are expected to positively impact overall performance in FY19."

Highlights:

- **Semglee™, Insulin Glargine** co-developed by **Biocon** and **Mylan,** is the first biosimilar from the partnered portfolio to be approved in the developed markets of **EU** and **Australia.**
- **Biocon** also received **Insulin Glargine approval** in **South Korea** and **biosimilar Trastuzumab approval** in **Turkey.**
- **Biocon** and **Mylan** agreed to accelerate the introduction of biosimilar **Adalimumab** in **Europe** through Mylan's in-licensing arrangement with Fujifilm Kyowa Kirin Biologics, to enable launch in **EU**, around market formation.
- **Biocon** and **Mylan** have agreed to expand their long-standing collaboration to add two new next-generation biosimilar programs with **Insulin Glargine** 300 units/mL and **Pertuzumab.**

FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q4 & FULL YEAR FY18

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

Particulars	Q4FY18	Q4FY17	Growth	FY18	FY17	Growth
INCOME						
Small Molecules	**426**	395	**8%**	**1,508**	1,641	**-8%**
Biologics	**241**	163	**47%**	**770**	702	**10%**
Branded Formulations	**149**	131	**14%**	**612**	549	**11%**
Research Services	**409**	283	**45%**	**1,423**	1,193	**19%**
Inter-segment	(55)	(41)	**35%**	(183)	(163)	13%
Revenue from Operations#	**1,170**	931	**26%**	**4,130**	3,922	**5%**
Other Income	**67**	43	**56%**	**206**	157	**31%**
TOTAL REVENUE	**1,237**	**974**	**27%**	**4,336**	4,079	**6%**
EBITDA	**300**	231	**30%**	**1,035**	1,137	**-9%**
Interest & Finance charges	**17**	5	**238%**	**61**	26	**137%**
Depreciation & Amortisation	**95**	73	**31%**	**385**	277	**39%**
PBT	**193**	159	**22%**	**610**	850	**-28%**
Net Profit	**130**	**127**	**2%**	**372**	612	**-39%**
R&D Expenses in P&L	**51**	65	**-22%**	**216**	267	**-19%**
Gross R&D Spends	**98**	98	**0%**	**380**	402	**-5%**
EBITDA Margin	**24%**	24%		**24%**	28%	
Core EBITDA Margin	**26%**	30%		**27%**	32%	
Net Profit Margin	**11%**	13%		**9%**	15%	
#includes Licensing Income	**2**	16		**23**	145	

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

EXECUTIVE COMMENTARY:

PERFORMANCE REVIEW: Q4FY18

Biocon's **Total Revenue** for Q4FY18 at Rs 1,237 Crore grew by 27% with **Revenue from Operations** at Rs 1,170 Crore growing by 26%.

EBITDA grew 30% at Rs 300 Crore, with an **EBITDA margin** of 24% for Q4FY18. **Core EBITDA margin** for Q4FY18 (net of licensing, impact of forex and R&D) stood at 26%.

Reported Net Profit for the quarter was Rs 130 Crore, which represents a **Net Profit margin** of 11%.

Licensing Income for the quarter was Rs 2 Crore and **Other Income** stood at Rs 67 Crore.

Net R&D expenses for the quarter stood at Rs 51 Crore while **Gross R&D expenses** were Rs 98 Crore corresponding to 13% of our operating revenue (excluding Syngene).

PERFORMANCE REVIEW: FY18

Biocon's **Total Revenue** for FY18 stood at Rs 4,336 Crore with **Revenue from Operations** at Rs 4,130 Crore.

EBITDA stood at Rs 1,035 Crore, with an **EBITDA margin** of 24% for FY18. **Core EBITDA margin** for FY18 (net of licensing, impact of forex and R&D) stood at 27%.

Reported Net Profit for the year was Rs 372 Crore, which represents a **Net Profit margin** of 9%.

Other Income stood at Rs 206 Crore **in FY18.**

Licensing Income for the year declined 84% to Rs 23 Crore in FY18.

Net R&D expenses for FY18 stood at Rs 216 Crore while **Gross R&D expenses** were Rs 380 Crore representing 14% of our operating revenue (excluding Syngene)

The overall profitability for FY18 was largely impacted due to pricing pressures in generics business, lower licensing income in biologics, planned shut down for plant requalification post regulatory audits and inclusion of fixed and operating costs related to the Malaysia facility.

Recent regulatory approvals of our biosimilars coupled with strong performance by Syngene bode well for FY19. While market dynamics for Small Molecules and India Branded Formulations remain challenging, we expect the segments to recover from the pressures faced in FY18, going forward.

BUSINESS SEGMENT REVIEW: Q4FY18

SMALL MOLECULES: APIs & Generic Formulations

The **Small Molecules** business reported a revenue growth of 8% for the quarter at Rs 426 Crore. This was largely led by a higher uptake in key statins & Rosuvastatin formulations and a steady performance by immunosuppressants. Regulatory filings for key APIs in developed and emerging markets prepare the business for a better play, going forward. Generic formulations business is on track with a few ANDA submissions being made in Q4.

BIOLOGICS: Biosimilars & Novels

The **Biologics** vertical, comprising Novel Biologics and Biosimilars, recorded a strong growth of 47% at Rs 241 Crore in the quarter, led by Insulins as well as biosimilar monoclonal antibodies (mAbs).

The strong growth in Insulins business was driven by a good traction in key markets like **Mexico, Malaysia** and the **AFMET** region. The sales of mAbs were largely boosted by the expansion of our biosimilar **Trastuzumab** footprint in emerging markets.

However, on an annual basis, the Biologics business growth was muted due to higher licensing income in the previous year and planned plant shut down for requalification post audit. Excluding Licensing Income, **Biologics** reported a growth of 29% in FY18.

Biosimilars

Insulins & Analogs: Regulatory & Other Developments

The approval of our biosimilar Insulin Glargine **Semglee™** by the **European Commission** (EC) in Q4FY18, following a positive recommendation earlier by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), was an important milestone for our Insulins business.

Semglee™, 100 units/mL 3 mL prefilled disposable pen, is the first biosimilar from Biocon and Mylan's joint portfolio to be approved in **Europe**. Additionally, **Semglee™** 100 IU/mL 3 mL prefilled pen was approved by the Therapeutic Goods Administration (TGA), **Australia**. The EC approval of **Semglee™** applies to all 28 European Union (EU) member states and the European Economic Area (EEA) member states of Norway, Iceland and Liechtenstein.

Semglee™ is expected to be launched by our partner Mylan in **Australia** and **Europe** in the second half of CY 2018.

Biocon also obtained regulatory approvals for biosimilar **Insulin Glargine** in **South Korea** and our local partner is expected to commercialize the product later this year.

In the **U.S.**, Mylan's application for **Insulin Glargine** under the NDA pathway is under review by the Food & Drug Administration (FDA).

For **Insulin Aspart** we just completed our Phase I study and expect comparative PK/PD results in H1FY19.

Monoclonal Antibodies & Recombinant Proteins: Regulatory & Other Developments

In order to accelerate the introduction of biosimilar **Adalimumab** in **Europe**, Biocon and Mylan agreed for an in-licensing arrangement between Mylan and Fujifilm Kyowa Kirin Biologics (FKB).

FKB's product is at an advanced stage of review and could potentially obtain approval in Europe in the second half of 2018, clearing the way for a potential launch by Mylan around market formation. Biocon retains its economic interest in this arrangement vis-a-vis Mylan, in line with our existing global collaboration for monoclonal antibodies.

Biocon and **Mylan** have also agreed to expand their long-standing collaboration with the addition of **two new next-generation biosimilars, Insulin Glargine 300 units /mL** and **Pertuzumab.** This will bolster our existing global biosimilars portfolio comprising antibodies & insulin analogs.

During the quarter, our **Trastuzumab** became the **first biosimilar Trastuzumab** to be approved in **Turkey** which is the 4th largest emerging market for this molecule. This approval enables us to expand access to this lifesaving therapy for breast cancer patients in Turkey.

In **Europe**, the regulatory review of our Marketing Authorization Applications (MAAs) for biosimilar **Trastuzumab** and **Pegfilgrastim** are progressing well and we expect decisions by CHMP by end of CY 2018.

The review of our Biologics License Application (BLA) for biosimilar **Pegfilgrastim** by **USFDA** is progressing. We have responded to all information requests received till date and are awaiting their response by June 4, 2018. The **global Phase III** trial of our biosimilar **Bevacizumab** continues to make good progress.

Novel Biologics

Our Novel Biologics programs, including **Insulin Tregopil**, **SiRNA**, **Itolizumab** and **Fusion Proteins,** are on track. We continued to make progress in the pivotal Phase II/III clinical study with Insulin Tregopil, in people with Type 2 diabetes in India, with patients being dosed.

BRANDED FORMULATIONS

The **Branded Formulations** business, which includes sales in **India** and **UAE**, reported a revenue of Rs 149 Crore, a YoY growth of 14% in Q4FY18.

Branded Formulations - India business performance was led by some of the key brands like **CANMAb™, BIOMAb EGFR®, TACROGRAF™** and **PSORID™.** Many of our key brands, holding a double digit market share, continue to be ranked amongst the 'Top 3' brands in their respective segment. **KRABEVA®,** our second oncology biosimilar launched in India in December 2017, crossed the 'first 100 patients' milestone in Q4FY18. However, the business continues to face operational challenges which has resulted in muted growth in FY 18.

The **Branded Formulations** business in **UAE** reported strong growth led by increase in sales of **key branded generic products**, newly introduced biosimilar Insulin Glargine, **Glaricon** and in-licensed novel products **Jalra** and **Imprida**.

NeoBiocon continues to be ranked among the **Top 15** pharma companies in UAE, while improved market share of brands like **Statix, Zargo** and **Valis** have improved the Company's ranking in the cardiovascular segment to **No 4**.

RESEARCH SERVICES – SYNGENE

The **Research Services** business through Syngene registered a growth of 45% at Rs 409 Crore for Q4FY18, driven by the Chemical Development vertical and good traction in Discovery Services, as well as, strong support from the Biologics business.

During the quarter, Syngene signed a strategic, multi-year collaboration with GlaxoSmithKline (GSK) focusing on new drug discovery using Syngene's discovery services platform. The collaboration also involves the setting up of a customized research facility for GSK. Syngene's manufacturing facilities in Bengaluru were approved by the Japanese regulator, Pharmaceuticals and Medical Devices Authority (PMDA).

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 April 27, 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 1860 420 4242 or +91 44 7100 7405 (PIN - 740719#).** 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 May 3, 2018 (23:59 IST) on +91 22 3804 5003 Playback code: 943081#**. Transcript of the conference call will be uploaded on the company website in due course.*

FOR MORE INFORMATION	
MEDIA RELATIONS **Seema Ahuja** **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 ✆ +91 95383 80801 ✉ saurabh.paliwal@biocon.com
Rumman Ahmed **Sr.Manager, Corporate Communications** ☎+91 80 2808 2223 ✆ +91 98451 04173 ✉ rumman.ahmed@biocon.com	

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