

## Biocon delivers 16% growth led by Research Services & Branded Formulations

# 9MFY14 Performance: Revenues at Rs. 2,187 Crores; EBITDA at Rs. 550 Crores; PAT at Rs. 301 Crores

Bengaluru, India: January 22, 2014

Commenting on the quarterly performance and highlights, Chairman and Managing Director, Kiran Mazumdar-Shaw stated, "Q3 FY14 has been a very eventful quarter for us, with several research milestones across our novel molecules and biosimilars portfolio. The key highlight was the DCGI approval for our biosimilar Trastuzumab, which paved the way for its commercial launch in India as CANMAb $^{\text{TM}}$ . CANMAb $^{\text{TM}}$  is not only the world's first biosimilar Trastuzumab, but is also the most affordable worldwide. We have also strengthened our R&D pipeline with 2 new alliances giving us access to novel technology platforms.

The performance of the Biopharmaceuticals segment has been steady as we continue our efforts to optimise the product basket. We have witnessed sustained business momentum in Research Services, and a return to growth for our Branded Formulations vertical. Our investment efforts in Malaysia continue and we are on track to commission our insulin facility in FY15. We expect to close this financial year with a strong performance across business verticals."

# Highlights:

- > Revenue growth in 9M FY14 reflects the strength of our differentiated portfolios
  - ❖ Biopharmaceuticals segment: 14% YoY
  - Research Services segment: 35% YoY
- ➤ 9MFY14 Group EBITDA and PAT margins at 25% and 14% respectively
- ➤ R&D investments for 9MFY14: 102 Crores (6% of Biopharmaceutical segment sales)
- ➤ Announced the launch of CANMAb<sup>™</sup>, world's first biosimilar Trastuzumab, in India
- Strategic partnerships with:
  - Quark Pharmaceuticals to develop siRNA based novel therapeutics
  - o Advaxis Inc. for a novel cancer immunotherapy
- Ranked at No 6. in the 'Global Top 20 Employers' list for Bio pharma sector by the Science Magazine, 2013



# **Quarterly Business Performance**

Financial Highlights: Q3 FY14 (In Rs. Crores)

Revenue : 719

**R&D Expenses: 20** (4% of Biopharmaceutical segment sales)

**EBITDA: 187** (*EBITDA Margin: 26%*)

**PAT: 105** (*PAT Margin: 15%*)

## Revenue Breakup:

Biopharmaceuticals: 517

• Research Services: 183

Other Income: 19

## **Biopharmaceuticals**

The Biopharmaceuticals segment delivered a growth of 9% YoY at Constant Exchange Rate (CER) during 9M FY14. For Q3 FY14, at CER, the segment performance declined 2% YoY.

#### **Small Molecules**

As indicated earlier, the small molecules portfolio is currently being optimized to balance margin accretion with growth platforms. We have seen good momentum in Immunosuppressants and Orlistat, while the changing product mix for statins have helped balance out the headwinds in the industry.

#### **Biosimilars**

Our biosimilar Insulins portfolio continues to deliver strong growth. Our generic rh-Insulin is now approved in over 50 countries. Along with our partner Mylan, we continue with the groundwork to initiate a global Phase III trial for our generic Insulin Glargine.

We have announced the launch of CANMAb™, our biosimilar Trastuzumab in India. Our product is the first biosimilar Trastuzumab to be commercialized anywhere in the world; and comes with robust data from a 2 year long Phase III biosimilarity trial conducted in India on over 130 patients. Keeping the emerging market needs in perspective, we have launched the drug in two strengths (150 mg and 440 mg). The 150 mg presentation will help eliminate drug wastage and enable additional savings for patients, when used in conjunction with the standard 440 mg vial. CANMAb™ will be sold in India through Biocon's Oncotherapeutics division under the Branded Formulations vertical and will be available to patients in early February 2014.

#### **Branded Formulations**

The Branded Formulations vertical grew at 15% YoY in Q3 FY14, vis-à-vis the industry growth of 5% YoY, closing the period with 99 Crs in sales. The impasse between the trade and the pharma companies has largely been resolved, and we have seen growth return to the market driven by chronic therapies.

The growth for this quarter has been led by our flagship brands of Basalog® Insupen®, BioMab EGFR® and Abraxane®. In addition, we have seen very enthusiastic uptake of Cytosorb®, a novel therapy in sepsis management that we had launched last quarter.



We have signed a licensing and co-development agreement with Advaxis Inc. for ADXS-HPV, a novel cancer immunotherapy to treat Human Papilloma Virus (HPV)-associated cervical cancer in India and key emerging markets.

#### **Novel Molecules**

We commenced global trials for our oral insulin (IN 105) program in the US. Our partnership with BMS on this asset continues, in line with their decision to retain this asset.

We entered into a strategic collaboration with Quark Pharmaceuticals this quarter, to develop a range of siRNA based novel therapeutics. This co-development alliance will leverage Quark's proprietary technology platform to target various unmet medical needs. The lead candidate in this program is QPI-1007, a novel siRNA drug candidate for ophthalmic conditions.

### **Research Services**

The Research Services segment grew 22% YoY and 15% YoY at Constant Exchange Rate (CER) for 9M FY14 and Q3 FY14 respectively, with widespread growth across our service platforms.

Commenting on this performance, Peter Bains, Director Syngene International, said, "We are pleased with the strong growth delivered by Research Services through 9MFY14. This reflects sustained business momentum and an increasing penetration of our integrated service offerings. As pharma and biopharma continue to evolve their R&D models, we see a sustained emphasis on collaborative externalization. In addition, there is increasing interest from allied sectors such as nutrition, consumer & animal health and agrichemicals to create partnerships between our research and development capabilities and their product pipelines. I am also pleased to report that Syngene has successfully cleared its first USFDA audit of its quality systems, with no observations or 483s. The audit was triggered by an application from one of our existing clients, and gives further credence to the world class quality systems, underpinning our service platforms."

## **Outlook**

The outlook for FY14 remains positive while we strive to balance our revenue growth and R&D spend. Our portfolio and cost optimization initiatives continue, helping us manage our margins more effectively. We continue to invest in our R&D pipeline, and the several milestones achieved over the course of this year are indicative of the growth opportunities ahead of us. Our Malaysia facility is on track for commissioning in FY15.

#### **About Biocon**

Established in 1978, Biocon Limited, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is India's largest and Asia's leading biotechnology company with a strategic focus on biopharmaceuticals and research services. It is a fully integrated, innovation-driven biopharma enterprise offering affordable solutions for chronic diseases to patient's worldwide. Biocon's robust product portfolio includes the world's first Pichia-based recombinant human Insulin (INSUGEN®), Glargine (BASALOG®), as well as MAbs like BioMAb-EGFR® for head & neck cancer and Alzumab™ for Psoriasis. It has now successfully developed the world's first biosimilar



Trastuzumab, being introduced as CANMAb™ for HER2 positive breast cancer in India, in 2014. 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.

## **Earnings Call**

The company will conduct an hour long call at 3:30 PM IST on January 23, 2014 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 five to ten minutes ahead of the scheduled start time. The dial-in number for this call is +91-22-6629 5889/ 3065 2542. Other toll numbers are listed in the conference call invite which is posted on the company website <a href="https://www.biocon.com">www.biocon.com</a>. The operator will provide instructions on asking questions before the start of the call. To receive reminders for the earnings call, you can register <a href="here">here</a>. A replay of this call will also be available from January 23, 2014 – January 31, 2014 on +91 22 3065 1212, Playback ID: 311121. The transcript of the conference call will be posted on the company website within 7 working days of the investor conference call. <a href="https://encloses.com/Encloses-the-consolidated Income Statement and Balance Sheet">within GAAP</a>)

# **Contact Information:**

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