



Biocon's Earnings Surge in Q1 FY16

Revenue up by 15% at Rs. 857 Crore, Net Profit up by 23% at Rs. 126 Crore

Bengaluru, India: July 23, 2015

Biocon Ltd (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, announced today that it has delivered a strong consolidated financial performance for Q1 FY16.

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

"The strong performance this quarter reflects the overall growth of our business backed by a combination of product sales and monetization of R&D assets through licensing. Our Biosimilars strategy is playing out well with five programs in phase 3 clinical development. During the quarter we successfully licensed biosimilar Trastuzumab in key emerging markets. Our Insulins business was boosted with the launch of insulin Glargine in Mexico and Colombia. Our focus on key brands in Branded Formulations has begun to translate into a better quality of earnings."

Highlights:

- Dr Narendra Chirmule, appointed as Head of Biocon's R&D.
- Two new biosimilar molecules, Pegfilgrastim (PEG-G-CSF) and Adalimumab have entered Global Phase 3 clinical trials, taking the tally to five partnered programs in Phase III clinical development, others being; Trastuzumab, insulin Glargine and Bevacizumab.
- The Insulins Drug Products facility in Malaysia successfully completed a cGMP audit by Malaysia's National Pharmaceutical Control Bureau (NPCB).
- INSUPen® and INSUPen® EZ received GDPMD (Good Distribution Practice for Medical Device) Certification in Malaysia.

Financial Highlights: Q1 FY16

In Rs Crore, except growth numbers

	Q1 FY16	Q1 FY15	Growth (%)
Revenue	857	742	15
EBITDA	236	191	24
Net Profit	126	103	23
R&D Expenses in P&L	50	31	60
Total R&D Spends	93	63	47
EBITDA Margin	28	26	N/A
Net Profit Margin	15	14	N/A



Business Performance

Biopharmaceuticals

The Biopharmaceuticals segment benefitted from a strong contribution from our Insulins and Biosimilars business in the emerging markets.

Our partner, Denmark headquartered Veloxis, received USFDA approval for its proprietary Envarus XR formulation (tacrolimus extended release tablets) for prophylactic use in kidney transplant patients.

We have established a new entity Biocon Pharma Ltd, to support our finished dosage generics business. We see this as an important future growth driver.

Two licensing deals were signed in key emerging markets for Trastuzumab. Significant inroads were made in Mexico and Colombia with the launch of insulin Glargine.

We received GDPMD (Good Distribution Practice for Medical Device) Certification for INSUPen® and INSUPen® EZ in Malaysia this quarter.

Our Insulins drug product facility in Malaysia, underwent a cGMP audit by the National Pharmaceutical Control Bureau (NPCB), Malaysia. We expect to receive the formal certification in a few weeks. This will be followed by the initiation of the validation batches for the drug product.

Biocon's partnered programs in generic insulin analogs and biosimilars, continue to advance in the clinic. While the global phase III clinical trials for Trastuzumab and Pegfilgrastim are progressing towards completion, the patient recruitment for the global phase III trials of insulin Glargine for both type 1 and type 2 diabetes studies have been completed this quarter.

Branded Formulations

Our strategy of optimizing our product offering with a focus on key brands has begun to bear fruit as reflected in the 14% sequential growth (QoQ) with sales of Rs. 112 Crore in Q1FY16. This performance was led by the Metabolics, Nephrology and Market Access divisions.

We continue to grow well in the addressable Insulins market, with a growth of 20%, against the market growth of 14% (Source: IMS, TSA May MAT 2015). CANMAb™, our affordable biosimilar Trastuzumab continues to gain traction as a life-saving therapy for HER2-positive metastatic breast cancer patients.



Novel Molecules

A scientific paper titled '*Long-term Efficacy and Safety of Itolizumab in Patients with Moderate-to-Severe Chronic Plaque Psoriasis,*' authored by Dr Sunil Dogra, Additional Professor from PGI Chandigarh with other Key Opinion Leaders in Dermatology and Biocon's R&D team, has been published in the prestigious Journal of American Academy of Dermatology, which profiles the unique attributes of our novel anti-CD6 monoclonal antibody leading to positive patient outcomes.

Appointments:

Dr Narendra Chirmule, has been appointed as the Head of R&D at Biocon. He has taken over from Dr Abhijit Barve, who has moved back to the US for personal reasons. Dr Chirmule held senior leadership positions at Amgen and Merck, in the US, in the departments of Clinical Immunology overseeing drug development for regulated markets. He has deep expertise in the area of immunogenicity in biologics and has been involved in shaping the regulatory guidelines for biologics and biosimilars in EU & US. He holds a Ph.D. from Cancer Research Institute, University of Mumbai, with post-doctoral training at Cornell University Medical College, and has teaching and research experience as an Assistant Professor in the Human Gene Therapy Group of University of Pennsylvania.

-Ends-

[Encl.: Fact Sheet - Consolidated Income Statement and Balance Sheet \(Indian GAAP\)](#)

[Earnings Call](#)

The company will conduct an hour long call at **9:00 AM IST on July 24, 2015** 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 till **July 31, 2015** on **+91 22 6181 3322/ 3065 2322, Playback ID: 44711#**. We will aim to post the transcript of the conference call on the company website within seven working days of the investor conference call.

[About Biocon Limited](#)

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 85 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), CANMAb™ (Trastuzumab), BIOMAb-EGFR™ (Nimotuzumab) 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 including a high potential oral insulin. Visit: www.biocon.com



Disclaimer:

Certain statements in this release concerning our future growth prospects are forward-looking statements, which are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those contemplated in such forward-looking statements. Important factors that could cause actual results to differ materially from our expectations include, amongst others general economic and business conditions in India, 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 biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither our company, our directors, nor any of our affiliates, have any obligation to update or otherwise revise any statements reflecting circumstances arising after this date or to reflect the occurrence of underlying events, even if the underlying assumptions do not come to fruition.

Disclaimer:

Syngene International Limited is proposing, subject to receipt of requisite approvals, market conditions and other considerations, to make an initial public offering of its Equity Shares and has filed a Red Herring Prospectus with the Registrar of Companies, Bangalore. The Red Herring Prospectus is available on the website of SEBI and the websites of Axis Capital Limited, Credit Suisse Securities (India) Private Limited and Jefferies India Private Limited. Investors should note that investment in Equity Shares involves a high degree of risk and for details should refer to the Red Herring Prospectus which has been filed with the Registrar of Companies, Bangalore, including the section titled "Risk Factors".

This communication is not an offer of the Equity Shares for sale in the United States. Any public offering of the Equity Shares to be made in the United States will be made by means of a prospectus that may be obtained from the Company or the selling shareholder and that will contain detailed information about the company and management, as well as financial statements.

The Equity Shares have not been, and will not be, registered under the Securities Act or any other applicable law of the United States and, unless so registered, and may not be offered or sold within the United States, except pursuant to an exemption from, or in a transaction not subject to, the registration requirements of the Securities Act and applicable state securities laws. Accordingly, the Equity Shares are only being offered and sold (i) within the United States only to persons reasonably believed to be "qualified institutional buyers" (as defined in Rule 144A under the Securities Act and referred to in the Red Herring Prospectus as "U.S. QIBs", for the avoidance of doubt, the term U.S. QIBs does not refer to a category of institutional investor defined under applicable Indian regulations and referred to in the Red Herring Prospectus as "QIBs") in transactions exempt from, or not subject to, the registration requirements of the Securities Act, and (ii) outside the United States in reliance on Regulation S under the Securities Act."

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