

Press Release

## **Biocon Q3 FY17 Net Profit Up 65% at Rs 171 Crore**

Revenue Rises 32% at Rs 1092 Crore; EBITDA Increases 57% to Rs 324 Crore

**Bengaluru, Karnataka, India: January 24, 2017**

**Biocon Ltd** (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, announced today its consolidated financial results for the third quarter ended on December 31, 2016.

*Commenting on the quarterly performance and highlights, **Chairperson and Managing Director, Kiran Mazumdar-Shaw stated:** "Our strong performance in Q3FY17 was led by robust growth of our Biologics business with both insulins and biosimilar MABs gaining traction in Japan and key emerging markets. The commercialization of our Malaysian facility was a key milestone this quarter. Other major milestones this quarter were the acceptance of our first Biologics License Application (BLA) for the proposed biosimilar Trastuzumab by US FDA, and Marketing Authorization Application (MAA) for Insulin Glargine by EMA. These developments have strengthened Biocon's position as a front runner in the arena of biosimilars. Our Small Molecules and Research Services businesses also reported strong growth this quarter."*

### **Highlights of Q3FY17:**

- **Biologics License Application (BLA)** for a proposed biosimilar **Trastuzumab** accepted for review by the **US FDA**; Marks first US regulatory submission through the Mylan/Biocon collaboration.
- **Marketing Authorization Application (MAA)** for **Insulin Glargine** co-developed by Biocon and Mylan **accepted** for review by **European Medicines Agency (EMA)**
- **The prestigious Journal of the American Medical Association (JAMA)** **published** the clinical study results of biosimilar **Trastuzumab** after a rigorous peer review process.
- Biocon's Insulins facility in Malaysia commenced commercial operations with 'Made in Malaysia' product introduced in Malaysia.
- A **three year contract** for supplying **rh-Insulin cartridges** and re-usable insulin **pens** awarded to Biocon SDN. BHD. by Ministry of Health (MoH) Malaysia.
- Biocon ranked among the **world's Top Ten Best Employers** in Biotechnology by *Science* magazine; The only Asian company to feature in 2016 list.

- Biocon's novel **diabetes education initiative** for medical practitioners, **ABIDE**, conferred with the '**Award of Recognition**' by the prestigious **Research Society for the Study of Diabetes in India**.
- Biocon debuts on the prestigious **Asia IP Elite 2016** list; **Only pharmaceutical** company from India to be recognized for **IP-led value creation** by IP Business Congress Asia.

## FINANCIAL HIGHLIGHTS: Q3 FY17

As per IND-AS

In Rs Crore, except growth numbers

Particulars	Q3FY17	Q3FY16	Growth (%)
<b>INCOME</b>			
<b>Small Molecules</b>	<b>390</b>	315	<b>24</b>
<b>Biologics</b>	<b>120</b>	75	<b>61</b>
<b>Branded Formulations</b>	<b>123</b>	104	<b>18</b>
Licensing	<b>79</b>	32	148
<b>Syngene: Research Services</b>	<b>317</b>	270	<b>17</b>
<b>Total Sales</b>	<b>1029</b>	796	29
Other Income	<b>63</b>	33	88
<b>TOTAL REVENUE</b>	<b>1092</b>	829	<b>32</b>
<b>EBITDA</b>	<b>324</b>	206	<b>57</b>
<b>PBT</b>	<b>245</b>	143	<b>71</b>
<b>Net Profit</b>	<b>171</b>	104	<b>65</b>
<b>R&amp;D Expenses in P&amp;L</b>	<b>85</b>	68	<b>25</b>
<b>Gross R&amp;D Spends</b>	<b>100</b>	91	10
<b>EBITDA Margin</b>	<b>30%</b>	25%	
<b>Net Profit Margin</b>	<b>16%</b>	13%	

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

For financials in IGAAP kindly refer to the fact sheet

## EXECUTIVE COMMENTARY

### PERFORMANCE REVIEW

Biocon reported a revenue growth of 32% at Rs 1092 Cr in Q3FY17, which was led by a robust growth of 61% in the Biologics business, 24% growth recorded by Small Molecules, 18% by Branded Formulations and 17 % growth by Research Services businesses. Licensing Income stood at Rs 79 Cr and Other Income was Rs 63 Cr.

EBITDA rose 57% to Rs 324 Cr; Net Profit stood at Rs 171 Cr a growth of 65% over last year.

Net R&D spends during the quarter stood at Rs. 85 Cr, an increase of 25% YoY. At a Gross level, R&D spends in Q3FY17 were Rs 100 Cr largely on account of the clinical advancement of several of our programs.

Q3FY17 also saw a strong contribution from our international business wherein we supply both Active Pharmaceutical Ingredients (APIs) and formulations across our Small Molecules and Biosimilars segments.

## SMALL MOLECULES

The Small Molecules business reported strong revenue growth of 24% to Rs 390 Cr, led by good traction in its business in India, Europe, LatAm and NAFTA for statins, immunosuppressants and specialty products. A strong demand for Rosuvastatin API post genericization in the US market as well as the acquisition of new customers for statins and immunosuppressant APIs provided a fillip to the business.

Biocon received Final Approval from the US FDA for generic Rosuvastatin Calcium tablets, the first such approval for our Generic Formulations business in the US.

## BIOLOGICS

The Biologics segment comprising Novels and Biosimilars, including rh-insulin, insulin analogs, monoclonal antibodies and recombinant proteins, reported a strong growth of 61% at Rs 120 Cr. Biocon with its global partner Mylan made good regulatory progress in its biosimilar and insulin analogs global development programs.

### Biosimilars

#### Insulins & Analogs

Our Insulins business recorded a strong growth this quarter led by the expansion of our commercial footprint and increased traction in some of the key emerging markets.

Biocon commenced commercial operations from its Malaysian manufacturing facility with the launch of its rh-Insulin in Malaysia. The Company has been awarded a three-year contract by Ministry of Health (MoH) for supplying rh-Insulin cartridges and re-usable insulin pens for people with diabetes in Malaysia. The contract is extendable for additional two years, subject to government's approval.

Biocon's ready-to-use, prefilled disposable Insulin Glargine pen, launched in Japan in Q2FY17 continues to do well with increase in market share. The product has been introduced in a few more emerging markets this quarter.

During the quarter, the Marketing Authorization Application (MAA) for Insulin Glargine, co-developed by Biocon and Mylan was accepted for review by the European Medicines Agency (EMA). It is a significant development considering it is the first filing in a developed market incorporating a product validated at our state-of-the-art Malaysia facility.

Several other regulatory filings and audits are underway to enable commercial sales from the new Malaysian manufacturing facility.

## Monoclonal Antibodies & Recombinant Proteins

The Biocon-Mylan collaboration to co-develop a broad portfolio of biosimilar products for the global marketplace made good progress and achieved critical milestones in US and Europe in Q3FY17.

The most significant development was the acceptance for review of our Biologics License Application (BLA) for a proposed biosimilar Trastuzumab by the US FDA. This is Mylan and Biocon's first U.S. regulatory submission through the 351(k) pathway and the acceptance of the BLA positions the two companies among the first to be able to address the critical need of US patients for a high-quality biosimilar to treat certain HER2-positive breast cancers.

Earlier in the quarter, the *Journal of the American Medical Association (JAMA)* had published data from Biocon and Mylan's safety and efficacy study that demonstrated equivalent overall response rate for their proposed biosimilar Trastuzumab in comparison to branded Trastuzumab. The results indicate that a biosimilar can deliver similar safety, efficacy and immunogenicity in comparison to a branded product.

Biocon also entered into a strategic agreement for Trastuzumab in one of the leading emerging markets.

### Novel Biologics

Our Novel programs, Itolizumab (anti-CD6 monoclonal antibody) and QPI 1007 (SiRNA), are progressing actively in the ongoing clinical trials. The clinical study using a sub-cutaneous form of Itolizumab, currently on in Australia has completed stage-1 dose escalation and stage-2 is being initiated. No severe adverse safety events have been reported. QPI 1007, undergoing a global phase III trial in NIAON patients, a rare ophthalmic disease, is recruiting actively in several regions including India.

We have finalized the clinical plan to progress Insulin Tregopil and will file a Clinical Trial Application (CTA) with the Indian regulator to clinically validate its promise as an orally delivered, rapid acting prandial insulin.

New preclinical data on the novel immunotherapy product, Fmab2, was presented at the Society for Immunotherapy meeting in Washington DC, recently.

## BRANDED FORMULATIONS

The Branded Formulations business which includes sales in India and UAE reported sales of Rs 123 Cr during Q3FY17. The business was impacted by the discontinuance of in-licensed Abraxane®.

The Branded Formulations India business focuses on critical therapies and specialty brands. 16 of our brands are category leaders and feature amongst the Top three.

CANMAb™ our Trastuzumab brand continues to gain traction and features in the Top 10 Oncology brands in India with a market share of 22% (MAT-IPSoS).

Our novel diabetes education initiative for medical practitioners, ABIDE, was conferred with the 'Award of Recognition' by the prestigious Research Society for the Study of Diabetes in India.

Our key brands in UAE continue to gain traction with overall prescription share of the Company recording a 60% growth as per IMS (Apr-Sep 2016).

## RESEARCH SERVICES – SYNGENE

Our Research Services business through Syngene reported revenue growth of 17% to Rs 317 Cr, which was driven by broad-based growth across the Dedicated R&D Centers and Discovery Services verticals.

During the quarter, there was an unfortunate fire at one of the blocks of Syngene that housed some biologics and analytical laboratories. There were no injuries or loss of life due to the fire. Following the incident, Syngene implemented its business continuity plan and all ongoing projects of that block along with the scientific teams were relocated to other parts of the facility to minimize impact on the client projects. The Company's 'Industrial All Risk' policy will help in minimizing financial impact of the incident.

## NEW APPOINTMENT

The Board of Directors of the Company have approved the appointment of Rajiv Balakrishnan as the Company Secretary for Biocon Limited. Rajiv is a Fellow Company Secretary from Institute of Company Secretaries of India and brings with him over 15 years of diverse experience across Secretarial, Legal, Investor Relations and Finance functions. Prior to joining Biocon, he was working as Company Secretary & Additional General Manager – Investor Relations with VA Tech Wabag Limited.

## Enclosed: Fact Sheet – with Financials as per IND-AS and IGAAP

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

## Earnings Call

The company will conduct a call at **9.00 AM IST on Jan 25, 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 +91-22-3938 1081**. 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 **Jan 29, 2017 on +91 22 3065 2322/ 6181 3322 Playback ID: 44711**. Transcript of the conference call will be uploaded on the company website in due course.

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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.*