Press Release

# Biocon Q2FY19 Revenue at Rs 1,375 Cr, Up 35%; EBITDA at Rs 394 Cr, Up 69%; Net Profit at Rs 355 Cr; Net Profit (excluding exceptional income) at Rs 184 Cr; Up 167%

***Bengaluru, Karnataka, India: October 25, 2018:***

**Biocon Ltd** (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, today announced its consolidated financial results for the second quarter ended on September 30th, 2018.

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

***"We delivered a strong revenue growth of 35% this quarter, driven by robust performance across our Biologics, Small Molecules and Research Services segments. Net Profit, excluding net exceptional income of Rs 171 Cr, grew by 167% on account of strong topline growth, including biosimilar Pegfilgrastim sales in the U.S., and margin expansion.***

***"We are greatly encouraged by the U.S. FDA's acceptance of an IND submitted by our partner Equillium Inc. for Itolizumab, a novel monoclonal antibody, for an orphan indication. The positive opinions from the European CHMP for Biocon and Mylan's Pegfilgrastim and Trastuzumab augur well for the future growth of our biosimilars business."***

## Highlights:

- Our partner Mylan commenced commercial sales of **Fulphila**™, biosimilar Pegfilgrastim, in the U.S.
- EMA's **CHMP** issued positive opinions recommending approvals of Fulphila™, biosimilar Pegfilgrastim, and **Ogivri®**, biosimilar Trastuzumab
- Our partner **Equillium's** Investigational New Drug **(IND)** application for **EQ001** (Itolizumab) for an orphan indication of acute graft-versus-host disease (aGVHD) was **accepted** by the **U.S. FDA** in July 2018
- Biocon's **Drug Substance facility** in Bangalore completed **U.S. FDA** inspection with **no observations**
- Biocon's **Sterile Drug Product and Devices facilities** in Bangalore received Certificates of **GMP Compliance** from **EU**
- Biocon's **API facility** in Hyderabad successfully completed **GMP** audits from **TGA,** Australia and **COFEPRIS,** Mexico

## FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q2FY19

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

| Particulars | Q2FY19 | Q2FY18 | Growth |
|---|---|---|---|
| **INCOME** | | | |
| **Small Molecules** | **432** | 351 | **23%** |
| **Biologics** | **367** | 156 | **136%** |
| **Branded Formulations** | **164** | 176 | **(7)%** |
| **Research Services** | **419** | 335 | **25%** |
| Inter-segment | (61) | (49) | 25% |
| **Revenue from Operations#** | **1,321** | 969 | **36%** |
| Other Income | **54** | 50 | 7% |
| **TOTAL REVENUE** | **1,375** | **1,019** | **35%** |
| **EBITDA** | **394** | 233 | **69%** |
| **PBT** | **451** | 132 | 243% |
| **Net Profit** | **355** | 69 | **416%** |
| **Exceptional item** (net of tax) | **171** | Nil | |
| **Net Profit** (excluding exceptional item) | **184** | 69 | **167%** |
| **R&D Expenses in P&L** | **77** | 54 | **43%** |
| **Gross R&D Spends** | **120** | 96 | **25%** |
| **EBITDA Margin** | **29%** | 23% | |
| **Core EBITDA Margin** | **33%** | 26% | |
| **Net Profit Margin*** | **13%** | 7% | |
| *#includes Licensing Income* | **5** | 8 | |

*Notes: Figures above are rounded off to the nearest Cr; % based on absolute numbers.*
**excluding exceptional item and associated tax*

**EXECUTIVE COMMENTARY:**

## PERFORMANCE REVIEW: Q2FY19

**Biocon** reported a strong **Revenue growth** of 35% at Rs 1,375 Cr in Q2 FY19, led by Biologics, Small Molecules and Research Services business segments.

**Net Profit** at Rs 355 Cr was aided by net exceptional income of Rs 171 Cr related to change in the fair value of our investment in U.S.-based Equillium Inc.

**Net Profit, excluding exceptional item**, stood at Rs 184 Cr reflecting a strong growth of 167%.

**EBITDA** rose 69% to Rs 394 Cr. **EBITDA margin** was 29% in Q2FY19 versus 23% in Q2FY18. **Core EBITDA margin**, which is net of licensing, forex and R&D, improved to 33% in Q2FY19 from 26% in Q2FY18.

**Licensing Income** in Q2FY19 stood at Rs 5 Cr while Other Income reported was Rs 54 Cr, which includes a Forex gain of Rs 24 Cr.

**Net R&D spends** during the quarter stood at Rs 77 Cr, an increase of 43%. At a **gross level, R&D spends** in Q2FY19 were Rs 120 Cr.

## BUSINESS SEGMENT REVIEW

### SMALL MOLECULES: APIs & Generic Formulations

The **Small Molecules** business delivered a strong revenue growth of 23% at Rs 432 Cr, led by robust API sales in Latin America, Europe and the Middle East markets driven by a better product mix across immunosuppressants, statins and other key APIs.

The **Generic Formulations** business continues to gain traction in the U.S. with improved market share for Rosuvastatin calcium tablets and sales of Simvastatin tablets launched last quarter.

### BIOLOGICS: Biosimilars & Novels

Revenue from the **Biologics** segment, comprising Novel Biologics and Biosimilars, more than doubled to Rs 367 Cr in the quarter, driven by the the commercial launch of biosimilar Pegfilgrastim in the U.S. and strong sales of Insulins as well as biosimilar MAbs in key emerging markets.

#### Biosimilars

#### Insulins & Analogs

During the quarter, our insulins business recorded a strong growth led by sales in several emerging markets including Malaysia and Mexico where Biocon through its local partners continues to hold a dominant share of the rh-insulin market.

#### Monoclonal Antibodies & Recombinant Proteins

Our partner Mylan commenced commercial sales of **Fulphila**, the first biosimilar Pegfilgrastim approved in the U.S.

Our biosimilar **Trastuzumab** continues to do well in emerging markets with launches in newer geographies and increased prescription share in markets where it has already been commercialized. During the quarter, our partner launched the product as the first biosimilar Trastuzumab in Turkey. In Algeria, our Trastuzumab continues to enjoy a wide acceptance among patients and prescribers, while in Brazil it has witnessed a strong uptake since **Zedora** (Trastuzumab) was launched in March 2018.

The **European Medicines Agency's** (EMA) Committee for Medicinal Products for Human Use (CHMP) issued positive opinions recommending approvals of **Fulphila**, a biosimilar Pegfilgrastim, and **Ogivri**, a biosimilar Trastuzumab, co-developed by Biocon and Mylan.

The CHMP positive opinions will now be considered by the European Commission and the decisions on approvals are expected later in 2018.

Our partner Mylan initiated the commercial launch of **biosimilar Adalimumab** (FKB product) across major markets in Europe, post Oct 16, 2018. Biocon will receive economic benefit for this product in line with our global collaboration with Mylan.

### Novel Biologics

On **Insulin Tregopil,** our pivotal Phase 2/3 clinical study in people with Type 2 diabetes in India is progressing well.

Our **novel anti-CD6** monoclonal antibody, Itolizumab, progressed further in its clinical development journey. Our partner Equillium's Investigational New Drug (IND) application for EQ001 (Itolizumab) in an orphan indication of acute graft-versus-host disease (aGVHD) was accepted by the U.S. FDA in July 2018.

Equillium plans to initiate a Phase 1b/2 clinical trial of EQ001 (Itolizumab) for the treatment of aGVHD, in early 2019, and expects top-line data from the Phase 1b part of this trial within 12 months of initiation.

Equillium also plans to develop the asset for additional indications like cGVHD and Asthma.

To fund the clinical trials Equillium has raised USD 65 million in its maiden public offering and got listed on NASDAQ on Oct 12, 2018. Biocon's stake in Equillium post the IPO stands at approximately 13.5%.

## BRANDED FORMULATIONS

The **Branded Formulations** business, which includes sales in **India** and **UAE**, reported a revenue of Rs 164 Cr, slipping 7% on a YoY basis.

The **Branded Formulations – India (BFI)** business performance was muted due to the higher base of Q2FY18 which benefited from channel restocking post GST implementation. While some of our key brands like BIOMAb EGFR®, TACROGRAF™, and Renodapt® reported double-digit growth, other lead brands had to face severe pricing pressures leading to lower than expected sales. The lower sales seen in major divisions was offset by growth in Comprehensive Care and Nephrology.

In **UAE,** the in-licensed Metabolics product portfolio and Glaricon, our brand of Insulin Glargine, continued to gain market share, while in the Branded Generics market we faced challenges with repricing of products by the Ministry of Health.

## RESEARCH SERVICES – SYNGENE

The **Research Services** business continues to do well with a revenue growth of 25% at Rs 419 Cr, buoyed by good growth in Discovery Services and increased traction in the Dedicated R&D Centres.

During the quarter, Syngene has commissioned a new dedicated facility for Bristol-Myers Squibb (BMS) and renewed its collaboration with Baxter with a widened scope of engagement.

**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 a fully-integrated, innovation-led global biopharmaceutical company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune. It has developed and taken differentiated Small Molecules, Novel Biologics and a range of Biosimilars (Monoclonal Antibodies, Pegfilgrastim, rh- Insulin and Insulin Glargine) from 'Lab to Market' in India, key emerging and developed markets. It has a large portfolio of biosimilars under clinical development with three of these approved in developed markets of US, EU, Japan and Australia. Its Novel pipeline includes promising assets like Insulin Tregopil, anti-CD6 antibody and a fusion protein for immuno-oncology. Some of its key brands are INSUGEN® (rh-insulin), Basalog One® (prefilled Glargine pen), CANMAb™ (Trastuzumab), KRABEVA® (Bevacizumab), BIOMAb-EGFR® (Nimotuzumab) and ALZUMAb™ (Itolizumab). Follow-us on Twitter: @bioconlimited, www.biocon.com


| **FOR MORE INFORMATION** | |
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| **MEDIA RELATIONS**<br>**Seema Ahuja**<br>**VP & Global Head, Corporate Communications**<br>☎+91 80 2808 2222<br>✆ +91 99723 17792<br>✉ seema.ahuja@biocon.com | **INVESTOR RELATIONS**<br>**Saurabh Paliwal**<br>**Head, Investor Relations**<br>☎ +91 80 6775 2040<br>✆ +91 95383 80801<br>✉ investor.relations@biocon.com |
| **Rumman Ahmed**<br>**Sr.Manager, Corporate Communications**<br>☎+91 80 2808 2223<br>✆ +91 98451 04173<br>✉ rumman.ahmed@biocon.com | |


***Earnings Call***

*The company will conduct a call at **9.00 AM IST on October 26, 2018** where the senior management will discuss the company's performance and answer questions from participants. This call is not open to the members of the media (print/ electronic/online/wires). 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 Nov 4, 2018 on +91 22 7194 5757 Playback Code: 39623** 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.*