

Press Release

Biocon Q3FY19 Earnings

Revenue at Rs 1,566 Cr, Up 43%; Net Profit at Rs 217 Cr, Up 136%

EBITDA at Rs 406 Cr, Up 59%

Bengaluru, Karnataka, India: January 24, 2019:

Biocon Ltd (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, today announced its consolidated financial results for the third quarter ended on December 31st, 2018.

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

“We have delivered the highest ever Revenue and Profit growth in absolute terms in Q3FY19, driven by strong business performance. Our Biologics segment more than doubled in revenue and recorded an EBIT margin of 30% driven by increased penetration of our Pegfilgrastim in the U.S. Small Molecules, Branded Formulations and Research Services also registered a robust growth this quarter.

“Our biosimilars strategy is beginning to pay off with the launch of our biosimilars in the US and EU and we are greatly encouraged by the recent regulatory approvals of our key biosimilars in advanced markets like EU, Australia and Canada. We are committed to play a significant role in enhancing access to our high quality, affordable biologics for patients across the world.”

Highlights:

- **Biosimilar Pegfilgrastim** (Fulphila®) and **biosimilar Trastuzumab** (Ogivri®), co-developed by Biocon and Mylan, received marketing **approvals** in **EU**
- **Biosimilar Insulin Glargine** (Semglee®) and **biosimilar Adalimumab** were launched in **EU** by our partner Mylan
- We launched **Atorvastatin Calcium** tablets in the U.S.
- Our new **Oral Solid Dosage Forms** manufacturing facility in Bengaluru completed a **pre-approval inspection** by the **U.S. FDA** with no 483 observations
- Our **API manufacturing facility** in **Telangana** successfully completed a **GMP** audit by the **U.S. FDA** with no 483 observations
- We made it to the **Top Ten** Global Pharma & Biotech Employers List 2018, moving up two ranks to **No. 7**
- **The Hebbagodi Lake Revival Project**, a CSR initiative through **Biocon Foundation**, was dedicated to the community and it received the **SABERA Award** (Social And Business Enterprise Responsible Award) in the Environment category

- We also received the **Asia IP Elite Award** for 'Excellence in IP Value Creation' at the IPBC Asia Award 2018; recognized for the third consecutive year by the world's leading IP business information provider IAM

FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q3FY19

As per IND-AS

In Rs Crore, except growth numbers

Particulars	Q3FY19	Q3FY18	Growth
INCOME			
Small Molecules	469	369	27%
Biologics	449	190	136%
Branded Formulations	212	156	36%
Research Services	467	388	20%
Inter-segment	-56	-45	26%
Revenue from Operations[#]	1,541	1,058	46%
Other Income	25	34	-24%
TOTAL REVENUE	1,566	1,092	43%
EBITDA	406	256	59%
PBT	289	150	93%
Net Profit	217	92	136%
Exceptional item (net of tax)	6	-	
Net Profit (adjusted for exceptional item)	211	92	130%
R&D Expenses in P&L	77	53	45%
Gross R&D Spends	106	94	12%
EBITDA Margin	26%	23%	
Core EBITDA Margin	32%	27%	
Net Profit Margin*	14%	8%	
[#] includes Licensing Income	7	12	

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

*excluding exceptional item and associated tax

EXECUTIVE COMMENTARY:

PERFORMANCE REVIEW: Q3FY19

Biocon reported a strong **Revenue growth** of 43% at Rs 1,566 Cr in Q3 FY19, led by robust growth across all business segments: Biologics, Small Molecules, Branded Formulations and Research Services.

Net Profit for the quarter recorded a growth of 136% at Rs 217 Cr.

Net Profit, adjusted for exceptional item, stood at Rs 211 Cr reflecting a growth of 130%.

EBITDA rose 59% to Rs 406 Cr, despite a **Forex Loss** of Rs 28 Cr.

EBITDA margin was 26% in Q3FY19 versus 23% in Q3FY18.

Core EBITDA margin, which is net of licensing, forex and R&D, improved to **32%** in Q3FY19 from 27% in Q3FY18.

The strong operating performance in Q3FY19 was led by a higher contribution of Biologics segment driven by our biosimilars portfolio. This segment recorded the highest ever EBIT margins of 30% this quarter.

BUSINESS SEGMENT REVIEW

SMALL MOLECULES: APIs & Generic Formulations

The **Small Molecules** business delivered a revenue growth of **27%** at **Rs 469 Cr**, led by robust sales of our core APIs and continued growth in the U.S. generic formulations business. We recorded an increase in API sales in Latin America, Europe and to India-based customers delivering to the U.S. market.

We continue to file Drug Master Files (DMFs) in developed and key emerging markets in order to strengthen our Small Molecule APIs pipeline.

The **Generic Formulations** business in the U.S. continued to record robust growth. We successfully launched Atorvastatin Calcium tablets in the U.S. and continue to gain traction for previously launched Rosuvastatin and Simvastatin formulations in this market.

BIOLOGICS: Biosimilars & Novels

Revenue from the **Biologics** segment, comprising Biosimilars and Novel Biologics, more than doubled to **Rs 449 Cr**, recording a strong growth of **136%** YoY during the quarter.

Biosimilars

Our Biosimilars Sales during the quarter were driven by a strong performance across our portfolio of insulins, monoclonal antibodies (MAbs) and other biologics in key developed and emerging markets.

Biosimilar Pegfilgrastim, launched in the U.S. by our partner Mylan, continues to gain market share. We sustained sales momentum of biosimilar Trastuzumab in Latin America and AFMET. Our partner Mylan also launched biosimilar Adalimumab in EU this quarter, in-licensed from Fujifilm Kyowa Kirin Biologics. Biocon receives economic benefit from this.

The insulins portfolio growth was led by sales in Malaysia and Latin America. In terms of new markets, Semglee®, the **biosimilar Insulin Glargine** co-developed by Biocon and Mylan, was launched **in EU**.



Our **biosimilar Insulin Glargine**, Glarzia, was launched in **South Korea** through a local partner.

Regulatory Approvals

During the quarter Fulphila®, **biosimilar Pegfilgrastim** jointly developed by Biocon and Mylan, received Marketing Authorization from the **European Commission** and a Notice of Compliance (NOC) from **Health Canada's** Biologics and Genetic Therapies Directorate. Fulphila, is now approved in **U.S., EU, Canada and Australia**.

Ogivri®, **biosimilar Trastuzumab**, received **regulatory approvals** in the developed markets of **EU and Australia** during the quarter. It is already approved in the U.S.

Additionally, we received regulatory approvals for **our biosimilar Trastuzumab** in several emerging markets this quarter.

Novel Biologics

Our Novel Biologics programs, including **Insulin Tregopil** (oral insulin), **Itolizumab**, **FmAb2** (fusion protein for immuno-oncology) and **QPI-1007** (siRNA molecule), are progressing as planned.

Our partner Equillum received a 'fast track' designation from the U.S. FDA for **EQ001**, or **Itolizumab**, our out-licensed novel anti-CD6 monoclonal antibody, for the treatment of acute graft-versus-host disease (aGVHD). The Company is planning to initiate a Phase 1b/2 clinical trial in early 2019.

BRANDED FORMULATIONS

The **Branded Formulations** business, which includes sales in **India** and **UAE**, reported a quarterly revenue growth of **36% YoY** at **Rs 212 Cr**.

The **Branded Formulations – India (BFI)** business performance was led by the Metabolics, Nephrology, Immunotherapy, and Market Access divisions. As a specialty products company, 70% of our overall India business is now accounted for by biologics / biosimilars products.

Our strategy of focusing on building premium brands in chronic therapeutic areas is working well. The Top 10 brands in our India portfolio, which account for a significant share of BFI sales, grew 26% YoY this quarter. Key brands like Insugen®, Basalog® and Tacrograf™ reported strong double-digit YoY growth in Q3FY19.

The **Branded Formulations** business in **UAE** reported a strong revenue growth YoY, driven by branded generic products. NeoBiocon is the No. 1 generic company in UAE in the Cardiovascular and Diabetes markets and is ranked No. 13 amongst the overall pharma companies. (IMS MAT Nov 2018). During the quarter, we launched our **biosimilar Trastuzumab** under the brand name **CANHERA** in **UAE**.

RESEARCH SERVICES – SYNGENE

The **Research Services** business continues to do well with a revenue growth of **20% YoY** at **Rs 467 Cr**, buoyed by good growth in **Discovery Services** and increased traction in the **Biologics business**.

During the quarter, Syngene commissioned a new dedicated facility for Baxter and extended its collaboration with Merck KGaA until 2022, with a widened scope of engagement.

RANKED AMONG TOP GLOBAL BIOTECH EMPLOYERS

Biocon moved up in the **Top 10 Global Biotech Employers** ranking for 2018 and continued to be the **only Company from Asia to feature** on the prestigious U.S.-based Science magazine's annual '**Science Careers Top 20 Employers**' list, since its debut in 2012. **Ranked at No. 7** among global pharma and biotech companies in 2018, Biocon's position has moved up two ranks from No. 9 last year. Biocon has been recognized for these **three key attributes**: 'innovative leader in the industry', 'is socially responsible' and 'makes changes needed'.

CORPORATE SOCIAL RESPONSIBILITY

As a part of our CSR efforts to ensure environmental sustainability, Biocon Foundation has brought back to life the dying 35-acre **Hebbagodi Lake** by using a three-step eco-friendly bioremediation process, leading to a significant improvement in the water quality and the return of flora and fauna. The bio-rejuvenated lake in Anekal taluk of Karnataka was dedicated to the local community along with a children's park and a safe drinking water facility, during the quarter. The Foundation's innovation of creating artificial floating wetlands for continuous natural cleaning of the lake water, has secured a place in the **Limca Book of World Records** for being the 'Largest Area of Artificial Floating Wetlands Created in a Lake in India'.

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 U.S., EU, Japan and Australia. Its Novel pipeline includes promising assets like Insulin Tregopil, anti-CD6 antibody and a fusion protein for immunoncology. 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

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Earnings Call

The company will conduct a call at **9.00 AM IST on January 25, 2019** 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 60 minutes post the conclusion of the call **till February 1, 2019 on +91 22 7194 5757 Playback Code: 25346**. 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.