

For Immediate Release

Bangalore, India January 24, 2012

# Biocon's nine-month revenues driven by growth in Branded Formulations, Emerging Markets and Research Services

## Revenues at Rs 1,511 Crores; EBITDA at Rs 425 Crores; PAT at Rs 241 Crores

Commenting on the results, Chairman and Managing Director Kiran Mazumdar-Shaw stated, "Our performance in the first 3 quarters of FY12 has been good on the manufacturing & services fronts where profits were up nearly 29% (excluding licensing income). Licensing income, however, was sharply down from the exceptional levels recorded last fiscal which resulted in flat earnings overall. As I have frequently stated, licensing income is a timing issue and subject to periodic variability. We have seen exceptional growth in our Research Services business, an outcome of the strategic investments we have made in enhancing our integrated service offerings. Moving up the value chain is integral to our growth strategy which is reflected in the strong growth delivered by our Branded Formulations vertical. Our focus on Emerging Markets is also enabling us to realize a greater potential for our APIs and Insulins portfolios. Our R&D pipeline is advancing satisfactorily with 2 late-stage candidates and several early stage programs with enormous value creation potential through licensing. We have shaped our broad-based business into key growth verticals, which we believe will enable us to deliver sustainable, long-term value to our shareholders."

# Highlights:

- ☑ 9 months FY12 Financials reflect a robust performance by :
  - Branded Formulations vertical which grew by 40% YoY.
  - ➤ Emerging Markets which now contribute ~50% of Biocon's revenues.
  - Research services: 28% YoY growth in revenues, reflecting the growing traction in our integrated offering for accelerating innovation for our global customers.
- Announced Positive Efficacy Data on Novel Monoclonal Antibody, Itolizumab in Pivotal Phase 3 Psoriasis Study in India.
- Successful launch of INSUPen®, an innovative delivery device for Insulin and analogs enabling us to comprehensively expand the market through vials and cartridges.
- ☑ EBITDA and PAT margins at 28% and 16% respectively.

# Biocon Group (consolidated; excluding Axicorp)

(Rs Crores)	3 Months Ended December 31,2011	Nine Months Ended December 31,2011
Revenues	532	1,511
EBITDA	142	425
PAT	85	241
EBITDA Margin (%)	27%	28%
Earnings Per Share (Rs)	4.2	12.0
Head Count	6,000+ employees	

## **Business Performance and Outlook (Vertical-wise)**

## **Small Molecules & Biosimilars**

A comprehensive portfolio of over 100 products spread across 70 nations has helped the Biopharma business (excluding licensing income) post 11% YoY increase in revenues in the first nine months of this fiscal. The growth in the third quarter was driven by robust performances in Immunosuppressants and the branded formulations segments.

Immunosuppressants have grown over 40% in Q3FY12 vs. Q3FY11 on the back of strong Tacrolimus and MMF sales.

Statins have remained buoyant with improved margin realization.

Biocon's Fidaxomicin commercialization partner, Optimer, has received marketing approval for DIFICLIR™ tablets in the European Union in December 2011. In its press release, Optimer has indicated plans to launch in EU by the fourth quarter of FY12 with their marketing partner Astellas Pharma. Biocon is the sole supplier of the drug substance for the global markets. Fidaxomicin is used for the treatment of adults with CDI (*Clostridium difficile* Infections) and CDAD (*Clostridium difficile*-associated diarrhea).

Dr. Arun Chandavarkar, Chief Operating Officer, Biocon Ltd, said: "We believe that our strategy of investing in technology platforms to create a differentiated API portfolio has begun to yield results as seen by the ramp up in immunosuppressant sales. Whilst we continue to expand our portfolio of APIs, we will explore select opportunities to add value through developing formulations to support our domestic branded formulations business as well as exports."

#### **Branded Formulations**

The Indian pharmaceutical market is expected to grow at a CAGR of 15% over the next 10 years and quadruple to a size of \$55 billion by 2020 from a 2010 market size of \$12.6 billion (IMS). The chronic therapy segment, that represents only 25% of the market, is outpacing the acute segment growth by 5 percentage points. Biocon is present in the chronic segment with over 70 brands spread across six verticals namely, Diabetology, Oncotherapeutics, Nephrology, Cardiology, Immunotherapy and Comprehensive Care. Outpacing the market, this vertical has posted a combined YoY growth of 40% for the 9MFY12.

➤ <u>Diabetology</u> – Biocon ranks #3 in the 40 IU insulin space, with a growth rate of 43% that outpaces the market growth of 17% (ORG IMS Nov 2011 MAT). This growth has come on the

back of our presence in the vials segment. INSUPen®, our foray into insulin delivery devices in November'11, will enable us to compete effectively in the cartridges segment thereby revving up growth. INSUPen® has garnered strong support from doctors and patients alike. It has also received accolades for its high quality and ease of use features, unique packaging of insulin Refills and a comprehensive IT- based patient-care model that also offers on-call and on-field support through 120 diabetes care advisors.

The existing product portfolio's growth as of ORG IMS MAT November 2011 was led by Basalog®, the largest brand in the Glargine vials market.

Insugen® 100 IU, a FY 10-11 launch, has made steady in-roads into the 100 IU insulin market and has garnered 8% of market share in the first year of its launch.

- ➤ <u>Comprehensive Care</u> In the third quarter of FY12, the comprehensive care business unit delivered a strong performance driven by Albubet®, Penmer® and Biopiper®. The current portfolio was strengthened with the launch of Suprava®, Cegava® and Albubet Safe®. Within a year of the division's launch, three of its brands now feature among the top 10 brands in their respective categories.
- Nephrology The third quarter of FY12 saw the Nephrology business unit deliver a strong growth driven by commendable performances in both the renal transplant and dialysis portfolios. This quarter was marked by the launch of Tacrograf® 0.25mg, the lowest strength of Tacrolimus to be launched globally for the management of post-transplant recipients on Tacrolimus.
- ➤ Oncotherapeutics Abraxane® completed three years of launch in the last quarter, and is the fastest growing brand in the highly competitive taxane market. In its fifth year since launch, BIOMAb EGFR® continues to be developed via a robust clinical development program in multiple difficult-to-treat-tumors such as glioblastoma multiforme, esophageal cancer, cervical and lung cancer. BIOMAb EGFR® has gained the trust of over 250 Indian oncologists who have extended the benefit of this molecule to over 3500 Indian patients. BIOMAb EGFR® features in the 2011 Top 20 most successful New Drug Launches in India (IMS Market Intelligence).
- ➤ Immunotherapy The division has grown robustly over the last quarter driven by the three flagship brands: TBIS® (Tacrolimus) PICON® (Pimecrolimus) and PSORID® (Cyclosporin). According to ORG IMS Nov 2011 MAT, TBIS® has now moved from 4<sup>th</sup> to the 3<sup>rd</sup> place value-wise over the last quarter. PICON is now ranked 2<sup>nd</sup> in volume terms as per ORG IMS November MAT 2011. The business unit also launched Calpsor® (Calcipotriol) and Calpsor C® (Calcipotriol + steroid) in the last quarter. Both these products have been well received by dermatologists.
- <u>Cardiology</u> The Injectible portfolio has demonstrated strong growth of 55%. STATIX® (Atorvastatin) is now a visible brand in the market.

#### **Research Services**

The research services business has built on the momentum of the first half and delivered a robust 28% growth in top line for 9MFY12 vs. 9MFY11.

<u>Syngene</u> – This quarter saw Syngene tying up with Cellectis Bioresearch, a specialist in genome customization and a subsidiary of Cellectis for the development of novel, genetically customized cell lines by employing Syngene's biology platform.

<u>Clinigene</u> – In December 2011, Clinigene partnered with Pacific Biomarkers Inc. (PBI), a premier biomarker and specialty efficacy testing services provider to the American drug development industry, for addressing specialty biomarker and high-end clinical lab needs of the global pharma and biotech industry.

Commenting on this performance Peter Bains, Director, Syngene International, said, "This has been a very encouraging quarter for Syngene. We are retaining and growing our customer base and we are seeing clear traction against our strategy to broaden our range of discovery and development capabilities to provide a more integrated service capability to support our customers changing R&D models and goals. Growth has been anchored in our small molecule discovery and development services which has been supported by encouraging acceleration in our Biologics, Discovery Biology and Custom manufacturing services".

## **Novel Molecules**

Biocon continues to advance its novel portfolio, including the Anti-CD20 and fusion MAb programs.

Itolizumab: The phase III study for Chronic Plaque Psoriasis (TREAT-PLAQ) was completed in December 2011.Results from the interim, 28-week data analysis have shown promising results, indicating that Itolizumab has successfully met the primary endpoint of significant improvement in PASI-75 (Psoriasis Area and Severity Index) score after 12 weeks of treatment in patients with moderate to severe psoriasis compared to placebo. The results also indicate that multiple secondary endpoints after 12 and 28 weeks of treatment have also been met. In this 28-week interim analysis, the treatment regimens were statistically significantly better than placebo. The molecule also exhibited an excellent safety and tolerability profile with very low rates of infection (~10%) in active treatment arms suggesting a favorable risk benefit profile compared to currently available biologic treatments.

<u>IN-105:</u> We are continuing to engage with global pharmaceutical companies for partnering the novel IN-105 oral insulin program.

Peptide Hybrid: A US IND has been filed by our partner, Amylin, for AC165198.

#### About Biocon

Biocon Limited (**BSE code:** 532523, **NSE Id:** BIOCON, **ISIN Id:** INE376G01013) is India's premier biotechnology company with a strategic focus on biopharmaceuticals and research services. Established in 1978 by Dr. Kiran Mazumdar-Shaw, the Group is an integrated, innovation-driven healthcare enterprise with offerings that traverse the entire drug development value chain. Balancing its novel molecule research pipeline with a diversified product portfolio, Biocon delivers affordable solutions to partners and customers in over 70 countries across the globe. Many of these products have USFDA and EMA acceptance. Stellar products from Biocon's stable include the world's first *Pichia* based

recombinant human Insulin, INSUGEN® and glargine, BASALOG® coupled with a state of the art insulin pen device, INSUPen® and India's first indigenously produced monoclonal antibody BIOMAb-EGFR®. 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 pm IST on January 25, 2012 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 1800 102 1300 (India Toll Free number is accessible through all mobiles and landline services). Other toll numbers are listed in the conference call invite which is posted on the company website <a href="www.biocon.com">www.biocon.com</a>. The operator will provide instructions on asking questions before the start of the call. A replay of this call will also be available from January 25, 2012 – February 1, 2012 on the same dial-in numbers provided above. The transcript of the conference call will be posted on the company website.

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Encl: Fact Sheet - Consolidated Income Statement and Balance Sheet (Indian GAAP)