



Biocon Limited
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Date of Submission: October 25, 2018

To The Secretary BSE Limited Department of Corporate Services Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai – 400 001 Scrip Code - 532523	To The Secretary National Stock Exchange of India Limited Exchange Plaza, Bandra Kurla Complex Mumbai – 400 050 Stock Code- Biocon
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Dear Sir/Madam,

Sub: Press Release for the quarter and half year ended September 30, 2018

With reference to the captioned subject, please find enclosed Press Release pertaining to the unaudited Financial Results (Standalone and Consolidated) for the quarter and half year ended September 30, 2018.

Kindly take the above said information on record.

Thanking You,
Yours faithfully
For **BIOCON LIMITED**

A handwritten signature in blue ink that reads "Satish Kumar SS".

Satish Kumar SS
Company Secretary and Compliance Officer
Encl: A/A

Press Release

**Biocon Q2FY19 Revenue at Rs 1,375 Cr, Up 35%;
EBITDA at Rs 394 Cr, Up 69%; Net Profit at Rs 355 Cr;
Net Profit (excluding exceptional income) at Rs 184 Cr; Up 167%**

Bengaluru, Karnataka, India: October 25, 2018:

Biocon Ltd (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, today announced its consolidated financial results for the second quarter ended on September 30th, 2018.

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

“We delivered a strong revenue growth of 35% this quarter, driven by robust performance across our Biologics, Small Molecules and Research Services segments. Net Profit, excluding net exceptional income of Rs 171 Cr, grew by 167% on account of strong topline growth, including biosimilar Pegfilgrastim sales in the U.S., and margin expansion.”

“We are greatly encouraged by the U.S. FDA’s acceptance of an IND submitted by our partner Equillum Inc. for Itolizumab, a novel monoclonal antibody, for an orphan indication. The positive opinions from the European CHMP for Biocon and Mylan’s Pegfilgrastim and Trastuzumab augur well for the future growth of our biosimilars business.”

Highlights:

- Our partner Mylan commenced commercial sales of **Fulphila™**, biosimilar Pegfilgrastim, in the U.S.
- EMA’s **CHMP** issued positive opinions recommending approvals of Fulphila™, biosimilar Pegfilgrastim, and **Ogivri®**, biosimilar Trastuzumab
- Our partner **Equillum’s** Investigational New Drug (**IND**) application for **EQ001** (Itolizumab) for an orphan indication of acute graft-versus-host disease (aGVHD) was **accepted** by the **U.S. FDA** in July 2018
- Biocon’s **Drug Substance facility** in Bangalore completed **U.S. FDA** inspection with **no observations**
- Biocon’s **Sterile Drug Product and Devices facilities** in Bangalore received Certificates of **GMP Compliance** from **EU**
- Biocon’s **API facility** in Hyderabad successfully completed **GMP** audits from **TGA**, Australia and **COFEPRIS**, Mexico

FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q2FY19

As per IND-AS

In Rs Crore, except growth numbers

Particulars	Q2FY19	Q2FY18	Growth
INCOME			
Small Molecules	432	351	23%
Biologics	367	156	136%
Branded Formulations	164	176	(7)%
Research Services	419	335	25%
Inter-segment	(61)	(49)	25%
Revenue from Operations[#]	1,321	969	36%
Other Income	54	50	7%
TOTAL REVENUE	1,375	1,019	35%
EBITDA	394	233	69%
PBT	451	132	243%
Net Profit	355	69	416%
Exceptional item (net of tax)	171	Nil	
Net Profit (excluding exceptional item)	184	69	167%
R&D Expenses in P&L	77	54	43%
Gross R&D Spends	120	96	25%
EBITDA Margin	29%	23%	
Core EBITDA Margin	33%	26%	
Net Profit Margin*	13%	7%	
[#] includes Licensing Income	5	8	

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

*excluding exceptional item and associated tax

EXECUTIVE COMMENTARY:

PERFORMANCE REVIEW: Q2FY19

Biocon reported a strong **Revenue growth** of 35% at Rs 1,375 Cr in Q2 FY19, led by Biologics, Small Molecules and Research Services business segments.

Net Profit at Rs 355 Cr was aided by net exceptional income of Rs 171 Cr related to change in the fair value of our investment in U.S.-based Equillum Inc.

Net Profit, excluding exceptional item, stood at Rs 184 Cr reflecting a strong growth of 167%.

EBITDA rose 69% to Rs 394 Cr. **EBITDA margin** was 29% in Q2FY19 versus 23% in Q2FY18. **Core EBITDA margin**, which is net of licensing, forex and R&D, improved to 33% in Q2FY19 from 26% in Q2FY18.

Licensing Income in Q2FY19 stood at Rs 5 Cr while Other Income reported was Rs 54 Cr, which includes a Forex gain of Rs 24 Cr.

Net R&D spends during the quarter stood at Rs 77 Cr, an increase of 43%. At a **gross level**, R&D spends in Q2FY19 were Rs 120 Cr.

BUSINESS SEGMENT REVIEW

SMALL MOLECULES: APIs & Generic Formulations

The **Small Molecules** business delivered a strong revenue growth of 23% at Rs 432 Cr, led by robust API sales in Latin America, Europe and the Middle East markets driven by a better product mix across immunosuppressants, statins and other key APIs.

The **Generic Formulations** business continues to gain traction in the U.S. with improved market share for Rosuvastatin calcium tablets and sales of Simvastatin tablets launched last quarter.

BIOLOGICS: Biosimilars & Novels

Revenue from the **Biologics** segment, comprising Novel Biologics and Biosimilars, more than doubled to Rs 367 Cr in the quarter, driven by the the commercial launch of biosimilar Pegfilgrastim in the U.S. and strong sales of Insulins as well as biosimilar MABs in key emerging markets.

Biosimilars

Insulins & Analogs

During the quarter, our insulins business recorded a strong growth led by sales in several emerging markets including Malaysia and Mexico where Biocon through its local partners continues to hold a dominant share of the rh-insulin market.

Monoclonal Antibodies & Recombinant Proteins

Our partner Mylan commenced commercial sales of **Fulphila**, the first biosimilar Pegfilgrastim approved in the U.S.

Our biosimilar **Trastuzumab** continues to do well in emerging markets with launches in newer geographies and increased prescription share in markets where it has already been commercialized. During the quarter, our partner launched the product as the first biosimilar Trastuzumab in Turkey. In Algeria, our Trastuzumab continues to enjoy a wide acceptance among patients and prescribers, while in Brazil it has witnessed a strong uptake since **Zedora** (Trastuzumab) was launched in March 2018.

The **European Medicines Agency's** (EMA) Committee for Medicinal Products for Human Use (CHMP) issued positive opinions recommending approvals of **Fulphila**, a biosimilar Pegfilgrastim, and **Ogivri**, a biosimilar Trastuzumab, co-developed by Biocon and Mylan.

The CHMP positive opinions will now be considered by the European Commission and the decisions on approvals are expected later in 2018.

Our partner Mylan initiated the commercial launch of **biosimilar Adalimumab** (FKB product) across major markets in Europe, post Oct 16, 2018. Biocon will receive economic benefit for this product in line with our global collaboration with Mylan.

Novel Biologics

On **Insulin Tregopil**, our pivotal Phase 2/3 clinical study in people with Type 2 diabetes in India is progressing well.

Our **novel anti-CD6** monoclonal antibody, Itolizumab, progressed further in its clinical development journey. Our partner Equillium's Investigational New Drug (IND) application for EQ001 (Itolizumab) in an orphan indication of acute graft-versus-host disease (aGVHD) was accepted by the U.S. FDA in July 2018.

Equillium plans to initiate a Phase 1b/2 clinical trial of EQ001 (Itolizumab) for the treatment of aGVHD, in early 2019, and expects top-line data from the Phase 1b part of this trial within 12 months of initiation.

Equillium also plans to develop the asset for additional indications like cGVHD and Asthma.

To fund the clinical trials Equillium has raised USD 65 million in its maiden public offering and got listed on NASDAQ on Oct 12, 2018. Biocon's stake in Equillium post the IPO stands at approximately 13.5%.

BRANDED FORMULATIONS

The **Branded Formulations** business, which includes sales in **India** and **UAE**, reported a revenue of Rs 164 Cr, slipping 7% on a YoY basis.

The **Branded Formulations – India (BFI)** business performance was muted due to the higher base of Q2FY18 which benefited from channel restocking post GST implementation. While some of our key brands like BIOMAb EGFR[®], TACROGRAF[™], and Renodapt[®] reported double-digit growth, other lead brands had to face severe pricing pressures leading to lower than expected sales. The lower sales seen in major divisions was offset by growth in Comprehensive Care and Nephrology.

In **UAE**, the in-licensed Metabolics product portfolio and Glaricon, our brand of Insulin Glargine, continued to gain market share, while in the Branded Generics market we faced challenges with repricing of products by the Ministry of Health.

RESEARCH SERVICES – SYNGENE

The **Research Services** business continues to do well with a revenue growth of 25% at Rs 419 Cr, buoyed by good growth in Discovery Services and increased traction in the Dedicated R&D Centres.

During the quarter, Syngene has commissioned a new dedicated facility for Bristol-Myers Squibb (BMS) and renewed its collaboration with Baxter with a widened scope of engagement.

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

About Biocon Ltd:

Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is a fully-integrated, innovation-led global biopharmaceutical company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune. It has developed and taken differentiated Small Molecules, Novel Biologics and a range of Biosimilars (Monoclonal Antibodies, Pegfilgrastim, rh- Insulin and Insulin Glargine) from 'Lab to Market' in India, key emerging and developed markets. It has a large portfolio of biosimilars under clinical development with three of these approved in developed markets of US, EU, Japan and Australia. Its Novel pipeline includes promising assets like Insulin Tregopil, anti-CD6 antibody and a fusion protein for immuno-oncology. Some of its key brands are INSUGEN® (rh-insulin), Basalog One® (prefilled Glargine pen), CANMAb™ (Trastuzumab), KRABEVA® (Bevacizumab), BIOMAb-EGFR® (Nimotuzumab) and ALZUMAb™ (Itolizumab). Follow-us on Twitter: @bioconlimited, www.biocon.com

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Earnings Call

The company will conduct a call at **9.00 AM IST on October 26, 2018** where the senior management will discuss the company's performance and answer questions from participants. This call is not open to the members of the media (print/ electronic/online/wires). 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 6280 1151**. Other toll numbers are listed in the 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 Nov 4, 2018 on +91 22 7194 5757 Playback Code: 39623** Transcript of the conference call will be uploaded on the company website in due course.

DISCLAIMER: *This press release may include statements of future expectations and other forward-looking statements based on management's current expectations and beliefs concerning future developments and their potential effects upon Biocon and its subsidiaries/ associates. These forward-looking statements involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from our expectations include, amongst other: general economic and business conditions in India and overseas, 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 and global biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither Biocon, nor our Directors, or any of our subsidiaries/associates assume any obligation to update any particular forward-looking statement contained in this release.*

BIOCON GROUP

FACT SHEET

September - 2018

BIOCON LIMITED (CONSOLIDATED)
BALANCE SHEET
(Rs Cr)

	September 30, 2018	March 31, 2018
ASSETS		
Non-current assets		
(a) Property, plant and equipment	4,145	3,630
(b) Capital work-in-progress	847	779
(c) Goodwill	26	26
(d) Other intangible assets	65	43
(e) Intangible assets under development	635	524
(f) Investments in associates and a joint venture	63	64
(g) Financial assets	-	-
Investments	412	-
Derivative assets	61	111
Other financial assets	28	25
(h) Income tax asset, net	135	127
(i) Deferred tax asset, net	384	193
(j) Other non-current assets	326	319
	7,127	5,841
Current assets		
(a) Inventories	878	723
(b) Financial assets		
Investments	470	611
Trade receivables	1,039	1,064
Cash and cash equivalents	576	501
Other bank balances	660	822
Derivative assets	57	99
Other financial assets	481	192
(c) Other current assets	156	137
	4,317	4,149
TOTAL	11,444	9,990
EQUITY AND LIABILITIES		
Equity		
(a) Equity share capital	300	300
(b) Other equity	5,404	4,881
Equity attributable to owners of the Company	5,704	5,181
Non-controlling interests	486	468
	6,190	5,649
Non-current liabilities		
(a) Financial liabilities		
Borrowings	1,846	1,790
Derivative liability	180	18
Other financial liabilities	-	-
(b) Provisions	53	49
(c) Other non-current liabilities	633	342
	2,712	2,199
Current liabilities		
(a) Financial liabilities		
Borrowings	270	130
Trade payables	1,073	1,006
Derivative liability	67	6
Other financial liabilities	675	556
(b) Provisions	60	47
(c) Income tax liability, net	195	89
(d) Other current liabilities	202	308
	2,542	2,142
TOTAL	11,444	9,990

BIOCON LIMITED (CONSOLIDATED)			
PROFIT & LOSS STATEMENT			(Rs. Crores)
Particulars	H1 FY 2019	H1 FY 2018	Variance
<u>INCOME</u>			
Small molecules	832	713	17%
Biologics	617	340	82%
Branded formulations	311	306	2%
Research services	825	626	32%
Inter-segment	(140)	(83)	68%
Revenue from operations #	2,445	1,902	29%
Other income	123	105	18%
TOTAL REVENUE	2,568	2,007	28%
<u>EXPENDITURE</u>			
Material & Power costs	997	833	20%
Staff costs	500	397	26%
Research & Development expenses*	121	112	8%
Other expenses	249	186	34%
Manufacturing, staff & other expenses	1,867	1,528	22%
EBITDA	701	479	46%
Interest & Finance charges	37	30	22%
Depreciation & Amortisation	211	192	10%
Share of profit in JV / Associate, net	-	(10)	-104%
PBT BEFORE EXCEPTIONAL ITEM	453	267	70%
Exceptional item, Net	189	-	-
PBT	642	267	140%
Taxes	107	80	34%
Taxes on exceptional item	18	-	-
NET PROFIT BEFORE MINORITY INTEREST	517	187	176%
Minority interest	42	37	13%
NET PROFIT FOR THE PERIOD	475	150	217%
EPS Rs.	7.9	2.5	
<i>Note: The figures are rounded off to the nearest crores, percentages are based on absolute numbers</i>			
# Licensing Income	11	9	
* Gross Research & Development expenses	208	189	

BIOCON LIMITED (CONSOLIDATED)			(Rs. Crores)
PROFIT & LOSS STATEMENT			
Particulars	Q2 FY 19	Q2 FY 18	Variance
INCOME			
Small molecules	432	351	23%
Biologics	367	156	136%
Branded formulations	164	176	-7%
Research services	419	335	25%
Inter-segment	(61)	(49)	25%
Revenue from operations #	1,321	969	36%
Other income	54	50	7%
TOTAL REVENUE	1,375	1,019	35%
EXPENDITURE			
Material & Power costs	506	423	20%
Staff costs	263	204	29%
Research & Development expenses*	77	54	43%
Other expenses	135	105	28%
Manufacturing, staff & other expenses	981	786	25%
EBITDA	394	233	69%
Interest & Finance charges	19	14	36%
Depreciation & Amortisation	112	93	20%
Share of profit in JV / Associate, net	1	(6)	-115%
PBT BEFORE EXCEPTIONAL ITEM	262	132	99%
Exceptional item, Net	189	-	-
PBT	451	132	243%
Taxes	55	43	30%
Taxes on exceptional item	18	-	-
NET PROFIT BEFORE MINORITY INTEREST	378	89	324%
Minority interest	23	20	13%
NET PROFIT FOR THE PERIOD	355	69	416%
EPS Rs.	5.9	1.1	
<i>Note: The figures are rounded off to the nearest crores, percentages are based on absolute numbers</i>			
# Licensing Income	5	8	
* Gross Research & Development expenses	120	96	

BIOCON LIMITED (CONSOLIDATED)			(Rs. Crores)
PROFIT & LOSS STATEMENT			
Particulars	Q2 FY 19	Q1 FY 19	Variance
INCOME			
Small molecules	432	400	8%
Biologics	367	250	47%
Branded formulations	164	147	11%
Research services	419	406	3%
Inter-segment	(61)	(79)	-23%
Revenue from operations #	1,321	1,124	18%
Other income	54	69	-21%
TOTAL REVENUE	1,375	1,193	15%
EXPENDITURE			
Material & Power costs	506	491	3%
Staff costs	263	237	11%
Research & Development expenses*	77	44	74%
Other expenses	135	114	18%
Manufacturing, staff & other expenses	981	886	11%
EBITDA	394	307	28%
Interest & Finance charges	19	18	7%
Depreciation & Amortisation	112	99	13%
Share of profit in JV / Associate, net	1	(1)	-280%
PBT BEFORE EXCEPTIONAL ITEM	262	191	37%
Exceptional item, Net	189	-	-
PBT	451	191	136%
Taxes	55	52	6%
Taxes on exceptional item	18	-	0%
NET PROFIT BEFORE MINORITY INTEREST	378	139	172%
Minority interest	23	19	24%
NET PROFIT FOR THE PERIOD	355	120	196%
EPS Rs.	5.9	2.0	
<i>Note: The figures are rounded off to the nearest crores, percentages are based on absolute numbers</i>			
# Licensing Income	5	5	
* Gross Research & Development expenses	120	88	