



**Biocon Limited**

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Date of Submission: July 26, 2018

To The Secretary Listing Department BSE Limited Department of Corporate Services Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai – 400 001 Scrip Code - 532523	To The Secretary Listing Department National Stock Exchange of India Limited Exchange Plaza, Bandra Kurla Complex Mumbai – 400 050 Stock Code- Biocon
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Dear Sir/Madam,

**Sub: Press Release for the quarter ended June 30, 2018**

With reference to the captioned subject, please find enclosed Press Release pertaining to the Un-Audited Financial Results (Standalone and Consolidated) for the quarter ended June 30, 2018.

Kindly take the above said information on record.

Thanking You,  
Yours faithfully  
For BIOCON LIMITED

Akhilesh Nand  
Compliance Officer  
Encl: A/A

## **Biocon Q1FY19 Revenue Rs 1,193 Cr, Up 21%; EBITDA Up 25% at Rs 307 Cr; Net Profit Up 47% at Rs 120 Cr**

**Bengaluru, Karnataka, India: July 26, 2018:**

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

Commenting on the highlights, **Chairperson & Managing Director, Kiran Mazumdar-Shaw stated:** *"We started the year with a robust Q1FY19 recording an overall revenue growth of 21% at Rs 1,193 Crore and a 47% increase in Net Profit at Rs 120 Crore, driven by a strong performance across our business segments. This performance was led by a 36% growth in our Biologics business and a 39% increase in Research Services revenues.*

*"The approval and launch of our biosimilar Pegfilgrastim, Fulphila™, in the U.S. is a significant milestone for Biocon and sets the tone for the future success of our biosimilars business. The cGMP approvals for our Drug Products manufacturing facility in Bengaluru by both the U.S. FDA and EMA demonstrates our commitment to provide high quality products to address the growing needs of patients for affordable biosimilars in these markets. These developments augur well for a strong financial performance in FY19."*

### **Highlights:**

- **Fulphila™**, co-developed by Biocon and Mylan, becomes the first biosimilar **Pegfilgrastim** to be approved and launched in the **U.S.** **Biocon** is the first Company from India to have two biosimilars approved by the U.S. FDA.
- **Biocon's** sterile Drug Product manufacturing facility in Bengaluru receives **EIR** from **U.S. FDA** and **EU GMP certification**.
- **Presentations** made at **American Society of Clinical Oncology (ASCO)** annual meeting in June 2018 for novel biologic **Nimotuzumab (BIOMAb EGFR®)** and biosimilar **Trastuzumab (Ogivri™)**.
- PK-PD data on novel **Insulin Tregopil** presented at **American Diabetes Association Scientific Sessions** in June 2018.
- **Syngene** extends its collaboration with Baxter upto 2024 and strengthens its growing client base.

## FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q1FY19

As per IND-AS

In Rs Crore, except growth numbers

Particulars	Q1FY19	Q1FY18	Growth
<b>INCOME</b>			
Small Molecules	400	363	10%
Biologics	250	184	36%
Branded Formulations	147	130	13%
Research Services	406	291	39%
Inter-segment	(79)	(34)	129%
Revenue from Operations <sup>#</sup>	1124	934	20%
Other Income	69	54	27%
<b>TOTAL REVENUE</b>	<b>1193</b>	<b>988</b>	<b>21%</b>
<b>EBITDA</b>	<b>307</b>	<b>246</b>	<b>25%</b>
Interest & Finance charges	18	16	9%
Depreciation & Amortisation	99	99	0%
PBT	191	135	41%
<b>Net Profit</b>	<b>120</b>	<b>81</b>	<b>47%</b>
R&D Expenses in P&L	44	58	(24%)
Gross R&D Spends	88	96	(8%)
<b>EBITDA Margin</b>	<b>26%</b>	<b>25%</b>	
<b>Core EBITDA Margin</b>	<b>27%</b>	<b>29%</b>	
<b>Net Profit Margin</b>	<b>10%</b>	<b>8%</b>	
<sup>#</sup> includes Licensing Income	5	8	(38%)

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

### EXECUTIVE COMMENTARY:

#### PERFORMANCE REVIEW: Q1FY19

Biocon's **Total Revenue** for Q1FY19 at Rs 1,193 Crore grew by 21%, **Net Profit** at Rs 120 Crore reported a growth of 47%.

**EBITDA** at Rs 307 Crore grew 25%, with an **EBITDA margin** of 26% for Q1FY19.

**Core EBITDA margin** for Q1FY19 (net of licensing, impact of forex and R&D) stood at 27%.

**Net Profit margin** stood at 10%.

**Licensing Income** for the quarter was Rs 5 Crore and **Other Income** stood at Rs 69 Crore.

**Net R&D expenses** for the quarter stood at Rs 44 Crore while **Gross R&D expenses** were Rs 88 Crore corresponding to 12 % of our operating revenue (excluding Syngene).

## BUSINESS SEGMENT REVIEW: Q1FY19

### SMALL MOLECULES: APIs & Generic Formulations

The **Small Molecules** business reported a revenue growth of 10% for the quarter at Rs 400 Crore. This was largely led by the sales of key APIs including immunosuppressants and Generic Formulations.

We filed several Drug Master Files (DMFs) in developed markets and key emerging markets during the quarter, strengthening our Small Molecule APIs pipeline.

Our **Generic Formulations** business, which currently accounts for a small fraction of Small Molecules segment revenue, recorded strong topline growth on the back of market share gains for our Rosuvastatin Calcium formulation in the U.S. We also launched Simvastatin tablets in the U.S. this quarter.

### BIOLOGICS: Biosimilars & Novels

The **Biologics** segment, comprising Novel Biologics and Biosimilars, recorded a strong growth of 36% at Rs 250 Crore in the quarter. This was largely driven by higher sales of biosimilar monoclonal antibodies (mAbs) in emerging markets, supported by Insulins business.

#### Biosimilars

##### **Insulins & Analogs**

During the quarter, our insulins portfolio gained market share in several emerging markets such as **Malaysia, Algeria** and **UAE**. Our brand Insugen<sup>®</sup>, now holds a 75% share of the rh-insulin market in Malaysia.

During the quarter, we made several regulatory submissions for Insulin Glargine in CIS (Commonwealth of Independent States) and MENA (Middle East & North Africa) regions.

For the US market Biocon and its partner Mylan are generating additional clinical data for **Insulin Glargine**, in support of the manufacturing site change from Bengaluru to Malaysia. All activities as agreed with the US FDA in this regard are progressing as planned and we will expeditiously provide the requested data to the regulator in response to the Complete Response Letter (CRL) we received for Insulin Glargine. We do not anticipate any impact on the approval and launch timing of **Insulin Glargine** in the U.S.

##### **Monoclonal Antibodies & Recombinant Proteins**

Biocon's partner Mylan has launched the first U.S. FDA-approved biosimilar Pegfilgrastim, **Fulphila™**, as a more affordable therapy option for cancer patients undergoing chemotherapy in the U.S.

**Fulphila™** is the first biosimilar **Pegfilgrastim (pegfilgrastim-jmdb)** to be approved by the **U.S. FDA** in June 2018. **Biocon** is the **first company from India** to have its biosimilar commercialized in the U.S.

The regulatory reviews of our biosimilar **Pegfilgrastim** dossier in EU, Australia and Canada are progressing well.

Through our biosimilar **Trastuzumab**, we continued to enhance access to a critical biologics therapy for cancer patients in several emerging markets. During the quarter, we witnessed strong retail market uptake of our biosimilar Trastuzumab in **Brazil**. **Zedora®**, sold through our partner Libbs Farmaceutica, is the first biosimilar Trastuzumab approved in **Brazil**. We also maintained a robust market share for our biosimilar Trastuzumab in **Algeria**, where it enjoys wide acceptance from patients and prescribers.

We made several regulatory submissions for our biosimilar Trastuzumab in the CIS, LATAM & MENA regions, during Q1.

Our biologics **Drug Substances** and **Drug Products** facilities in Bengaluru and Malaysia received approvals from regulatory agencies of several emerging and developed markets, including **EU GMP certification** and **US FDA EIR** for the Drug Products facility in Bengaluru.

During Q1, Biocon and Mylan presented 48-week additional data from the **HERITAGE study** at the 2018 **American Society of Clinical Oncology (ASCO) Annual Meeting** in Chicago, which further demonstrated that our biosimilar **Trastuzumab, Ogivri™**, does not have any clinically meaningful differences in terms of safety, purity and potency in comparison to the reference product, Herceptin®.

In order to advance our market entry in EU and certain other markets, Biocon and Mylan agreed to a commercial arrangement between Mylan and a third party for an advanced stage Etanercept asset. Biocon **retains its economic interest** in this arrangement vis-a-vis Mylan, in accordance with our existing Etanercept collaboration agreement.

### **Novel Biologics**

Our basket of novel assets under development, representing an interesting combination of early and advanced stage programs, progressed in the clinics in Q1FY19.

Our oral insulin candidate, **Insulin Tregopil**, advanced in a pivotal Phase II/III study in Type 2 diabetes, with more patients in India being randomized during the quarter.

We presented data from the Insulin Tregopil clinical program at the **American Diabetes Association's (ADA) 78th Scientific Sessions** held at Orlando, Florida. The pharmacokinetic-pharmacodynamic (PK-PD) data on Tregopil presented at ADA suggests an oral rapid acting insulin option for Type 2 diabetes patients.

## BRANDED FORMULATIONS

The **Branded Formulations** business, which includes sales in **India** and **UAE**, reported a revenue of Rs 147 Crore, representing a YoY growth of 13% in Q1FY19.

The **Branded Formulations – India (BFI)** business performance was led by the Metabolics, Nephrology, Immunotherapy and Comprehensive Care divisions, with a strong growth reported by key brands like **Insugen<sup>®</sup>**, **Basalog<sup>®</sup>**, **TACROGRAF<sup>™</sup>**, **Renodapt<sup>®</sup>** and **PSORID<sup>™</sup>**.

In line with our focus on key brands, the **Top 10 brands** in our India portfolio, reported a strong **double digit growth** accounting for a significant share of BFI sales this quarter.

A large investigator-initiated study of **BIOMAb EGFR<sup>®</sup>** (Nimotuzumab), **India's first indigenously produced novel biologic** launched by Biocon in 2006, established the 'best-in-class' status of the innovative therapy for **head and neck cancer**. The **results** of this large randomized, controlled **clinical study** at the Tata Memorial Hospital (TMH), Mumbai, were **presented** at the 2018 **ASCO** Annual Meeting. This study in head and neck cancer patients in India **demonstrated** that **Nimotuzumab combined with chemo-radiotherapy** successfully met the primary endpoint of median **Progression Free Survival**, which was **three times than that of Standard of Care**.

We also made **two poster** and **two paper** presentations on managing diabetes with insulin therapy, at the global ADA Congress in Florida, which were well received.

## RESEARCH SERVICES – SYNGENE

The **Research Services** business through Syngene sustained its strong growth trajectory, reporting a revenue growth of 39% at Rs 406 Crore, buoyed by the performance of discovery and development services for small molecules and continued traction in the biologics business.

During the quarter, Syngene extended its collaboration with Baxter till 2024 with an increased scope of work at its dedicated R&D center in Bengaluru. It also made significant progress in making the GSK collaboration operational, where a dedicated team of Syngene scientists continue to work closely with GSK's global R&D teams in accelerating drug discovery using Syngene's discovery services platforms.

## 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, 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](http://www.biocon.com)

### **Earnings Call**

The company will conduct a call at **9.00 AM IST on July 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 +91 22 6280 1151**. Other toll numbers are listed in the conference call invite which is posted on the company website [www.biocon.com](http://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 August 3, 2018 on +91 22 7194 5757, Playback Code: 80672**. Transcript of the conference call will be uploaded on the company website in due course.

<b>FOR MORE INFORMATION</b>	
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**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.