

Press Release

**Biocon Q3FY16 Net Profit Up 13% at Rs 103 Crore,  
EBITDA Increases 23% to Rs 209 Crore,  
Revenues at Rs 857 Crore, up by 10%**

**Bengaluru, India: January 21, 2016**

**Biocon Ltd** (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, announced Q3 FY16 results today.

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

*“Biocon’s four most advanced biosimilar and generic insulin programs, Insulin Glargine, Trastuzumab, Pegfilgrastim and Adalimumab, continue to cross critical clinical milestones and are on track for regulatory filings in US & Europe in CY2016. These filings are likely to provide us an early mover advantage in an addressable US\$30 Billion market. The progress made in our biosimilars and novel programs is reflected in the increase in R&D spends this quarter to Rs 68 crore. Excluding profit contribution from Syngene, Biocon’s net profit this quarter has increased by 28% y-o-y despite a 45% jump in R&D spends and a significant increase in tax. This reflects a marked improvement in the quality of our earnings led by better realizations from biosimilars and immunosuppressants in emerging markets. Syngene, our research services company, has delivered yet another strong quarter both in terms of revenues and profits.”*

**Highlights: Q3FY16**

- Biocon’s R&D spends at Rs 68 crore (Cr) grew by 45% reflecting progress of its biosimilars and novel programs
- Biocon continues to cross critical milestones in global Phase III clinical trials of Biosimilars Trastuzumab, Pegfilgrastim, Adalimumab and Insulin Glargine
- Licensing Income of Rs 32 Cr this quarter demonstrates our ability to monetize our biosimilars portfolio in emerging markets
- Biocon reports positive clinical data from key studies for Insulin Tregopil
- NeoBiocon launched Jalra (*Vildagliptin*) and Jalra M (*Vildagliptin+ Metformin*) for diabetes in UAE, in collaboration with Novartis Middle East FZE
- Branded Formulations business strengthened its Virology portfolio with the launch of Cimivir-L™, a once-a-day oral therapy for Hepatitis C, in India

- Construction of Biocon's potent oral solid dosage formulations facility in Bengaluru has commenced
- Biocon has made it to the Top 20 Global Biotech Employers 2015 List by ScienceCareers, USA. It has been recognized for being the most innovative leader in the industry, having loyal employees and being socially responsible
- Biocon has won five awards for its best practices in the areas of Environment Management, Supply Chain, Product Packaging and Intellectual Property
- Syngene, post its successful listing in the previous quarter, has reported a strong revenue growth of 23% y-o-y to Rs 270 Cr

### Financial Highlights: Q3 FY16

*In Rs crore, except growth numbers*

Particulars	Q3 FY16	Q3 FY15	Growth (%)
<b>Income</b>			
Biopharma*	454	436	4%
Branded Formulations	104	105	
Research Services	270	220	23%
<b>Total Sales</b>	<b>828</b>	<b>761</b>	<b>9%</b>
Other Income	29	18	60%
<b>TOTAL REVENUE</b>	<b>857</b>	<b>779</b>	<b>10%</b>
<b>EBITDA</b>	<b>209</b>	<b>170</b>	<b>23%</b>
<b>Net Profit</b>	<b>103</b>	<b>91</b>	<b>13%</b>
<b>R&amp;D Expenses in P&amp;L</b>	<b>68</b>	<b>47</b>	<b>45%</b>
<b>Gross R&amp;D Spends</b>	<b>91</b>	<b>85</b>	<b>7%</b>
<b>EBITDA Margin</b>	<b>24%</b>	<b>22%</b>	<b>-</b>
<b>Net Profit Margin</b>	<b>12%</b>	<b>12%</b>	<b>-</b>

Note:

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

\* Biopharma numbers include licensing income of Rs 32 Cr in Q3FY16 and Rs 10 Cr in Q3FY15, respectively

### Executive Commentary

#### R&D UPDATE

The company recorded R&D spends of Rs 91 Cr in Q3FY16 at the gross level, an increase of 7% y-o-y, on account of the clinical advancement of several Biosimilars and Novel programs. At a P&L level, R&D spends rose 45% to Rs 68 Cr.

#### **Clinical Development of Biosimilars**

The Biocon-Mylan partnership includes six biosimilar programs (Trastuzumab, Pegfilgrastim, Adalimumab, Bevacizumab, Etanercept and Filgrastim) and three insulin analog programs (Glargine, Lispro and Aspart).

Four of our most advanced programs, Insulin Glargine, Trastuzumab, Pegfilgrastim and Adalimumab, continue to cross critical milestones in global Phase III clinical trials and are on track for regulatory filings in US & Europe in CY2016. These filings are likely to provide us an early mover advantage in an addressable US\$30 billion market.

The Bevacizumab global Phase I trial and the RoW-focused Phase III trial are advancing as per plan.

### **Novel Programs**

#### ***Insulin Tregopil – The Oral Insulin***

The results of the global Phase I study conducted in the US has established the important role of Insulin Tregopil in post prandial glycemic control. It has demonstrated fast action of Insulin Tregopil with distinct properties compared to other prandial insulins like Aspart. Based on the positive results of these clinical studies Biocon plans to move to the next phase of clinical development on its own.

#### ***Itolizumab- Novel anti-CD6 MAb***

We stay committed to developing this novel asset, a first-in-class anti-CD6 monoclonal antibody for a range of autoimmune conditions. During the quarter, in consultation with our global clinical advisory team a Phase I study in normal healthy volunteers has been initiated in Australia. The study also aims to evaluate the pharmacokinetics of a sub-cutaneous route of administration of Itolizumab in comparison to intravenous route.

#### ***siRNA- based Therapeutics***

Biocon in collaboration with Quark Pharma, one of the leaders in the siRNA therapeutics, is developing QPI-1007, a novel siRNA asset, for a rare ophthalmic condition -- Non-arteritic ischemic optic neuropathy (NAION). Patient enrolment for a global Phase III study for this program has commenced.

### **OPERATIONAL PERFORMANCE**

The overall Sales at Rs 828 Cr registered a growth of 9% in Q3FY16. The Biopharmaceutical segment delivered sales of Rs 558 Cr, reporting a growth of 3% y-o-y. Within the segment, Biopharma grew 4% delivering Rs 454 Cr, while Branded Formulations sales stood at Rs 104 Cr for this quarter.

#### **Biopharmaceuticals**

##### ***Biopharma***

The overall Biopharma business continues to report a steady growth, with an increasing contribution from immunosuppressants and generic insulins in the emerging markets.

The API development work for ANDA submissions has gained traction, putting us on track to file 20-25 dossiers over the next few years. The construction of our potent oral solid dosage formulations facility in Bengaluru, supports our vertically integrated ANDA strategy.

The process qualification of our Insulins facility in Malaysia has commenced, which puts us on track to file for approvals in FY17, as planned.

We have made good progress in partnering and seeking approvals for biosimilar Trastuzumab in some of the major emerging markets.

The introduction of Jalra (*Vildagliptin*) and Jalra M (*Vildagliptin+ Metformin*) for diabetes, in-licensed from Novartis Middle East by NeoBiocon strengthens our position as the fastest growing pharmaceutical company in UAE.

### **Branded Formulations**

The Branded Formulations business continues to clock in over Rs 100 Cr each quarter, post rationalization of its product portfolio. The focus is on strengthening Biocon's presence as a specialty pharma company by promoting its key brands across Metabolics, Onco-therapeutics, Immunology, Nephrology, Critical care and newly introduced Virology. All the divisions are also focusing on improving the profitability of this business.

The Metabolics division continues to be the flagship segment of this business. It has held a steady 10% market share in the represented Insulins market. Biocon continues to be the largest Indian Insulins company.

The newly introduced Virology division expanded its portfolio with the introduction of CIMIVIR-L™ (Ledipasvir+ Sofosbuvir) for Hepatitis-C Genotype 1 patients in India. It is estimated that nearly one lakh people die annually in India from HCV infections and co-morbidities.

The Market Access division has also been successful in winning a few institutional tenders this quarter.

### **Research Services – Syngene**

Our research services business through Syngene reported a strong revenue growth of 23% to Rs 270 Cr, this quarter, driven by a robust performance across three verticals- discovery services, dedicated centers and development & manufacturing services. Syngene has also appointed Jonathan Hunt, as CEO designate, who brings in over two decades of expertise in the global biopharma sector and will lead the company towards its stated goal of achieving sales of US\$ 250 million by FY18.

### **Other Highlights: Awards & Recognitions**

Biocon's commitment to operational excellence has been duly recognized through various awards received during this period, a few of them being:

- 'Pharmexcil Gold Patent Award' 2014-15 for maximum number of patents granted during the year
- 'Procurement Excellence Awards' 2015 for the 'Best- in- Class Excellence in Cost Management'
- Two 'India Star 2015 Packaging Awards' for innovative packaging of CANMAb™ and Genextor®
- Gold 'Greentech Environment Award' 2015 for excellence in Environment Management in the Indian Pharma Industry

Biocon also gained recognition as the '**Best Employer Brand**' in Q3FY16. It is the only Asian biopharma company to be included in the 'Top 20 Global Biotech Employers 2015' list by US-based ScienceCareers magazine. It has recognized Biocon as the most innovative leader in the industry, having loyal employees and being socially responsible.

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

## Earnings Call

The company will conduct a call at **9.00 AM IST on January 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 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 **January 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.

## 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 Insulin Tregopil, a high potential oral insulin analog. 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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