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Biocon's earnings surge in Q1 FY16

July 24, 2015 | News | By BioSpectrum Bureau

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Biocon announced 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:

Ã?Æ?Ã?Å? Dr Narendra Chirmule, appointed as Head of Biocon's R&D.

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Ã?Æ?Ã?Å? 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.

Ã?Æ?Ã?Å? The Insulins Drug Products facility in Malaysia successfully completed a cGMP audit by Malaysia's National Pharmaceutical Control Bureau (NPCB).

Ã?Æ?Ã?Å? 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

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

Net Profit Margin Ã?Â Ã?Â Ã?Â Ã?Â Ã?Â Ã?Â Ã?Â Ã?Â Ã?Â Ã?Â 15 Ã?Â Ã?Â Ã?Â Ã?Â 14 Ã?Â Ã?Â Ã?Â N/A

Business Performance

Biopharmaceuticals

The Biopharmaceuticals segment benefitted from a strong contribution from its 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, the company said.

"We have established a new entity Biocon Pharma, 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," Biocon said in a statement.

Dr Kiran added, "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

Biocon's strategy of optimizing its 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%.

CANMAb, our affordable biosimilar Trastuzumab continues to gain traction as a life-saving therapy for HER2-positive metastatic breast cancer patients," Biocon stated.

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 holds a PhD 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.