

Press Release

Biocon Q2 FY17 Revenue Up 21%; EBITDA Up 45%

Revenues at **Rs 992 Crores**; EBITDA at **Rs 277 Crores**;
Net Profit at **Rs 147 Crores**

Bengaluru, Karnataka, India: October 20th, 2016

Biocon Ltd (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, announced today its consolidated financial results for the second quarter ended on September 30th, 2016.

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

“Our performance in Q2 FY17, was led by strong growth across Small Molecules, Biologics and Research Services. Expansion of our biologics footprint in emerging markets and licensing agreements boosted the revenue further. Our ready-to-use Insulin Glargine pen launched in Japan has been well received which augurs well for this business. The acceptance of our proposed biosimilar Trastuzumab filing for review by EMA was a critical milestone this quarter. This is our second filing in EU. The tentative USFDA approval for Rosuvastatin calcium tablets heralds our entry into the US generics market.”

She added: “Our long term investments in R&D, manufacturing facility in Malaysia and clinical advancement of our programs will enable us to unlock greater value, going forward.”

Highlights of Q2 FY17:

- European Medicines Agency (EMA) accepted for review Marketing Authorization Application (MAA) for proposed biosimilar Trastuzumab co-developed by Biocon and Mylan; first MAA for Trastuzumab biosimilar to be submitted in the regulated markets.
- Generic Rosuvastatin Calcium tablets received Tentative Approval from US FDA; first for Biocon’s Generic Formulations business.
- Glargine pen launched in Japan has been well received, prescriptions beginning to gain traction.
- Expanded footprint of our Biologics business in emerging markets through licensing arrangements.

- Suresh Subramanian has been appointed as Senior Vice President & Head of Branded Formulations- India, business.
- Biocon facilities in India, successfully completed regulatory audits by some international agencies like US FDA and MCC South Africa.
- Kiran Mazumdar-Shaw conferred 'Knight of the Legion of Honour' by France for her constant contribution and dedication to the Biosciences and Research field globally.
- Biocon was recognized as the 'Biotechnology Company of the Year' at Frost & Sullivan India Best Practices Award 2016, for innovation and achievements across the healthcare spectrum.
- Biocon Foundation named among the winners of the CSR Impact Awards 2016 for 'Primary Healthcare – eLAJ clinics' project.

FINANCIAL HIGHLIGHTS: Q2 FY17

As per IND-AS

In Rs Crore, except growth numbers

Particulars	Q2 FY17	Q2 FY16	Growth (%)
Income			
Small Molecules	389	338	15
Biologics	96	76	26
Branded Formulations	137	120	15
Licensing	32	2	1950
Syngene: Research Services	286	250	14
Total Sales	940	786	20
Other Income	52	33	56
TOTAL REVENUE	992	819	21
EBITDA	277	192	45
PBT Before Exceptional Item	207	138	50
PBT	207	30	596
Net Profit including Exceptional Item	147	(11)	N.A.
Net Profit excluding Exceptional Item	147	97	52
R&D Expenses in P&L	65	57	14
Gross R&D Spends	113	91	
EBITDA Margin	28%	23%	
Net Profit Margin*	15%	12%	

*Net Profit margin after excluding for exceptional items in Q2 FY16

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 robust performance with a revenue growth of 21% at Rs 992 Cr led by a strong growth of Small Molecules, Biologics and Syngene. Licensing Income this quarter stood at Rs 32 Cr while Other Income reported was Rs 52 Cr.

EBITDA rose 45% to Rs 277 Cr; Net Profit stood at Rs 147 Cr a growth of 52% over last year (after excluding impact of exceptional items due to INDAS adjustment to Q2FY16 numbers)

Net R&D spends during the quarter stood at Rs. 65 Cr, an increase of 14% YOY. At a Gross level, R&D spends in Q2 were Rs 113 Cr.

SMALL MOLECULES

The **Small Molecules** business delivered revenue of Rs 389 Cr, a robust growth of 15% led by a better product-mix of differentiated APIs and a higher contribution from statins. Sales in emerging markets of AFMET, LATAM as well as sales to India based customers servicing the needs of the US market made a significant contribution to the improved performance of this business.

Our **Generic Formulations** business marked a key milestone in the second quarter following the receipt of a Tentative Approval from the US FDA for generic Rosuvastatin Calcium tablets, which is a first for Biocon. Commercial launch preparations for Rosuvastatin Calcium in US are underway.

BIOLOGICS

The **Biologics** vertical comprising Novel Biologics and Biosimilars, including rh-insulin, insulin analogs, monoclonal antibodies and recombinant proteins, reported a strong growth of 26% at Rs 96 Cr on account of good performance in key emerging markets.

We made significant progress with Trastuzumab sales and licensing in some of the key emerging markets of AFMET and LATAM, which augurs well for this business.

Biocon is among the first wave of biosimilars players, and is well positioned to leverage the global biosimilars opportunity along with its partner Mylan. Our portfolio of follow-on biologics continues to make good clinical progress.

Biosimilars

Monoclonal Antibodies & Recombinant Proteins

The **Biocon-Mylan** global partnership for Generic Insulins and Biosimilars is progressing well with products on track for filing during FY17. During Q2 FY17, the Marketing Authorization Application (MAA) for a proposed biosimilar Trastuzumab for treating certain HER2-positive breast and gastric cancers was accepted by the European Medicines Agency (EMA) for review.

This is the second biosimilar submission developed by the partnership that has been accepted for review in Europe. Earlier in FY17, Mylan's MAA for the proposed biosimilar Pegfilgrastim was also accepted for review by EMA.

The results of two pivotal Pegfilgrastim studies were presented at the prestigious European Society of Medical Oncology (ESMO) Annual Congress at Copenhagen, Denmark. The findings of these studies have confirmed the comparability of the efficacy, safety and immunogenicity profiles of Pegfilgrastim versus the reference product.

Also, in continuation to the Trastuzumab biosimilar Phase III data (from the HERITAGE study) presented at the annual meeting of the American Society of Clinical Oncology (ASCO) earlier this year, 48-week data from the same study was presented at ESMO. These data confirmed the clinical similarity of Trastuzumab and the reference product at 48 weeks.

The encouraging clinical advancement of our programs puts us on track for regulatory filings for some of these molecules in the developed markets in FY17.

Insulins & Analogs

Biocon's ready-to-use, prefilled disposable Insulin Glargine pen launched in Japan by our partner FUJIFILM Pharma (FFP) earlier this quarter, has been well received and is likely to make significant inroads in this stringent market. This augurs well for our filings in some of the other developed markets.

Regulatory filings are underway to enable commercial sales from the new Malaysian facility, to some of the emerging markets.

Novel Biologics

The clinical development of our two novel assets – Insulin Tregopil and the first-in-class anti-CD6 antibody, Itolizumab – is on track. We have finalized the clinical study design for a non-inferiority Phase II/III study of Insulin Tregopil. For Itolizumab, the Phase I trial is in progress and in addition, we have initiated a psoriasis biomarker study in India.

Two scientific papers on the use of ALZUMAB™ (Itolizumab) in psoriasis have been accepted for publication in international journals: the *Dermatology and Research Practise* and *Journal of Clinical and Diagnostic Research*.

BRANDED FORMULATIONS

The **Branded Formulations** business includes our finished dosages business in India and overseas including UAE. Q2 FY17 sales at Rs 137 Cr reported a growth of 15 %.

Business was impacted as some of our key products were brought under drug price control in India. Most of our key brands continue to garner growth in terms of prescriber- base and prescriptions.

Our Oncology franchise comprising several specialty products like BIOMAb EGFR®, CANMAb™, EVERTOR™, Genxtor™, Nufil SF™ etc. continues to benefit several thousand patients. However, we will no longer be offering Abraxane®, an in-licensed product, for sale due to a decision taken by the licensor to discontinue supplies.

New Appointment:

Mr Suresh Subramanian has been appointed as Senior Vice President and Head of the Company's Branded Formulations (India) business. He has over 30 years of experience in the pharmaceuticals market and a proven track record of delivering robust business growth. Suresh has worked with several multinational companies including GSK, Novartis, AstraZeneca and Pfizer. He has deep expertise in diverse therapy areas including Oncology, Cardiology and Critical Care.

RESEARCH SERVICES – SYNGENE

Our Research Services business through Syngene reported a strong revenue growth of 14% to Rs 286 Cr. During the quarter, Syngene acquired the bioinformatics platforms of Strand Life Sciences to complement its existing integrated service platforms and also meet its customers' growing needs for bioinformatics and data analytic support. Syngene also commissioned a new state-of-the-art dedicated R&D center for Amgen, which will be staffed by a team of more than 100 highly qualified Syngene scientists working in close association with Amgen researchers around the world on the discovery and development of innovative medicines. This is Syngene's fourth dedicated R&D Centre, it already operates exclusive R&D centers for Bristol-Myers Squibb, Abbott Nutrition and Baxter Inc.

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 100 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

Earnings Call

The company will conduct a call at **9.00 AM IST on Oct 21, 2016** 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/ 6746 5891**. 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 **Oct 29, 2016 on +91 22 6181 3322/ 3065 2322, Playback ID: 44711**. Transcript of the conference call will be uploaded on the company website in due course.

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