

# Biocon delivers a strong performance of 18% Revenue Growth in FY13 driven by an evolving Product Portfolio & Research Services

Board recommends a dividend of *Rs* 5/share (100%) and a Special Dividend of *Rs* 2.50/share (50%) following the re-licensing of insulin analogs portfolio

## Revenues at Rs 2,538 Crores; EBITDA at Rs 596 Crores; PAT at Rs 509 Crores

Bengaluru, India: April 25, 2013

Commenting on the results, Chairman and Managing Director, Kiran Mazumdar-Shaw stated, "We are pleased to close fiscal 2013 on a very strong note. The key contributors to growth this fiscal have been Research Services, Branded Formulations and our growing biosimilar business, led by generic Insulins. Biocon's Insulin franchise continues to garner market share across India & emerging markets and now accounts for more than 10% of our sales. This quarter saw us enhance our partnership with Mylan through the re-licensing of our portfolio of generic insulin analogs. The partnership with Mylan endorses the intrinsic value of this asset and significantly reduces our burden of development costs involved in global commercialization. Looking ahead, we intend to sustain our growth momentum by optimizing our small molecules portfolio, further expanding our insulin footprint in emerging markets, and continuing to deliver robust growth in Branded Formulations and Research Services. I am also pleased to state that the Board has recommended a Dividend payout of Rs 5/share (100%) and a Special Dividend of Rs 2.50/share (50%) pursuant to the re-licensing of our insulin analogs portfolio, as our on-going commitment to building incremental shareholder value."

## Highlights:

- Revenue growth in FY13 reflects the growing play in Emerging Markets:
  - Biopharma Business: 10% YoY to Rs 1,523 Crores
  - Branded Formulations: 34% YoY to Rs 347 Crores
  - Research Services (Syngene and Clinigene): 36% YoY to Rs 557 Crores
- > For FY13, the Group EBITDA and PAT margins at 23% and 20% respectively
- Mylan expands the scope of partnership to incorporate generic insulin analogs. Biocon received US\$ 20 million as an upfront, for further development



- > Global Phase III trial for Biosimilar Trastuzumab gains momentum in Europe
- > Dan Bradbury, former CEO of Amylin Pharmaceuticals joins the board of Biocon Ltd

## **Quarterly Business Performance**

#### Financial Highlights: Q4 FY13 (In *Rs* Crores)

Revenue : 649	
R&D Expenses: 43 (11% of biopharma sales)	
EBITDA: 124	(EBITDA Margin-19%)
PAT*: 249 (PAT Margin- 38%)	

Sales Breakup:

- Biopharma: 380
- Research Services: 166
- Branded Formulations: 84

\*includes exceptional items

#### **Biopharma: Small Molecules & Biosimilars**

#### Small Molecules

The small molecules portfolio was driven by strong sales in Fidaxomicin & Immunosuppressants. Our statins portfolio, with its evolving product mix, has remained robust despite industry headwinds. Our ANDA portfolio continues to make progress, and currently has 20+ products under its ambit.

#### Biosimilars

<u>Insulins</u> -The biosimilars vertical continues to be driven by the increasing footprint of our generic rh-Insulin & generic insulin glargine in Emerging Markets. We currently have approval in 40+ countries for generic rh-Insulin and in 5+ countries for generic insulin glargine.

In FY14, we intend to commence clinical and regulatory development for marketing registration of generic rh-Insulin in the US, under the purview of our existing US IND. We intend to take up the development responsibility on our own, in accordance with our discussions with the FDA.

We have planned meetings with the FDA where we propose to discuss the strategy associated with the commencement of the generic Insulin Glargine Phase III clinical trials. We also continue to engage with the EMEA prior to our dossier filing for generic rh-insulin in EU.

A key milestone this quarter was the further strengthening of our generic partnership with Mylan by the addition of 3 generic insulin analogs to the development portfolio. The codevelopment partnership entails sharing of development & capital costs for global commercialization. Mylan will have exclusive commercialization rights in key regulated markets whilst the two partners will have co-exclusive commercialization rights in the other



regions. Through this collaboration, Biocon gains a stable co-development partner with strong marketing capabilities along with a profit share on commercialization.

Kiran Mazumdar-Shaw, Biocon's CMD commented on this development, "Mylan is a natural preferred partner for our portfolio of generic Insulin analogs and this collaboration further strengthens our existing successful partnership. We are excited to team up with Mylan to be able to cost effectively address the disease and economic burden that diabetes poses to global health. We are confident that together we can build a strong global presence in generic Insulin analogs and thereby provide access to affordable therapy options to physicians, healthcare providers and diabetes patients worldwide."

<u>Monoclonal Antibodies (MAbs)</u> - Our global phase III trial for biosimilar trastuzumab has gained further traction with ongoing recruitment and trial approval in major European countries including Germany. We have also completed patient recruitment in a separate Phase III trial for biosimilar trastuzumab being conducted in India.

#### **Novel Molecules**

Our oral insulin candidate, IN-105, continues to make progress. The partnership with Bristol Myers-Squibb has enabled us to better structure the bridging trials to be completed prior to the initiation of Phase II. We intend to commence these trials shortly, in line with the receipt of approval from the regulators.

We continue our work on the novel anti-CD6 molecule Itolizumab, currently authorized for the treatment of chronic plaque psoriasis. Its novel and differentiated mechanism of action holds promise for other autoimmune indications as well. We have completed a pre-IND meeting for Itolizumab with the US FDA, where we have received encouraging feedback. We have initiated the process of tailoring our data package in line with the feedback for the US IND filing.

#### **Branded Formulations**

Our branded formulations business unit recorded an impressive performance in the last quarter delivering to 30% YoY growth. The principal growth drivers have been Oncology, Comprehensive Care, Diabetology and Bioproducts. Specifically our brands Insugen<sup>™</sup>, Basalog<sup>™</sup>, BioMab EGFR<sup>™</sup>, Evertor<sup>™</sup>, Abraxane<sup>®</sup>, IVNEX<sup>®</sup> and Erypro<sup>®</sup> have been the leading contributors. In FY14, we look forward to the successful launch of our brand Alzumab<sup>™</sup>, a novel anti CD6 for the treatment of moderate-to-severe Psoriasis. Alzumab<sup>™</sup> is a differentiated biologic drug with a superior safety profile compared to other approved biologic therapies given its very low infection rates.

Commenting on this performance, Rakesh Bamzai, President- Marketing said, "The robust growth that Biocon has witnessed in Branded Formulations reflects our focus on building brands. Against the industry growth of 12%, we have grown by 34% in FY13. Biocon is committed to invest in its brands and people in India and other emerging markets. This will strengthen the foundation that will sustain these healthy growth rates."



## **Research Services**

The research services businesses have built strongly on the growth momentum from the previous quarters, to deliver a Q4 revenue growth of 41% YoY. For the full year, Syngene and Clinigene have posted combined revenues of Rs 557 Crores, reflecting early traction from the investments we have been making across our multiple platforms. We have also concluded the GE investment of Rs 125 Crores this quarter, with the funds earmarked for capital investments to fuel the next phase of growth.

Commenting on this performance, Peter Bains, Director Syngene International, said, "FY13 has been a milestone year for us with research services' revenues crossing the US\$ 100 million threshold for the first time. Our strategy has been to expand our discovery and development capabilities in small molecules and biologics, enabling us to offer more integrated and value added services to our customers. Our growth reflects a strong mix of retained and expanded clientele as well as the addition of important new customers across all our major platforms. The extensive nature of our scientific platforms has empowered us to diversify beyond biopharma helping us serve leading companies in the nutritional, consumer health, agrichemical, food science and electronics sectors. Today we have ~90 life-sciences customers including 16 of the top 20 pharma companies of the world. The current growth momentum and strong order book, indicates that we are moving in the right direction."

## **Outlook**

The emphasis in FY14 will be on the execution of development plans for the generic biologics portfolio with a firm leash on costs and portfolio margins. We expect our R&D costs to increase in line with the progress being made by our generic biologics and novel molecules. Revenues should keep pace with the increasing R&D investments, as we gain further traction in emerging markets this fiscal. We intend to further optimize our small molecules portfolio to ensure healthy margins. Our Malaysian facility continues to advance and is poised to come on stream by FY15, helping Biocon transform into a leading generic insulin player.

## Induction of a new Board Member

Biocon announced the induction of Daniel M. Bradbury as an additional non-executive board member of Biocon Limited. Dan Bradbury is a Life Sciences Executive with over 30 years of experience in creating and implementing strategies that transform businesses, bring novel medicines to market and maximize shareholder value. He is the Managing Member of BioBrit, LLC, a Life Sciences Consulting and Investment Firm. Dan has spent 18 years at Amylin Pharmaceuticals and was the CEO at Amylin until its acquisition by Bristol Myers Squibb. He received a Bachelor of Pharmacy from Nottingham University and a Diploma in Management Studies from Harrow and Ealing Colleges of Higher Education in the United Kingdom.

## 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 75 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®.

#### **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 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 **03:15 pm IST on April 26, 2013** 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 <u>www.biocon.com</u>. The operator will provide instructions on asking questions before the start of the call. A replay of this call will also be available from **April 26, 2012 – May 3, 2013** on the same dial-in numbers provided above. The transcript of the conference call will be posted on the company website.

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

Investor Relations	
Saurabh Paliwal	Sweta Pachlangiya
+91 95383	+91 96865
80801 <u>saurabh.paliwal@biocon.com</u>	09372 <a href="mailto:sweta.pachlangiya@biocon.com">sweta.pachlangiya@biocon.com</a>
Media	Relations
Media Seema Ahuja	Relations Rumman Ahmed

#### **Contact Information:**