Press Release

Biocon Q1FY20 Revenue Rs 1,490 Cr, Up 25%; EBITDA Up 51% at Rs 462 Cr; Net Profit *(excluding exceptional item)* Up 86% at Rs 223 Cr

Small Molecules up 20% at Rs 480 Cr, Biologics Up 96% at Rs 490 Cr

Bengaluru, Karnataka, India: July 25, 2019:

Biocon Ltd (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, today announced its consolidated financial results for the fiscal first quarter ended June 30, 2019.

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

*"Robust performance by our Biologics and Small Molecules business segments fuelled the **25%** growth in Q1FY20 Revenue to **Rs 1,490 Crore**. Our long-term investments in biosimilars are delivering expected results as demonstrated by the **96%** growth in our Biologics revenue at **Rs 490 Crore** this quarter, led by the expansion of our geographical footprint and increased penetration of our products in key developed and emerging markets. Small Molecules Revenue at **Rs 480 Crore** was driven by steady API sales and a multi-fold growth in Generic Formulations. Our Research Services business continues to provide profitable growth. The consolidated **EBITDA** for Q1 stood **at Rs 462 Crore** up by **51%** and **Net Profit** (excluding exceptional item) at **Rs 223** Crore grew by **86%.***

"We remain committed to develop high quality bio-therapeutics and enable affordable access to patients across world markets".

Highlights:

- **Fulphila®**, biosimilar Pegfilgrastim co-developed by Biocon and Mylan, captures 21% volume share of the Pegfilgrastim syringes market in the U.S.
- **Ogivri®**, co-developed by Biocon and Mylan, becomes the **first biosimilar Trastuzumab** to be approved in **Canada.**
- **Phase 1b/2 trial** with **Itolizumab** in patients with acute graft-versus-host disease (aGVHD) and a **Phase 1b trial** in patients with uncontrolled moderate to **severe asthma** are being conducted by our partner Equillium.
- A **greenfield project** for a **fermentation- based manufacturing facility** initiated at Visakhapatnam, Andhra Pradesh to cater to the anticipated strong volume growth in the **Small Molecules APIs and Generic Formulations** business.

FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q1FY20

As per IND-AS *In Rs Crore, except growth numbers*

Particulars	Q1FY20	Q1FY19	Growth
INCOME			
Small Molecules	**480**	400	**20%**
Biologics	**490**	250	**96%**
Branded Formulations	**133**	147	**-9%**
Research Services	**421**	406	**4%**
Inter-segment	(58)	(79)	
Revenue from Operations#	**1466**	1124	**30%**
Other Income	**24**	69	**-65%**
TOTAL REVENUE	**1490**	**1193**	**25%**
EBITDA	**462**	307	**51%**
PBT	**313**	191	64%
Net Profit *(excluding exceptional item)*	**223**	120	**86%**
Exceptional Item, Net of Tax	(17)	-	
Net Profit	**206**	**120**	**72%**
R&D Expenses in P&L	**79**	44	**78%**
Gross R&D Spends	**110**	88	
EBITDA Margin	**31%**	26%	
Core EBITDA Margin	**36%**	27%	
Net Profit Margin *(excluding exceptional item)*	**15%**	10%	
Net Profit Margin	**14%**	10%	
#includes Licensing Income	**7**	5	

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

EXECUTIVE COMMENTARY:

PERFORMANCE REVIEW: Q1FY20

- In Q1FY20, our **Consolidated Revenue** grew **25%** to **Rs 1,490 Crore** from Rs 1,193 Crore in Q1FY19.
- **Net Profit** (*excluding exceptional item*) stood at **Rs 223 Crore** reporting a growth of **86%.**
- Net Profit was impacted due to an exceptional item on account of tax on group entities restructuring.
- **Net Profit** reported a **growth of 72%** at **Rs 206 Crore** (*vs. Rs 120 Crore in Q1FY19*).
- **Earnings before Interest, Depreciation and Amortization (EBITDA)** increased **51%** to **Rs 462 Crore** (*vs. Rs 307 Crore in Q1FY19*).
- We reported a better quality of earnings this quarter as reflected in the consolidated **EBITDA margin** of **31%** in Q1FY20 (*vs. 26% in Q1FY19*).

- **Core EBITDA margin** for Q1FY20 (*net of licensing, impact of forex and R&D*) stood at **36%** (*vs. 27% in Q1FY19*).
- **Net Profit margin** *(excluding exceptional item)* stood at **15%.**
- **Net Profit margin** stood at **14%** *(vs. 10% in Q1FY19).*
- **Net R&D expenses** for the quarter at **Rs 79 Crore** was up by **78%** (*vs. Rs 44 Crore in Q1FY19*).
- **Gross R&D expenses** were **Rs 110 Crore**, corresponding to **11%** of our revenue (*excluding Syngene*).

BUSINESS SEGMENT REVIEW: Q1FY20

SMALL MOLECULES: APIs & Generic Formulations

The **Small Molecules** business reported a revenue growth of **20%** for the quarter at **Rs 480 Crore**, led by strong sales of our key APIs and a robust performance of our Generic Formulations business.

Our statins, immunosuppressants and specialty molecule APIs witnessed steady demand from customers in India, EU, LATAM, APAC, CIS and NAFTA regions. We also filed new Drug Master Files (DMF) for our specialty APIs in key regulated markets this quarter.

The **Generic Formulations** revenue grew multi-fold as the business built on its strong performance in the previous quarters, with Rosuvastatin and Simvastatin formulations maintaining their market shares, and recently introduced Atorvastatin registering good growth through the acquisition of key accounts in the U.S. market.

All our **Small Molecules manufacturing sites**, both APIs and formulations, have valid EIRs/ EU cGMP certifications. Over the years we have built a good track record with the leading regulatory agencies across the globe including U.S. FDA and EMA.

We have initiated a **greenfield project** at Visakhapatnam, Andhra Pradesh with an investment of Rs 600 Crore to secure our anticipated **growth in fermentation-derived APIs**, including our strong portfolio of immunosuppresants. This expansion will enable us to deliver on our vertically integrated strategy of developing and commercializing our own ANDAs and also service the needs of our global API customers. We expect this facility to be operational over the next 3 years followed by commercialization based on regulatory approvals in major markets.

BIOLOGICS: Biosimilars & Novels

The **Biologics** segment was the strongest performing segment in the quarter, reporting a **96%** revenue growth at **Rs 490 Crore**, led by the expansion of our biosimilars footprint in new markets and increased penetration of products already launched in some developed and emerging markets.

Biosimilars

The encouraging trend of significant biosimilars adoption in both Europe and U.S. provides an opportunity for Biocon to increase penetration of its portfolio thus enabling wider patient access leading to a dominant market share, going forward. Fulphila®, biosimilar Pegfilgrastim co-developed by Biocon and Mylan reported strong sales this quarter recording a **21% volume share** of the Pegfilgrastim syringes market in U.S. till May 2019. (*Bloomberg Symphony data, Goldman Sachs report June 2019)*.

During the quarter **Ogivri®**, co-developed by Biocon and Mylan, was approved by **Health Canada** as the **first biosimilar Trastuzumab** to be approved in the country. We also extended our geographic footprint **in EU** with the commercialization of Ogivri® (biosimilar Trastuzumab) thus expanding access to a high quality biosimilar for breast and gastric cancer patients in these markets.

Our partner Mylan continues to commercialize **Semglee®**, biosimilar Insulin Glargine, in **EU** which furthers our mission to provide affordable insulin therapy to a larger patient pool in the region.

Emerging Markets

We witnessed robust sales of our **biosimilar Trastuzumab**, **Insulin Glargine** and **rh-Insulin** in key emerging markets in **AFMET** and **LATAM** regions. We also received regulatory approvals in some **key emerging markets** for biosimilar Trastuzumab and Insulin Glargine, which augurs well for the future.

Biosimilar Adalimumab

Our partner Mylan, which recently launched **in-licensed biosimilar Adalimumab** (Hulio) in Europe has extended the commercialization rights for the biosimilar from Europe to **global markets**. Biocon retains its economic interest in this expanded in-licensing arrangement and will gain a share of profits from global markets.

Regulatory Updates

Biocon received the **Certificate of GMP compliance** from **EMA** for its manufacturing facilities for **Biologics Drug Product**, including an additional manufacturing line, and **Drug Substance** facility at Biocon Park, Bengaluru, following an inspection by the European agency in March 2019. This certification will enable us to continue addressing the growing needs of patients in the EU markets and enhance access to our high quality biosimilars. We have also received **Certificate of GMP Compliance** from **TGA, Australia** for the **Drug Product facilities** at Biocon Park.

The **U.S. FDA pre-approval** inspection of Biocon Malaysia's **Insulin Glargine Drug Substance**, **Drug Product** and **Device** assembly facilities resulted in 12 observations across the three units. We are **confident of addressing these** expeditiously. We **do not expect any change** to our partner Mylan's commercialization plans for Insulin Glargine in the U.S.

Our biosimilars business is **gaining global recognition** with three of our molecules being commercialized in developed markets viz. Pegfilgrastim in U.S., Trastuzumab in EU and

Canada, and Insulin Glargine in EU and Japan. We have also commercialized our key biosimilars in many emerging markets across AFMET, LATAM, APAC regions.

We aspire to be a global leader in biologics, making a difference to patients, people, partners and business through affordable and innovative healthcare solutions, going beyond the product. We believe we have the science, scale, scope and technology to gain market-share by addressing growing patient needs, worldwide.

Novel Biologics

Our partner Equillium, which has licensed **Itolizumab** for development in U.S. and Canada, is conducting a **Phase 1b/2 trial** in patients with acute Graft-Versus-Host Disease (**aGVHD**) and a **Phase 1b trial** in patients with uncontrolled moderate to **severe Asthma** with Itolizumab (EQ001) and plans to initiate a **Phase 1b proof-of-concept** trial for the treatment of **Lupus Nephritis** during the second half of CY 2019.

BRANDED FORMULATIONS

The **Branded Formulations** business, which includes sales in **India** and **UAE**, reported a de-growth of **9%** at **Rs 133 Crore**, as uncertainty in the UAE market continued to weigh down the overall performance of this segment.

In **India**, our Top Ten brands contributed 78% to overall sales. Our key brands like Basalog®, CANMAb™ , BIOMAb EGFR® and KRABEVA ® reported a strong double digit growth. Our flagship insulin products, Insugen® and Basalog®, have cumulatively made a difference to over 35,800* diabetes patients in India this quarter. Our biologic cancer therapies, BIOMAb EGFR®, CANMAb™ & KRABEVA® benefited over 1,250# patients in India during Q1FY20.

Our business in **UAE** continued to be impacted due to re-pricing of branded generic products mandated by the Ministry of Health. On the other hand, CANHERA (biosimilar Trastuzumab) has captured a high-twenties share of the market for Trastuzumab in UAE *(Source: IMS YTD May 2019)* in volume terms. Glaricon, our biosimilar Insulin Glargine, is one of the fastest growing brands *(Source: IMS YTD May 2019)* in the market.

RESEARCH SERVICES – SYNGENE

Revenue from the **Research Services** business this quarter stood at **Rs 421 Crore** driven by Discovery Services and Dedicated R&D Centre businesses. Overall the company reported a modest **4%** growth.

During the quarter, Syngene completed a U.S. FDA inspection for its Human Pharmacology Unit (HPU) in clinical development, making it the seventh successful FDA inspection without any observations. The Company is setting up a new research centre in Hyderabad to support its long term growth strategy.

** The estimated patient reach numbers have been calculated indirectly based on volume supplied and certain assumptions related to dosage per patient, duration of treatment, units sold, internal data and market research reports.*
#IPSOS data.

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 biopharmaceuticals company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune diseases. The Company has developed and commercialized a range of Biosimilars (Monoclonal Antibodies, Pegfilgrastim, rh- Insulin and Insulin Glargine), Novel Biologics and differentiated Small Molecules in India and key emerging markets. It has a large portfolio of biosimilars under global clinical development with three of these commercialized in the developed markets of EU, U.S. and Japan. It has promising novel assets in immunotherapy under development. Some of its key brands are INSUGEN® (rh-insulin), Basalog One® (prefilled Glargine pen), CANMAb™ (Trastuzumab), KRABEVA® (Bevacizumab), BIOMAb-EGFR® (Nimotuzumab) and ALZUMAb™ (Itolizumab). www.biocon.com Follow-us on Twitter: @bioconlimited

Earnings Call

The company will conduct a call at 9.00 AM IST on July 26, 2019 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 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 August 2, 2019 on +91 22 7194 5757 or +91 22 6663 5757, Playback Code: 30993. Transcript of the conference call will be uploaded on the company website in due course.

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***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

F A C T S H E E T

June - 2019

BIOCON LIMITED (CONSOLIDATED)
BALANCE SHEET

(Rs Cr)

	June 30, 2019	March 31, 2019
ASSETS		
Non-current assets		
(a) Property, plant and equipment	4,269	4,253
(b) Capital work-in-progress	1,501	1,287
(c) Right-of-use assets	45	-
(d) Goodwill	26	26
(e) Other intangible assets	187	192
(f) Intangible assets under development	669	612
(g) Investments in associates and a joint venture	35	43
(h) Financial assets		
Investments	102	139
Derivative assets	82	71
Other financial assets	40	39
(i) Income-tax asset, net	176	169
(j) Deferred tax asset, net	333	325
(k) Other non-current assets	269	213
	7,735	**7,370**
Current assets		
(a) Inventories	1,187	1,032
(b) Financial assets		
Investments	665	829
Trade receivables	1,149	1,292
Cash and cash equivalents	773	730
Other bank balances	286	327
Derivative assets	82	78
Other financial assets	584	387
(c) Other current assets	175	149
	4,901	**4,823**
TOTAL	**12,636**	**12,192**
EQUITY AND LIABILITIES		
Equity		
(a) Equity share capital	600	300
(b) Other equity	5,664	5,798
Equity attributable to owners of the Company	**6,264**	**6,098**
Non-controlling interests	625	609
	6,888	**6,707**
Non-current liabilities		
(a) Financial liabilities		
Borrowings	1,634	1,542
Derivative liability	56	35
Other financial liabilities	-	-
(b) Provisions	69	66
(c) Other non-current liabilities	852	805
	2,611	**2,448**
Current liabilities		
(a) Financial liabilities		
Borrowings	265	261
Trade payables	1,278	1,198
Derivative liability	8	14
Other financial liabilities	1,004	991
(b) Provisions	101	81
(c) Income tax liability, net	169	124
(d) Other current liabilities	311	369
	3,137	**3,038**
TOTAL	**12,636**	**12,192**

BIOCON LIMITED (CONSOLIDATED)
PROFIT & LOSS STATEMENT (Rs. Crores)

Particulars	Q1 FY 20	Q1 FY 19	Variance
INCOME			
Small molecules	480	400	20%
Biologics	490	250	96%
Branded formulations	133	147	-9%
Research services	421	406	4%
Inter-segment	(58)	(79)	-27%
Revenue from operations #	**1,466**	**1,124**	**30%**
Other income	24	69	-65%
TOTAL REVENUE	**1,490**	**1,193**	**25%**
EXPENDITURE			
Material & Power costs	491	491	0%
Staff costs	309	237	31%
Research & Development expenses*	79	44	78%
Other expenses	149	114	31%
Manufacturing, staff & other expenses	**1,028**	**886**	**16%**
EBITDA	**462**	**307**	**51%**
Interest & Finance charges	17	18	-6%
Depreciation & Amortisation	124	99	25%
Share of profit in JV / Associate, net	8	(1)	-1680%
PBT BEFORE EXCEPTIONAL ITEM	**313**	**191**	**64%**
Exceptional item, Net	-	-	-
PBT	**313**	**191**	**64%**
Taxes	69	52	32%
Taxes on exceptional item	17	-	-
NET PROFIT BEFORE MINORITY INTEREST	**228**	**139**	**65%**
Minority interest	21	19	15%
NET PROFIT FOR THE PERIOD	**206**	**120**	**72%**
EPS Rs.	**1.7**	**1.0**	
NET PROFIT BEFORE EXCEPTIONAL ITEM	**223**	**120**	**86%**
Exceptional item, net of taxes	(17)	-	
NET PROFIT FOR THE PERIOD	**206**	**120**	**72%**

Note: The figures are rounded off to the nearest crores, percentages are based on absolute numbers

# Licensing Income	*7*	*5*
** Gross Research & Development expenses*	*110*	*88*

BIOCON LIMITED (CONSOLIDATED)

PROFIT & LOSS STATEMENT (Rs. Crores)

Particulars	Q1 FY 20	Q4 FY 19	Variance
INCOME			
Small molecules	480	472	2%
Biologics	490	451	9%
Branded formulations	133	133	0%
Research services	421	534	-21%
Inter-segment	(58)	(61)	-6%
Revenue from operations #	**1,466**	**1,529**	**-4%**
Other income	24	28	-15%
TOTAL REVENUE	**1,490**	**1,557**	**-4%**
EXPENDITURE			
Material & Power costs	491	549	-10%
Staff costs	309	293	6%
Research & Development expenses*	79	92	-15%
Other expenses	149	193	-22%
Manufacturing, staff & other expenses	**1,028**	**1,126**	**-9%**
EBITDA	**462**	**431**	**7%**
Interest & Finance charges	17	16	4%
Depreciation & Amortisation	124	120	4%
Share of profit in JV / Associate, net	8	11	-29%
PBT BEFORE EXCEPTIONAL ITEM	**313**	**284**	**10%**
Exceptional item, Net	-	-	-
PBT	**313**	**284**	**10%**
Taxes	69	41	68%
Taxes on exceptional item	17	-	0%
NET PROFIT BEFORE MINORITY INTEREST	**228**	**243**	**-6%**
Minority interest	21	30	-28%
NET PROFIT FOR THE PERIOD	**206**	**214**	**-3%**
EPS Rs.	**1.7**	**1.8**	
NET PROFIT BEFORE EXCEPTIONAL ITEM	**223**	**214**	**4%**
Exceptional item, net of taxes	(17)	-	
NET PROFIT FOR THE PERIOD	**206**	**214**	**-3%**

Note: The figures are rounded off to the nearest crores, percentages are based on absolute numbers

# Licensing Income	*7*	*7*
** Gross Research & Development expenses*	*110*	*166*