

Press Release

**Biocon Q2FY16 Revenues up 12%; Net Profit up 200%**  
**Syngene delivers 30% growth**

**Revenues at Rs 861 Crores; EBITDA at Rs 222 Crores; Net Profit at Rs 306 Crores;  
Net Exceptional Income of Rs 203 Crores**

**Bengaluru, India: October 20, 2015**

**Biocon Ltd** (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, announced Q2 FY16 results today.

***Commenting on the quarterly performance and highlights, Chairperson and Managing Director, Kiran Mazumdar-Shaw stated:***

*“It has been a landmark quarter for Biocon with the hugely successful listing of Syngene. The resounding oversubscription of the IPO has reflected the trust and confidence of the investor community in Syngene’s value proposition. We are extremely proud and excited to take Syngene to its next phase of growth as India’s only publicly listed Research Services Company. For Q2FY16, Syngene reported a revenue growth of 30%.”*

*She added, “It has been a stable performance for Biocon this quarter with several growth triggers on the horizon focusing on Biosimilars in emerging markets. The clinical advancement of five of our Biosimilars programs has put us on track for regulatory filings for some of these in the US and Europe in FY17. The inauguration of our world-class manufacturing facility for a new generation insulin delivery device and the launch of BASALOG One™, a high-end, ready-to-use Insulin Glargine disposable pen in India, widens our insulins offering to diabetics in India. Our renewed focus on key brands has improved profitability of our Branded Formulations business. We expect the clinical progress in Biosimilars and Novels to augur well for the company, going forward.”*

***Highlights:***

- Syngene's IPO was oversubscribed 31 times with current market capitalization of over US\$ 1.15 Bn (as on October 19, 2015). Listing on NSE/BSE on Aug 11, 2015 was a landmark success.
- A world-class devices manufacturing facility, commissioned in India to make patient-friendly disposable devices for the insulins portfolio, will help address global needs.

- BASALOG One™, an international quality, ready-to-use, once-a-day Insulin Glargine disposable pen was introduced in India, for better blood sugar management for people with diabetes.
- Biocon's R&D expenses grew 64% with further advancement of global clinical development of generic Insulin Glargine and four other Biosimilar programs.
- Biocon acquired the business assets of the pharmaceutical manufacturing unit of M/s. Acacia Lifesciences Private Limited located at Vishakhapatnam with effect from October 01, 2015.

## Financial Highlights: Q2 FY16

In Rs Crore, except growth numbers

Particulars	Q2 FY16	Q2 FY15	Growth (%)
<b>Income</b>			
Biopharma	459	442	4%
Branded Formulations	119	116	3%
Research Services	250	192	30%
<b>Total Sales</b>	<b>828</b>	<b>750</b>	<b>11%</b>
Other Income	33	23	45%
<b>Total Revenue</b>	<b>861</b>	<b>773</b>	<b>12%</b>
<b>EBITDA</b>	<b>222</b>	<b>188</b>	<b>18%</b>
<b>Net Profit*</b>	<b>306</b>	<b>102</b>	<b>200%</b>
<b>R&amp;D Expenses in P&amp;L</b>	<b>57</b>	<b>35</b>	<b>64%</b>
<b>Gross R&amp;D Spends</b>	<b>90</b>	<b>81</b>	<b>12%</b>
<b>EBITDA Margin</b>	<b>26%</b>	<b>24%</b>	<b>-</b>
<b>Net Profit Margin*</b>	<b>36%</b>	<b>13%</b>	<b>-</b>

\*Includes exceptional income (net) of Rs.203 Cr (IPO receipts net of IPO expenses and tax, book value adjustment for 11% Syngene stake dilution & impairment charge for Itolizumab). Adjusting for exceptional income and associated tax, net profit was Rs.103 Cr, with net profit margin of 12%.

**Note:** The figures above are rounded off to the nearest Cr; % based on absolute nos.

## Executive Commentary

### R&D UPDATE

As an innovation driven organization, we continued to step up our investments in R&D. During Q2FY16, R&D spends at Rs.57 Cr represented an increase of 64% YoY, largely on account of the clinical advancement of several Biosimilars and Novel programs.

### Clinical Development of Biosimilars

Biocon's four Biosimilars programs partnered with Mylan, have made good clinical progress this quarter. As previously stated, patient recruitment in the Insulin Glargine global Phase III trials were

completed in the first quarter of this fiscal. Patient recruitment for multi-centric global Phase III clinical trials for Pegfilgrastim and Trastuzumab are nearing completion while the global Phase III clinical trial for Adalimumab is progressing well across multiple sites. The global Phase I PK study for Bevacizumab is approaching completion while the ROW focused Phase III trial is advancing as per plan. The encouraging clinical advancement across all our programs puts us on track for regulatory filings for some of these molecules in the developed markets of U.S. and Europe, in FY17.

## **Novel Programs**

### ***IN-105 (Insulin Tregopil)***

IN-105, our Novel Insulin molecule for oral delivery, is hereafter referred to as Insulin Tregopil, as per its international non-proprietary name (INN) granted by WHO. We have received the complete study report of the recently concluded trials in the U.S. which indicates the important role played by Insulin Tregopil in post prandial glycemic control. We are extremely excited with these findings and will decide the future course of this molecule in consultation with our partner BMS. We also plan to submit research papers for publication in peer reviewed international journals.

### ***Itolizumab***

We are actively engaged with our global clinical advisory team in developing this first-in-class anti-CD6, monoclonal antibody for a range of autoimmune conditions. However, we do expect procedural delays in developing this molecule in the US, on account of the requirement to obtain certain Governmental clearances. Based on recent feedback, we believe it is unlikely that we will receive waivers from the US authorities expeditiously. Whilst this has no impact on further development of this asset outside the US, we have taken an impairment charge against the US rights, in view of this uncertainty. Meanwhile, we continue to develop the molecule for other markets and hope to address the US market at an opportune time.

## **OPERATIONAL PERFORMANCE**

### **Biopharmaceuticals**

The Biopharmaceutical segment grew 4% YoY in Q2FY16, delivering sales of Rs.578 Cr. Within the segment, Biopharma grew 4% delivering Rs.459 Cr, while Branded Formulations grew 3% to Rs.119 Cr.

### ***Biopharma***

The overall performance of Biopharma business this quarter was affected due to slow offtake of some of the APIs and capacity constraints. However, we are taking steps to address this challenge.

Our Insulins facility in Malaysia is progressing towards qualification and emerging market filings in FY17. The expansion of our Biosimilars fill-finish facility in Bangalore is also on track for qualification in FY18.

Furthermore, we continue to pursue licensing opportunities in emerging markets for two key products, Trastuzumab and Insulin Glargine, and expect to commence sales of these products in some of these markets, this fiscal.

We have recently acquired the business assets including a USFDA approved synthesis facility of Acacia Life Sciences, in Vishakhapatnam, India. It presently manufactures advanced intermediates of potent APIs with sales to customers in India and overseas. This acquisition will enable us to vertically integrate our oncology related ANDA filings of the future.

### ***Branded Formulations***

The Branded Formulations business's focus on key brands has improved the profitability of this business. The growth of this business during the quarter, was largely driven by key brands in the Metabolics and Oncology divisions.

The Metabolics division is expected to get a fillip with the introduction of BASALOG One™, a long acting basal Insulin Glargine presented as an innovative, pre-filled pen, manufactured at our newly commissioned devices facility in Bangalore. This new facility will equip us to address the growing demand for disposable devices for diabetics around the world.

However, our inability to participate in some large institutional tender opportunities due to restrictions on the use of CMOs to meet these requirements, along with short supply of some key products, impacted the revenue growth of this business.

### **Research Services – Syngene**

It was a landmark quarter for Syngene, as it created immense value for its shareholders through a successful listing on NSE/BSE on August 11, 2015. Currently, it has a market cap of US\$ 1.15 Bn (as on Oct 19, 2015). In Q2 FY16, Syngene has delivered a remarkable YoY growth of 30%, recording sales of Rs.250 Cr. The business performance was driven by strong growth across its three verticals – discovery services, dedicated centers and development & manufacturing services. Business momentum is expected to continue into H2 FY16.

-Ends-

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

#### **Earnings Call**

The company will conduct a 45 minute long call at **4:15 PM IST on October 21, 2015** 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 conference call invite which is posted on the company website [www.biocon.com](http://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 **October 28, 2015** 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.

## About Biocon Limited

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 a high potential oral insulin. Visit: [www.biocon.com](http://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.*

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