

Press Release

**Biocon Q4FY16 Net Profit at Rs 361 Cr  
Revenue Crosses Rs 1,000 Cr; Up 17%  
FY 16 Revenues up 14% at Rs 3,570 Cr  
Net Profit at Rs 896 Cr**

**Bengaluru, India: April 26, 2016**

**Biocon Ltd** (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, announced its Q4 & FY16 results today.

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

*"Biocon has closed the year with a landmark quarter, crossing a milestone Rs 1,000 Cr consolidated revenues for the first time. Syngene also closed FY16 on a strong note by crossing a Rs 1,000 Cr annual revenue mark.*

*Key developments this quarter were:*

*1: The Japanese regulatory approval of our Insulin glargine which heralds the entry of our biosimilars into key regulated markets*

*2: A Co-development & Commercialization Partnership for Biocon's rh-Insulin for the US market with Lab Pisa, a leading Mexican Pharma company.*

*3: An important European approval for Rosuvastatin Calcium Tablets which marks the entry of our generic formulations foray in developed markets."*

*"Biocon's gross R&D expenses at Rs 152 crore this quarter were the highest till date reflecting the advancement of our innovation led drug pipeline comprising novels, biosimilars and ANDAs. We expect to file a number of regulatory submissions in US and Europe for many of these programs in FY17," she added.*

**Highlights of Q4 FY16:**

- Biocon recorded Exceptional Income of Rs 268 Cr in Q4, excluding Exceptional Income, Net Profit for Q4 stood at Rs 105 Cr
- Biocon's Insulin Glargine becomes the first biosimilar from India and 2<sup>nd</sup> biosimilar glargine to be approved in Japan.
- Biocon targets the rh-insulin opportunity in the US by collaborating with Lab PiSA, its long standing partner in Mexico. Pursuant to this, Biocon has recorded an Exceptional Income of Rs 268 Cr on account of the changes in the nature of Biocon's future obligations on the rh-insulin program.
- EU approval for Biocon's generic Rosuvastatin Calcium tablets will enable the company to take its first Generic Formulation to the developed markets

- Global Phase III clinical trials for biosimilar Insulin Glargine, Trastuzumab, Pegfilgrastim and Adalimumab are progressing well towards anticipated filings in FY 17.
- Biocon's quarterly consolidated revenue crosses the Rs 1,000 Cr milestone for the first time in Q4FY16.
- Syngene records a strong growth of 32% in Q4FY16 at Rs 316 Cr and crosses the Rs 1,000 Cr annual revenue milestone in FY16.
- Biocon's gross R&D expenses for the quarter cross Rs 150 Cr indicating the advancement of our Biosimilars, ANDA and Novel programs.

### Key Financials: Q4 & FY16

*In Rs crore, except growth numbers*

Particulars	Q4 FY16	Q4 FY15	Growth (%)	FY16	FY15	Growth (%)
<b>Income</b>						
Biopharma	554	494	12	1,954	1,806	8
Branded Formulations-India	101	98	3	437	430	2
Contract Research	316	238	32	1,060	823	29
<b>Total Sales</b>	<b>971</b>	<b>830</b>	<b>17</b>	<b>3,451</b>	<b>3,059</b>	<b>13</b>
Other Income	33	24	38	119	84	42
<b>TOTAL REVENUE</b>	<b>1,004</b>	<b>854</b>	<b>17</b>	<b>3,570</b>	<b>3,143</b>	<b>14</b>
<b>EBITDA</b>	<b>238</b>	<b>202</b>	<b>18</b>	<b>903</b>	<b>749</b>	<b>21</b>
Exceptional Item (Net)	268*	105	155	576	105	447
<b>Net Profit</b>	<b>361</b>	<b>201</b>	<b>79</b>	<b>896</b>	<b>497</b>	<b>80</b>
<b>R&amp;D Expenses in P&amp;L</b>	<b>100</b>	<b>56</b>	<b>78</b>	<b>275</b>	<b>169</b>	<b>63</b>
<b>Gross R&amp;D Spends</b>	<b>152</b>	<b>100</b>	<b>52</b>	<b>427</b>	<b>329</b>	<b>30</b>
<b>EBITDA Margin</b>	<b>24%</b>	<b>24%</b>	-	<b>25%</b>	<b>24%</b>	-
<b>Net Profit Margin</b>	<b>36%</b>	<b>24%</b>	-	<b>25%</b>	<b>16%</b>	-

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

**\*Note:** The newly signed co-development agreement for rh-insulin with Lab PiSA changes the nature of Biocon's future obligations on the rh-insulin program. Hence, the previously deferred amounts of Rs 268 Cr has been recognized as an exceptional income in the consolidated P&L for Q4 & FY 16.

### Restructuring of Legal Entities

Biocon has restructured its legal entities to align with its growth strategies represented by its strategic business units. We believe this restructuring will enable us to unlock greater value from our business segments at an opportune time. All our biosimilar assets will now be consolidated under the new legal entity, Biocon Biologics Limited incorporated in UK as a subsidiary of Biocon Limited, India.

### Transition to New India Accounting Standards

From Q1FY17, Biocon will start reporting its financial results based on the new Indian Accounting Standards, referred to as IND-AS. We do not foresee any significant impact on the earnings from this accounting transition.

### **Appointment of New Auditors**

Biocon's Board of Directors have recommended to shareholders the appointment of BSR & Co LLP as the new Statutory Auditors of the Company at the upcoming Annual General Meeting on June 30, 2016.

### **Appointment of Mr. M. Damodaran as Independent Director**

Biocon has strengthened its Board composition with the induction of Mr. M. Damodaran, a renowned financial expert and former Chairman SEBI, as an additional Independent Director. He has served both Central and State Governments in critical positions, besides being on the board of several leading companies and foreign institutions. After successful stints as Chairman UTI and IDBI during his career, he has set up Excellence Enablers Private Ltd (EEPL), a Corporate Governance and Board Advisory consultancy firm. He is also the founder Chairman of IIM, Tiruchirapalli and Chairman of Glocal Healthcare Systems Pvt Ltd, which provides quality healthcare in rural areas. His presence will enrich the board and further enhance the quality of governance and compliance at Biocon.

## **EXECUTIVE COMMENTARY**

### **R&D UPDATE**

R&D spends crossed Rs 100 Cr in Q4FY16 at the P&L level, an increase of 78% y-o-y, on account of the clinical advancement of Biosimilars, ANDAs and Novel programs. At a gross level, R&D spends rose 52% to Rs 152 Cr.

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

#### ***Insulins***

The Global Phase III clinical development program for Insulin Glargine has crossed key interim milestones putting us on track for regulatory filings in US and EU in FY 17. Insulin Aspart & Lispro collaboration programs are progressing as per plan and are expected to cross critical preclinical milestones in FY 17.

#### ***Monoclonal Antibodies & Proteins***

The Global Phase III study for Pegfilgrastim has been completed and it has met the primary endpoint of demonstrating clinical equivalence with the reference product. The global clinical development of our other biosimilar programs like Trastuzumab, Adalimumab and Bevacizumab is also making good progress. We are on track for regulatory submissions for some of them in Europe and in the US in FY17.

### **Clinical Development of Novel Programs:**

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

Biocon is committed to develop Insulin Tregopil for Type I and Type II diabetes patients as a follow up to the successful outcome of the clinical studies conducted in the US last fiscal. We are in consultation with our scientific board to design the next clinical study to be initiated in FY17.

#### ***Itolizumab – Novel Anti-CD6 MAb***

This novel first-in-class anti-CD6 monoclonal antibody is undergoing a bridging Phase I- PK & Safety study in healthy volunteers in Australia. During the quarter the first sentinel dosing has been completed. The drug was well tolerated with no adverse effects. The study is expected to enable a

global IND filing with a subcutaneous route of administration. Biocon is the first and the only company globally to clinically validate CD6 as a target for autoimmune diseases.

#### *siRNA-based Therapeutics*

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. A pivotal Global Phase II / III study investigating QPI-1007 in Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION) patients is ongoing.

#### *Fusion Proteins*

Novel immune check-point inhibitors have created much excitement in the field of cancer in general and cancer immunotherapy in particular. Biocon is building an exciting pipeline of fusion MAb molecules with the concept of preferentially delivering immune modulators to tumor sites thereby, enhancing efficacy while limiting systemic toxicity. The lead molecule in this program FmAb2 has achieved preclinical 'proof of concept' and is currently in advanced preclinical development.

During the quarter, Biocon successfully organized an Immuno-Oncology symposium with eminent scientists in the field such as Prof. Vijay Kuchroo (Harvard), Prof. Gordon Freeman (Harvard) and Prof. Varsha Gandhi (MD Anderson Cancer Center) as the key speakers.

### **OPERATIONAL PERFORMANCE**

The overall Sales at Rs 971 Cr registered a growth of 17% in Q4FY16. The Biopharmaceutical segment delivered sales of Rs 655 Cr, reporting a growth of 11% y-o-y. Within the segment, Biopharma grew 12% delivering Rs 554 Cr, while Branded Formulations reported a growth of 3% with sales at Rs 101 Cr for this quarter.

#### **BIOPHARMACEUTICALS:**

##### **Biopharma**

The Biopharma business reported a growth of 12% fuelled by a strong performance by biosimilars including insulins and MAb. Emerging markets contributed significantly this quarter with products like Trastuzumab and Insulin Glargine being commercialized in additional markets in MENA and South East Asia. We also partnered for Latin American markets thereby extending our footprint in over 10 countries there.

The **Small Molecules - APIs** business continues to report steady sales. We continue to see sustained margins through a better product mix and are focussed on vertically integrating our API strategy with our generic formulations business.

An important milestone in this endeavour was our first Generic Formulations approval for Rosuvastatin Calcium tablets in Europe through the decentralized procedure. This will provide Biocon access to over 15 European countries with a combined market opportunity of US\$ 1.2 billion, starting FY17.

Our business rests on a strong foundation and culture of compliance with the highest global quality standards.

## Insulins Make Inroads into Japan & USA

During Q4FY16, Biocon received regulatory approvals in Japan, for its world class, ready-to-use, prefilled, disposable Insulin Glargine pen from the Ministry of Health, Labour and Welfare (MHLW). The product developed by Biocon is expected to be commercialized in early FY17 by our partner and aims to capture a significant share of the US\$ 144 Mn Japanese Glargine market, which is dominated by disposable pens and is the second largest market outside of North America & Europe. Biocon's manufacturing facilities for Insulin Glargine and its state-of-the-art disposable pen assembly facility in Bangalore were inspected and approved by the Japanese regulatory authorities, prior to granting this approval.

Biocon also entered into a co-development agreement with its long-standing Mexican partner, Laboratorios PISA, to target the opportunity for generic recombinant human insulin in the US market.

We see the above developments as significant achievements in our journey of making a global impact in diabetes management through our affordable biosimilar insulins & analogs. Currently our insulins are registered in over 65 markets which represent 40% of the global diabetes population.

## Branded Formulations

The Branded Formulations-India business, which underwent product rationalization during the year, reported sales of Rs 101 Cr in Q4, driven by Metabolics, Onco-therapeutics and Market Access divisions. Our focus on anchor brands like Insugen<sup>®</sup>, Basalog<sup>®</sup>, BIOMAb EGFR<sup>®</sup>, CANMAb<sup>™</sup> and ALZUMAb<sup>™</sup> has enabled them to maintain their positions among the 'Top Three' brands in their respective segments. The nascent Virology division expanded its product basket with the launch Daclawin<sup>™</sup>, an advanced novel therapy for the treatment of chronic Hepatitis-C in India. We have also increased our prescriber base in order to provide affordable access to patients. Insugen<sup>®</sup> and Basalog<sup>®</sup> command a prescriber base of 26% in the specialty segment, while CANMAb<sup>™</sup> is currently the second preferred brand in its segment with a 20% patient market share. Market Access division continued to work closely with state and central government institutes to enable affordable access to biopharmaceuticals for diabetes and cancer, reporting a growth of 33% this quarter.

**NeoBiocon** in UAE has successfully carved its position at No. 21 amidst the crowded pharma market dominated by MNCs and local generic companies. For Q4, it reported a strong QoQ growth of 29%, driven by the branded generics products that cater to the high incidence of lifestyle diseases in the country.

## Research Services – Syngene:

Our Research Services business through Syngene reported a strong revenue growth of 32% to Rs 316 Cr this quarter, driven by a robust performance across three verticals- Discovery Services, Dedicated Centers and Development & Manufacturing Services. Syngene also crossed a major annual revenue milestone of Rs 1,000 Cr, with sales of Rs 1,060 Cr in FY16.

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

## [Earnings Call](#)

The company will conduct a call at **3.30 PM IST on April 27, 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 **May 4, 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 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](http://www.biocon.com)

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### 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.*

**BIOCON GROUP**

**FACT SHEET**

**March - 2016**

<b>BIOCON LIMITED (CONSOLIDATED)</b>		
<b>BALANCE SHEET</b>		(Rs Crore)
	March 31, 2016	March 31, 2015
<b>EQUITY AND LIABILITIES</b>		
<b>Shareholder's Funds</b>		
(a) Share capital	100	100
(b) Reserves and surplus	3,956	3,171
	<b>4,056</b>	<b>3,271</b>
<b>Minority interest</b>	311	172
<b>Non-current liabilities</b>		
(a) Long-term borrowings	2,072	770
(b) Deferred tax liability (net)	35	42
(c) Other long-term liabilities	350	552
(d) Long-term provisions	30	15
	<b>2,487</b>	<b>1,379</b>
<b>Current liabilities</b>		
(a) Short-term borrowings	395	261
(b) Trade payables	547	429
(c) Other current liabilities	598	706
(d) Short-term provisions	88	158
	<b>1,628</b>	<b>1,554</b>
<b>TOTAL</b>	<b>8,482</b>	<b>6,376</b>
<b>ASSETS</b>		
<b>Non-current assets</b>		
(a) Fixed assets	3,885	3,280
(b) Goodwill	26	26
(c) Long term loans and advances	412	369
(d) Other non-current assets	166	137
	<b>4,489</b>	<b>3,812</b>
<b>Current assets</b>		
(a) Current Investments	429	230
(b) Inventories	511	453
(c) Trade receivables	823	771
(d) Cash and cash equivalents	1,921	938
(e) Short term loans and advances	185	76
(f) Other current assets	124	96
	<b>3,993</b>	<b>2,564</b>
<b>TOTAL</b>	<b>8,482</b>	<b>6,376</b>



<b>BIOCON LIMITED (CONSOLIDATED)</b>			
<b>PROFIT &amp; LOSS STATEMENT</b>			(Rs Crore)
Particulars	FY 16	FY 15	Variance
<b>INCOME</b>			
<b>Biopharmaceuticals</b>	<b>2,391</b>	<b>2,236</b>	<b>7%</b>
Biopharma *	1,954	1,806	8%
Branded formulations - India	437	430	2%
<b>Contract research</b>	<b>1,060</b>	<b>823</b>	<b>29%</b>
<b>Total Sales</b>	<b>3,451</b>	<b>3,059</b>	<b>13%</b>
Other income	119	84	42%
<b>TOTAL REVENUE</b>	<b>3,570</b>	<b>3,143</b>	<b>14%</b>
<b>EXPENDITURE</b>			
Material & Power costs	1,486	1,423	4%
Staff costs	585	493	19%
Research & Development **	275	169	63%
Other expenses	321	309	3%
<b>Manufacturing, staff &amp; other expenses</b>	<b>2,667</b>	<b>2,394</b>	
<b>EBITDA</b>	<b>903</b>	<b>749</b>	<b>21%</b>
Interest & Finance charges	10	9	15%
Depreciation & Amortisation	242	221	10%
<b>PBT BEFORE EXCEPTIONAL ITEM</b>	<b>651</b>	<b>519</b>	<b>26%</b>
Exceptional item, Net	576	105	447%
<b>PBT</b>	<b>1,227</b>	<b>624</b>	<b>97%</b>
Taxes	140	96	
Taxes on exceptional item	117	-	
<b>NET PROFIT BEFORE MINORITY INTEREST</b>	<b>970</b>	<b>528</b>	<b>84%</b>
Minority interest	74	31	
<b>NET PROFIT FOR THE PERIOD</b>	<b>896</b>	<b>497</b>	<b>80%</b>
<b>EPS Rs.</b>	<b>44.8</b>	<b>24.8</b>	
<i>Note: The figures are rounded off to the nearest crore, percentages are based on absolute numbers</i>			
<i>* Biopharma Income includes:</i>			
Licensing Income	76	43	
<b>** Gross Research &amp; Development expenses</b>	<b>427</b>	<b>329</b>	<b>130%</b>

# FY 15 - Tax incidence in the hands of BRL on the sale of shares has been fully offset against business losses of BRL. BRL had created deferred tax asset of Rs 10 as at December 31, 2014 which has been utilised on consummation of sale.

<b>BIOCON LIMITED (CONSOLIDATED)</b>			
<b>PROFIT &amp; LOSS STATEMENT</b>			(Rs. Crore)
Particulars	Q4 FY 16	Q4 FY 15	Variance
<b>INCOME</b>			
<b>Biopharmaceuticals</b>	<b>655</b>	<b>592</b>	<b>11%</b>
Biopharma *	554	494	12%
Branded formulations - India	101	98	3%
<b>Contract research</b>	<b>316</b>	<b>238</b>	<b>32%</b>
<b>Total Sales</b>	<b>971</b>	<b>830</b>	<b>17%</b>
Other income	33	24	38%
<b>TOTAL REVENUE</b>	<b>1,004</b>	<b>854</b>	<b>17%</b>
<b>EXPENDITURE</b>			
Material & Power costs	402	376	7%
Staff costs	161	126	28%
Research & Development **	100	56	78%
Other expenses	103	94	10%
<b>Manufacturing, staff &amp; other expenses</b>	<b>766</b>	<b>652</b>	
<b>EBITDA</b>	<b>238</b>	<b>202</b>	<b>18%</b>
Interest & Finance charges	1	0	
Depreciation & Amortisation	63	59	7%
<b>PBT BEFORE EXCEPTIONAL ITEM</b>	<b>174</b>	<b>143</b>	<b>21%</b>
Exceptional item, Net	268	105	155%
<b>PBT</b>	<b>442</b>	<b>248</b>	<b>78%</b>
Taxes	46	22	
Taxes on exceptional item	12	10	
<b>NET PROFIT BEFORE MINORITY INTEREST</b>	<b>384</b>	<b>216</b>	<b>77%</b>
Minority interest	23	15	
<b>NET PROFIT FOR THE PERIOD</b>	<b>361</b>	<b>201</b>	<b>79%</b>
<b>EPS Rs.</b>	<b>18.0</b>	<b>10.0</b>	
<i>Note: The figures are rounded off to the nearest crore, percentages are based on absolute numbers</i>			
<i>* Biopharma Income includes:</i>			
<i>Licensing Income</i>	23	5	
<i>** Gross Research &amp; Development expenses</i>	152	100	

<b>BIOCON LIMITED (CONSOLIDATED)</b>			
<b>PROFIT &amp; LOSS STATEMENT</b>			(Rs Crore)
Particulars	Q4 FY 16	Q3 FY 16	Variance
<b><u>INCOME</u></b>			
<b>Biopharmaceuticals</b>	<b>655</b>	<b>558</b>	<b>17%</b>
Biopharma *	554	454	22%
Branded formulations - India	101	104	-3%
<b>Contract research</b>	<b>316</b>	<b>270</b>	<b>17%</b>
<b>Total Sales</b>	<b>971</b>	<b>828</b>	<b>17%</b>
Other income	33	29	16%
<b>TOTAL REVENUE</b>	<b>1,004</b>	<b>857</b>	<b>17%</b>
<b><u>EXPENDITURE</u></b>			
Material & Power costs	402	353	14%
Staff costs	161	146	10%
Research & Development **	100	68	47%
Other expenses	103	81	28%
<b>Manufacturing, staff &amp; other expenses</b>	<b>766</b>	<b>648</b>	
<b>EBITDA</b>	<b>238</b>	<b>209</b>	<b>14%</b>
Interest & Finance charges	1	2	-7%
Depreciation & Amortisation	63	62	1%
<b>PBT BEFORE EXCEPTIONAL ITEM</b>	<b>174</b>	<b>145</b>	<b>20%</b>
Exceptional item, net	268	-	
<b>PBT</b>	<b>442</b>	<b>145</b>	<b>204%</b>
Taxes	46	24	
Taxes on exceptional item	12	-	
<b>NET PROFIT BEFORE MINORITY INTEREST</b>	<b>384</b>	<b>121</b>	<b>217%</b>
Minority interest	23	18	
<b>NET PROFIT FOR THE PERIOD</b>	<b>361</b>	<b>103</b>	<b>250%</b>
<b>EPS Rs.</b>	<b>18.0</b>	<b>5.2</b>	
<i>Note: The figures are rounded off to the nearest crore, percentages are based on absolute numbers</i>			
* Biopharma Income includes:			
Licensing Income	23	32	
** Gross Research & Development expenses	152	91	