

Press Release

Biocon Q4 FY17 Revenue Rs 974 Cr; Net Profit Rs 127 Cr; FY17 Revenue at Rs 4,079 Cr; Net Profit at Rs 612 Cr

Board of Directors Recommends 2:1 Bonus Shares

Bengaluru, Karnataka, India: April 27, 2017

Biocon Ltd (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, announced today its consolidated financial results for the fourth quarter and full year FY17.

Commenting on the performance, **Chairperson and Managing Director Kiran Mazumdar-Shaw stated**: "We have closed the year FY 17 with a strong revenue growth of 18% led by a sturdy performance of our Biologics as well as Small Molecules businesses. On a full year basis, our EBITDA rose 34%, while Net Profit before exceptional item reported a robust growth of 54 %.

Our revenue growth was muted in Q4 FY 17. Our EBITDA margin at 24 % in Q4 reflects a healthy operational performance. Our Net Profit for Q4 at Rs 135 Cr, represents a growth of 75%, after adjusting for an exceptional item in Q4FY16."

She added: "FY17 was a landmark year wherein we established our credibility as a global biosimilars player with the launch of Biocon's Insulin Glargine pen in Japan and submission of five regulatory filings of our biosimilars in the developed markets of US and EU. Our Malaysia facility became operational with the Malaysian government's exclusive contract for Biocon's insulins, which expanded our footprint in emerging markets. The multiple clinical and regulatory milestones crossed in our biosimilars business augur well for the future."

Highlights of Q4 FY17:

- ➤ Biologics License Application (BLA) for a proposed biosimilar Pegfilgrastim accepted for review by the US FDA; Second Successful BLA filing of the Mylan/Biocon Partnership in the US.
- Marketing Authorization Application for biosimilar Bevacizumab, post completion of RoW-focussed Phase 3 clinical trial in metastatic colorectal cancer, has been submitted for approval in India.
- Regulatory submissions for Insulin Glargine were made in the developed markets of Australia and Canada.
- The Malaysia government's **3-year exclusive offtake agreement** for **rh-insulin cartridges and reusable** pen provided a fillip to this business in Q4FY17.



- ➤ **NeoBiocon** ranked among the **Top 15 pharmaceutical Companies**, in UAE.
- ➤ Biocon has won the **9th National IP Award 2017** and **WIPO Users Trophy** in the category **'Top Indian Company for Creating Global Brand'**.
- > Biocon's board recommends the issue of Bonus shares in the ratio of 2:1.
- **Biocon's** board recommends a **Final Dividend** of **Rs. 3/- per share for** FY17 (pre bonus).
- ➤ **Biocon Foundation** collaborated with the Department of Health & Family Welfare of Karnataka to establish **eLAJ smart clinics** in **15 PHCs across six districts** in the state.
- ➤ Biocon Academy achieved 100% placement for its Batch 8 of the Biocon KGI Program in Biosciences.

FINANCIAL HIGHLIGHTS: Q4 & FY17

As per IND-AS

In Rs Crore, except growth numbers

Particulars	Q4FY17	Q4FY16	Growth	FY17	FY16	Growth
INCOME						
Biocon	653	630	4%	2,738	2,277	20%
Small Molecules	387	395	(2%)	1,587	1,387	14%
Biologics	119	120	0%	458	342	34%
Branded Formulations	131	105	25%	549	440	24%
Licensing Income	16	10	50%	144	108	35%
Syngene: Research Services	272	316	(14%)	1,138	1,060	7%
Total Sales	925	946	(2%)	3,876	3,337	16%
Other Income	49	27	80%	203	123	65%
TOTAL REVENUE	974	973	0%	4079	3460	18%
EBITDA	231	221	5%	1137	847	34%
PBT (Before Exceptional	159	141	13%	850	591	44%
Items)						
Net Profit (Before	135	77	75%	620	403	54%
Exceptional Items)						
Exceptional Item (Net)	(8)	256*		(8)	147*	
Net Profit	127	333	(62%)	612	550	11%
R&D Expenses in P&L	65	99	(35%)	267	274	(3%)
Gross R&D Spends	98	152		402	427	
EBITDA Margin	24%	23%		28%	24%	
Net Profit Margin	13%	34%		15%	16%	

Notes: Figures above are rounded off to the nearest Cr; % based on absolute nos.

For financials in IGAAP kindly refer to the fact sheet

^{*} Exceptional item of **Rs 256 Cr** in Q4FY16 was on account of deferred revenue recognition pertaining to rh-insulin development and associated taxes. Additionally, FY16 Exceptional item includes impairment of an intangible asset of **Rs 109 Cr**



EXECUTIVE COMMENTARY: PERFORMANCE REVIEW:

Q4FY17

Our **Q4 Revenue** at Rs 974 Crore reported a muted growth due to elongated approval timelines in some emerging markets, discontinuance of some in-licensed products and impact of the fire at Syngene. Biocon, excluding Syngene, reported a topline growth of 4%.

EBITDA for Q4 stood at Rs 231 Crore. **EBITDA Margin** at 24% reflects a satisfactory operational performance. **Net Profit before exceptional item** for the quarter at Rs. 135 Cr, reflects a growth of 75% YoY. **Net Profit** for Q4FY17 was Rs 127 Cr. The exceptional income in Q4FY16 was on account of a deferred revenue recognition pertaining to partnering of our rh-insulin development program.

Net R&D spends at Rs. 65 Crore for Q4FY17 stood at 10% of our ex-Syngene sales, reflecting our commitment to our Novels and Biosimilars global development programs. At a **gross** level, **R&D spends** for the quarter were Rs 98 Crore.

Full Year FY 17

We closed **FY17** with a **Revenue** of Rs 4,079 Crore, an increase of 18%, on the back of robust growth in our Biologics as well as our Small Molecules businesses. Our **Research Services** business through Syngene contributed sales of Rs 1,138 Crore, reporting a muted growth of 7% in FY 17. On a **standalone** basis, **Syngene** reported a **revenue** growth of 14% at Rs 1,272 Crore.

Biocon's **EBITDA** at Rs 1,137 Crore reported a robust growth of 34%. **EBITDA margin** improved to 28% from 24% last year. Biocon reported **Net Profit before exceptional item** at Rs 620 Crore, a strong growth of 54% YoY. **Net Profit** for the full year stood at Rs 612 Crore, reporting a growth of 11%. **R&D Spends** in the P&L statement for FY17 were Rs 267 Crore, while **Gross R&D** spends were Rs 402 Crore.

SMALL MOLECULES

The **Small Molecules** business reported sales of Rs 387 Crore in Q4FY17. For the full year, this business recorded sales of Rs 1,587 Crore, reporting a growth of 14%. Our statin APIs and immunosuppressant APIs portfolio continues to do well.

We have entered new markets in **AFMET, LATAM, NAFTA** and **CIS regions** with some of our key statins, immunosuppressants and specialty molecules, which augurs well for this business. However, some of the products continue to face pricing pressure. A few regulatory submissions for key products in some emerging and regulated markets have also been made.



BIOLOGICS

The Biologics segment reported revenue of Rs 119 Crore for Q4FY17, largely driven by sales of Biosimilars, including rh-insulin, insulin glargine and trastuzumab in global markets. For the full year, the Biologics segment reported a strong growth of 34% at Rs 458 Crore.

Biosimilars: Insulins & Analogs

Biocon, which is among the **Top 3 biosimilar players globally**[#] **for Insulins** made further progress this quarter and recorded a strong growth led by increased traction in emerging markets along with expansion of its commercial footprint.

The robust sales of rh-Insulin cartridges and reusable insulin pens to the Ministry of Health (MoH), Malaysia contributed significantly to this growth.

Biocon launched **INSUPen Pro** a customized Insulin re-usable pen developed in partnership with a Swiss based company Ypsomed, in Malaysia this quarter. This further strengthens our portfolio of pen injectors which include **INSUPen**, **INSUPen EZ** and **BasalogOne**.

Regulatory submissions for **Insulin Glargine** were made in the developed markets of **Australia and Canada**, in partnership with Mylan. Filing for this product with the **USFDA** is expected shortly.

Biosimilars: Monoclonal Antibodies & Recombinant Proteins

The **Biocon-Mylan** collaboration to co-develop a broad portfolio of biosimilar products for the global marketplace made good progress in Q4FY17.

USFDA accepted our **Biologics License Application** (BLA) for a proposed biosimilar **Pegfilgrastim**, for review. This is the second BLA accepted by FDA this year, as a part of Mylan and Biocon partnership and builds upon the acceptance of regulatory filings for proposed biosimilar Pegfilgrastim in Europe, Australia, and Canada.

For **Bevacizumab**, our ROW-focussed **Phase 3 clinical trial** in metastatic colorectal cancer is complete and we have submitted our Marketing Authorization Application in India. An additional **global Phase 3** trial in non- small cell lung cancer has commenced. We continue to move towards regulatory submissions for our biosimilar **Adalimumab**.

Our biosimilar **Trastuzumab** has begun to make a difference with better penetration in some of the emerging markets which also boosted the overall growth of Biologics business this quarter and during FY17.

#in terms of volume market share-Units: Source: IMS MAT Sep 2016



Novel Biologics

Our **novel insulin** program made further progress in Q4FY17. A **Clinical Trial Application** (CTA) for **Insulin Tregopil** has been filed with the Indian regulator for a **pivotal Phase III study** to clinically validate its promise as an orally delivered, rapid acting prandial insulin in managing Type 2 diabetes. A multiple ascending dose study in Type 1 diabetes patient population is planned in FY18.

Our other Novel programs, **Itolizumab** (anti-CD6 monoclonal antibody) and **QPI 1007** (SiRNA), are also progressing actively in ongoing clinical trials. The clinical study using a sub-cutaneous form of Itolizumab, currently on in Australia has completed PK and immunogenicity assessment in Stage I and Stage 2 is scheduled to start soon.

BRANDED FORMULATIONS

The Branded Formulations business, which includes sales in India and UAE, reported **Revenue** of Rs 131 Crore, a growth of 25% during Q4FY17. For full year, Branded Formulations sales stood at Rs 549 Crore. Sales were impacted due to price caps on some of the key brands and the discontinuance of Abraxane®, a key in-licensed oncology molecule, in the India and UAE markets.

Biocon's focus on its specialty brands has led to an increase in prescriptions share for both Insugen® and Basalog®. During the quarter, Biocon launched **Parit** (Rabeprazole) and **Parit D** (Rabeprazole D) inlicensed from Japan's Eisai Pharma. These are anti-ulcer products of the class of proton-pump inhibitors and will further strengthen our metabolics portfolio.

RESEARCH SERVICES - SYNGENE

Syngene our **Research Services** business contributed Sales of Rs 272 Crore in Q4FY17 and Rs 1,138 Crore, for the full year reporting a muted growth. However, on a standalone basis Syngene reported a sustained revenue growth of 14% with a healthy growth in **EBITDA** and **PAT** at 24% and 19% respectively, for the full year. The performance was impacted due to temporary disruptions related to the fire in December 2016.

During this quarter, Syngene signed a strategic agreement with a Canadian biotech firm and also collaborated with Herbalife Nutrition to set up a dedicated Nutrition Research and Development Lab at Biocon Park. This is Syngene's fifth dedicated center and second for nutrition research. These strategic partnerships will provide a fillip to Syngene's business going forward.

RECOGNITION FOR STRONG IP CULTURE

Biocon is being recognized both nationally and internationally for consistently creating intellectual wealth through an incisive intellectual property strategy. We have won two awards recently, the 9th National Intellectual Property Award 2017 in the category of 'Top



Indian Company for Creating Global Brand' by the Office of Controller General of Patents, Designs and Trademarks, Dept. of Industrial Policy & Promotion, Govt. of India and 'WIPO Users Trophy' given jointly by the Indian Intellectual Property Office and World Intellectual Property Office, Geneva, Switzerland.

DECLARATION OF BONUS SHARES & FINAL DIVIDEND

The Board of Directors of the Company at the meeting held on April 27, 2017 recommended the issue of **2 bonus shares for every 1 share** held in Biocon.

The Board also recommended a **Final Dividend** of **Rs. 3/- per share** for FY17, (pre bonus).

Enclosed: Fact Sheet – with Financials as per IND-AS and IGAAP

About Biocon Ltd:

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 120 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), BIOMAb-EGFR™ (Nimotuzumab), CANMAb™ (Trastuzumab), Evertor® (Everolimus) 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. Visit: www.biocon.com

Earnings Call

The company will conduct a call at **9.00 AM IST on April 28, 2017** 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 223938 1081**. 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 the conclusion of the call **till May 5, 2017 on +91 22 3065 2322**. **Playback ID: 44711**. Transcript of the conference call will be uploaded on the company website in due course.

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