

Press Release

Biocon Reports a Strong Q1FY17

Revenues at Rs 952 Crore, up by 11 %; EBITDA Up 15% to Rs 271 Crore
Net Profit Up 17% at Rs 147 Crore

Bengaluru, India: July 21, 2016

Biocon Ltd (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, announced today that it has delivered a strong performance in Q1 FY17.

Commenting on the quarterly performance and highlights, **Chairperson and Managing Director, Kiran Mazumdar-Shaw stated:** "Our strong performance this quarter has been driven by an all- round growth of our business across Small Molecules, Biologics, Branded Formulations and Research Services. Our Biologics business delivered a growth of 53% driven by the sales of biosimilars in emerging markets. The submission of Pegfilgrastim, our first biosimilar filing in EU, is a critical milestone this quarter. Our Insulins business made a mark with the launch of Insulin Glargine in Japan. In addition we received regulatory approvals from MoH, Malaysia, for rh-Insulin and Glargine which will enable commercialization of these products. We are on track for filing some of our Biosimilars and Generic Formulations in the developed markets later this year."

Highlights of Q1 FY17:

- The Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for Mylan and Biocon's proposed biosimilar Pegfilgrastim has been accepted for review
- Biocon's Insulin Glargine was launched in Japan through our partner FUJIFILM Pharma
- Rh-Insulin became the first product from the new Malaysian facility to be approved by the Ministry of Health (MoH), Malaysia
- Biocon's Insulin Glargine received approval from Malaysian drug regulator
- Positive data from global confirmatory efficacy and safety study with our Trastuzumab for HER2-positive metastatic breast cancer was presented at the American Society of Clinical Oncology (ASCO) Annual Meeting
- Received approvals for key Small Molecules API DMFs in EU & Emerging Markets
- Initiated the India arm of the global Phase II/III clinical study of QPI-1007, our partnered program for a novel siRNA-based therapy for NAION, a rare eye disease
- Gross R&D spend stood at Rs 92 Cr, reflecting the progress of Generic Formulations, Biosimilars and Novel programs
- The Company's financial reporting will now be based on four business segments, namely Small Molecules, Biologics, Branded Formulations and Research Services
- Biocon wins 'National Award for Excellence in Training & Development 2016' for Best Training Initiatives in the Pharmaceutical Sector

Financial Highlights: Q1 FY17

As per IGAAP

In Rs Crore, except growth numbers

Particulars	Q1 FY17	Q1 FY16	Growth (%)
Income			
Small Molecules	357	329	9%
Biologics	107	70	53%
Branded Formulations	159	138	15%
<i>Licensing (including capacity reservation fees)</i>	17	64	-73%
Syngene: Research Services	263	224	18%
<i>Total Sales</i>	903	825	10%
<i>Other Income</i>	49	32	52%
TOTAL REVENUE	952	857	11%
EBITDA	271	236	15%
Net Profit	147	126	17%
R&D Expenses in P&L	52	50	4%
Gross R&D Spends	92	93	0%
EBITDA Margin	28%	28%	
Net Profit Margin	15%	15%	

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

EXECUTIVE COMMENTARY

Starting 1 April 2016, Biocon is reporting its financial results based on the new Indian Accounting Standards, referred to as IND-AS. The transition from Indian GAAP to IND-AS applies to both our standalone and consolidated financial statements. In line with IND-AS, we have made changes to our segment reporting to better reflect the way we view and measure our business. This segmental reporting is aligned with the growth strategies represented by our strategic business units: Small Molecules, Biologics, Branded Formulations and Research Services. For the ease of understanding, we will continue to publish Indian GAAP figures alongside IND-AS through FY17.

PERFORMANCE REVIEW

Biocon started FY 17 on a positive note with Total Revenue reporting a healthy growth of 11% at Rs 952 Cr led by all-round growth of its business verticals viz. Small Molecules, Biologics, Branded Formulations and Syngene, which represents our Research Services business. Licensing Income this quarter stood at Rs 17 Cr while Other Income reported was Rs 49 Cr. EBITDA rose 15% to Rs 271 Cr; Net Profit increased 17% to Rs 147 Cr.

Our Gross R&D spends at Rs 92 Cr in Q1 FY17 reflect the advancement of our Biosimilars, Generic Formulations and Novel programs. At a Net level, R&D spends were Rs 52 Cr.

SMALL MOLECULES

The **Small Molecules** vertical, which offers a strong portfolio of differentiated APIs across statins, immunosuppressants, specialty molecules and includes our Generic formulations business, reported a steady revenue **growth of 9% at Rs 357 Cr**, led by sales to our India based customers servicing the needs of the US market and to some key markets in the LATAM and Africa & Middle East regions. Several new regulatory filings made during the quarter along with two approvals of key APIs in EU and emerging markets augur well for this business. Our vertical integration strategy into **Generic Formulations** is working well with the completion of 'full-cycle' development of a few products positioning us for regulatory filings in the developed markets, later this fiscal.

BIOLOGICS

The **Biologics** vertical comprises our Novel Biologics and Biosimilars, including rh-insulin, insulin analogs, monoclonal antibodies and recombinant proteins. During Q1, this business reported a **growth of 53% to Rs 107 Cr**.

Biosimilars

Insulins & Analogs: Inroads into Japan & Malaysia

Post regulatory approvals for Insulin Glargine in Japan last quarter, Biocon received a milestone payment from FUJIFILM Pharma (FFP), our partner, this quarter. More importantly, Biocon's ready-to-use, prefilled disposable pen with 3 ml of 100IU Insulin Glargine was launched in Japan by our partner on July 15, 2016. The product has been developed & manufactured by Biocon, and is being commercialized by FFP. The product has the potential to capture a significant share of the Japanese Glargine market of US\$ 144 Mn[#], which is the second largest market outside of North America & Europe and is largely dominated by disposable pens. We also launched Insulin Glargine and rh-Insulin in some emerging markets in the LATAM and AFMET regions during the quarter.

We crossed a significant milestone in Malaysia with Biocon's rh-Insulin becoming the first product manufactured at Malaysia, to be approved for commercialization by the Ministry of Health, Malaysia. Biocon's Insulin Glargine was also approved by the MOH, Malaysia. These approvals will open up commercialization opportunities for the company and will enable us to address the needs of nearly 3.3 million* diabetes patients in Malaysia. Regulatory filings for several other emerging markets are underway to enable commercial sales from the Malaysian facility.

The development of Insulin Glargine partnered with Mylan is tracking towards regulatory filings in the developed markets during this fiscal.

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We see the above developments as significant achievements in our journey of making global impact in diabetes management through our affordable biosimilar insulins & analogs.

Source: IMS March 2015. * Source: International Diabetes Federation

Monoclonal Antibodies & Recombinant Proteins

The European Medicines Agency (EMA) has accepted our partner Mylan's Marketing Authorization Application (MAA) for our proposed biosimilar Pegfilgrastim for review. This submission represents the first filing in the developed markets, for Biocon and Mylan's joint biosimilars portfolio. The results from the trials of Biocon and Mylan's Pegfilgrastim are expected to be presented during the annual congress of European Society of Medical Oncology (ESMO 2016), to be held in October in Copenhagen.

The results of the global confirmatory, efficacy and safety study with Trastuzumab were featured as an oral presentation at the annual meeting of ASCO (American Society of Clinical Oncology) in June. The findings have confirmed the efficacy, safety and immunogenicity of Biocon & Mylan's Trastuzumab in comparison to branded Trastuzumab. This study is expected to enable regulatory submissions of this product in the developed markets.

The global clinical development of our other biosimilar programs like Adalimumab and Bevacizumab are also making good progress to support submissions in developed and emerging markets.

Novel Biologics

siRNA-based Therapeutics: Partnered Program

Biocon in collaboration with Quark Pharma, one of the leaders in small interfering RNA (siRNA) therapeutics, is developing two siRNA based programs, QPI-1007 and QPI-1024. During the quarter the India arm of the pivotal global Phase II/III study of QPI-1007, a novel siRNA (small interfering RNA) drug candidate for ocular neuroprotection was initiated with the randomization of the first patient. The Drug Controller General of India (DCGI) has given approvals for this first ever clinical trial of a siRNA therapy in India earlier during 2016.

BRANDED FORMULATIONS

*The **Branded Formulations** business includes our finished dosages business in India and overseas including UAE. This business posted a healthy **growth of 15% at Rs 159 Cr** during Q1FY17 led by the sales of our core brands in India and UAE.*

Basalog® our Insulin Glargine brand in India reported over 30% growth in the quarter which is significantly ahead of the market and Insugen® retained its position as the largest domestic brand of insulins. Two of our anchor brands in Oncology, BIOMAb EGFR® and Abraxane®, continue to consolidate their positions with over 50% Market Share. CANMAb™ our brand of Trastuzumab, continues to expand on its strong prescription base with over 25% prescription share. The newly launched Virology division posted a robust growth in the quarter, over 2000

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patients have benefited from our Hepatitis C franchise in the first year of its launch. We continue with our efforts to invest in scientific engagement for ALZUMAb™. Four scientific papers for the product are being published at the Psoriasis 2016 Congress in Paris.

Our business in UAE continues to make rapid strides growing at 28%^ which is significantly ahead of the market growth of 16%. This has been led by core brands in Cardiovascular, Anti-Histamines and PPI segments and new launches in diabetes in-licensed from Novartis. The UAE business crossed a critical milestone of AED 100 Million^ on a MAT basis. Jalra and Jalra-M launched last year have made significant inroads in the Anti-diabetes market thereby positioning us as one of the key players in this segment in UAE. The company continues to strengthen its presence in the Cardiovascular market and is amongst the top 10 companies in this segment.

^Source: IMS MAT May 2016

SYNGENE : RESEARCH SERVICES

*Our **Research Services** business through Syngene reported a robust revenue **growth of 18%** at **Rs 263 Cr** this quarter, driven by a strong performance across its three verticals - Dedicated R&D Centers, Discovery Services and Development & Manufacturing Services. Two new facilities, the first phase of the Syngene Research Centre and a Viral Testing Facility, are now operational, which augurs well for their biologics business. The positive growth and outlook positions Syngene for a strong performance in FY17.*

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

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 100 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), CANMAB™ (Trastuzumab), BIOMAb-EGFR™ (Nimotuzumab) 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 including Insulin Tregopil, a high potential oral insulin analog. Visit: www.biocon.com

Earnings Call

*The company will conduct a call at **9.00 AM IST on July 22, 2016** 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 +91-22-3938 1081/ 6746 5891**. Other toll numbers are listed in the*

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conference call invite which is posted on the company website www.biocon.com. 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 **July 29, 2016 on +91 22 6181 3322/ 3065 2322, Playback ID: 44711**. Transcript of the conference call will be uploaded on the company website in due course.

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