

Press Release

Biocon Q2FY20 Earnings
Revenue at Rs 1,611 Cr, Up 17 %; EBITDA at Rs 441 Cr, Up 12%;
Net Profit (excluding exceptional item) at Rs 189 Cr, Up 3%

Biologics Up 40% at Rs 516 Cr; Small Molecules up 23% at Rs 530 Cr;
Research Services up 11% at Rs 465 Cr

Bengaluru, Karnataka, India: October 23, 2019:

Biocon Ltd (BSE code: 532523, NSE: BIOCON), an innovation-led global biopharmaceuticals company, today announced its consolidated financial results for the fiscal second quarter ended September 30, 2019.

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

“A robust growth of 40% by Biologics and 23% by Small Molecules, coupled with a steady performance by the Research Services business drove the consolidated Revenue for the quarter to Rs 1,611 Crore, reporting a growth of 17% (YoY). We have increased investments in R&D for portfolio expansion as well as for high quality talent acquisition to enable independent management of Biocon Biologics, Small Molecules and Novels businesses under the new organizational structure. These costs have led to Net Profit (adjusted for exceptional item) of Rs 189 Crore, marginally higher than last year and positions us for a strong future. Reported Net Profit for Q2FY20 stood at Rs 216 Crore which is lower on a YoY basis due to an exceptional income of Rs 171 Crore reported in Q2FY19.*

“For H1FY20, revenue grew by 21% and EBITDA recorded a strong growth of 29% over last year. We have entered into licensing and strategic partnerships across our Small Molecules and Biosimilars businesses this quarter to deliver on our promise of providing affordable access to patients globally. We expect growth momentum to build further in the second half of FY20, driven by biosimilars launches in the U.S. and Generic Formulations business, and expected additional capacities coming online later this fiscal.”

**This includes one-time gain as company fair valued its investment in U.S. based Equillium.*

MANAGEMENT & BOARD UPDATE

- **Dr Arun Chandavarkar, Chief Executive Officer and Joint Managing Director of Biocon**, will retire on Nov. 30, 2019, after 29 years of outstanding contribution to the evolution and success of Biocon.
- **Mr Siddharth Mittal, Chief Financial Officer and President – Finance**, will take over as **Chief Executive Officer and Joint Managing Director of the Company** for a period of five years commencing from Dec. 1, 2019.

Recognising Dr Arun Chandavarkar's contribution to Biocon, Kiran Mazumdar -Shaw, said, "Arun has played a critical role in the evolution of Biocon for nearly three decades. He has made invaluable contribution to enable the company to deliver on its long term commitment to its stakeholders. On behalf of the entire board, I thank Arun for his leadership and dedication to Biocon's continued success. Arun's vision and drive have strengthened the foundations of Biocon and he leaves behind a rich legacy of excellence. We wish him great success in his next innings."

Welcoming Mr Siddharth Mittal she said: "I am extremely happy to have **Siddharth** take on the mantle of **CEO & Joint MD**. Siddharth has been a core member of the leadership team at Biocon since May 2013 and I am confident that, in his new role, he will build immense value for Biocon and its stakeholders."

- **Dr Jeremy Levin**, has expressed his desire to step down as an Independent Director of Biocon at the conclusion of Q3FY20 Board meeting in Jan 2020. His expanding commitments in the US have restricted his bandwidth to attend Biocon Board meetings in person. He will, however, continue to be associated with the Company in an advisory role. The Board acknowledges his immense contribution and his valuable insights over the past five years.

BUSINESS HIGHLIGHTS

- Biocon extended its **footprint** to **China**, the **world's 2nd largest pharma market**, licensed out **three Generic Formulations products** to **China Medical System Holdings**.
- Biocon Biologics **expanded its R&D footprint** through acquisition of the **R&D capital assets** for a 60,000 sq. ft. world-class integrated R&D facility at TICEL Bio Park, Chennai.
- **Biocon Biologics** will enable universal access to **rh-Insulin** by reducing prices to **less than 10 US cents / day** for **Low and Middle-Income Countries (LMICs)**.
- Biocon Biologics **in-licensed** an early-stage **biosimilar** asset from **Just - Evotec**, and will undertake development, manufacturing and commercialization under its own label.

- Received **U.S. FDA approval** for **additional Drug Product manufacturing filling line** for **Ogivri®** (*biosimilar Trastuzumab*) 150 mg / vials.
- Received the **Certificate of GMP compliance** from the **European Medicines Agency** for **Malaysia Insulin Glargine manufacturing facility**.
- **Small Molecule APIs manufacturing facility in Bengaluru** successfully underwent an inspection by **COFEPRIS**, the Mexican health regulatory agency, and reported **Zero observations**.

FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q2FY20

As per IND-AS

In Rs Crore, except growth numbers

Particulars	Q2FY20	Q2FY19	Growth
INCOME			
Small Molecules	530	432	23%
Biologics	516	368	40%
Branded Formulations	128	164	-22%
Research Services	465	419	11%
Inter-segment	(66)	(61)	
Revenue from Operations[#]	1,572	1,322	19%
Other Income	38	54	-29%
TOTAL REVENUE	1,611	1,376	17%
EBITDA	441	394	12%
PBT	354	451	-22%
Net Profit	216	355	-39%
Net Profit (adjusted for exceptional item)	189	184	3%
Exceptional Item (net of tax)	27	171	
R&D Expenses in P&L	104	77	36%
Gross R&D Spends	123	88	39%
EBITDA Margin	27%	29%	
Core EBITDA Margin	33%	33%	
Net Profit Margin	13%	26%	
Net Profit Margin (excluding exceptional item & associated tax)	12%	13%	
[#] includes Licensing Income	7	5	

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

EXECUTIVE COMMENTARY:

PERFORMANCE REVIEW: Q2FY20

- In Q2FY20, our **Consolidated Revenue** grew **17%** to **Rs 1,611 Crore** from Rs 1,376 Crore in Q2FY19.
- **Net Profit** on a YoY basis was lower at **Rs 216 Crore** (vs. *Rs 355 Crore in Q2FY19*) due to an exceptional income of Rs 171* Crore reported in Q2FY19.

- **Net Profit** (excluding exceptional item) at **Rs 189 Crore** (vs. Rs 184 Crore in Q2FY19) reported a growth of 3% .
This was impacted by an increase in our R&D expenses for enabling portfolio expansion and higher employee costs to support independent management of Small Molecules, Biocon Biologics and Novel Molecules businesses under new organizational structure.
- **Earnings before Interest, Depreciation and Amortization (EBITDA)** increased **12%** to **Rs 441 Crore** (vs. Rs 394 Crore in Q2FY19).
- **The consolidated EBITDA margin** stood at of **27%** in Q2FY20 (vs. 29% in Q2FY19).
- **Core EBITDA margin** for Q2FY20 (net of licensing, impact of forex and R&D) stood at **33%** (vs. 33% in Q2FY19).
- EBITDA margin was impacted due to an increase in employee benefit expenses and other costs including higher marketing and profit share expenses. While Core EBITDA margin was maintained at the same level as last year.
- **Net Profit margin** (excluding exceptional item) stood at **12%** (vs. 13% in Q2FY19).
- **Net Profit margin** stood at **13%** (vs. 26% in Q2FY19).
- **Net R&D expenses** for the quarter at **Rs 104 Crore** was up by **36%** (vs. Rs 77 Crore in Q2FY19).
- **Gross R&D expenses** were **Rs 123 Crore**, up 39%, (vs. Rs 88 Crore in Q2FY19) corresponding to **11%** of our revenue (excluding Syngene).

BUSINESS SEGMENT REVIEW: Q2FY20

SMALL MOLECULES: APIs & Generic Formulations

- Q2 FY20 Revenue at **Rs 530 Crore**, up 23% (YoY)
- H1 FY20 Revenue at **Rs 1009 Crore**, up 21% (YoY)

The **Small Molecules** business reported a revenue growth of **23%** for the quarter at **Rs 530 Crore**, led by stable business for our key APIs and a robust quarterly performance by our Generic Formulations business.

Our APIs portfolio of statins and immunosuppressants witnessed a strong demand across all key geographies, while our specialty APIs witnessed robust uptake in regulated markets this quarter.

The **Generic Formulations** revenue grew with the expansion of our client base for Rosuvastatin, Simvastatin and Atorvastatin formulations, which have been commercialized under our own label in the U.S.

Biocon **expanded its geographic reach to China** through a License and Supply Agreement with a subsidiary of China Medical System Holdings Ltd. (CMS) for **three Generic Formulations** products. This agreement will allow Biocon to take its U.S.-approved Generic Formulations to patients in China, allowing an early **entry into the world's second largest** pharmaceuticals

market. Biocon will be responsible **for the development, manufacturing and supply** of the products, while CMS will be responsible for registration and commercialization. The total addressable **market size** for these three products in Mainland China is about **US\$ 0.8 billion**, as per recent IQVIA data.

During the quarter, our **APIs manufacturing facility in Bengaluru** successfully underwent an inspection by COFEPRIS, the Mexican health regulatory agency, and reported **Zero observations**.

Our **Small Molecules APIs** manufacturing facility in Hyderabad won the **‘Annual Greentech Environment Award 2019’** for ‘Outstanding Achievements in Environment Management in the Pharmaceutical Sector’.

BIOCON BIOLOGICS: Biosimilars

- Q2 FY20 **Revenue** at **Rs 516 Crore**, up 40% (YoY)
- H1 FY20 **Revenue** **Rs 1006 Crore**, up 63% (YoY)
- **Patient Reach** of Biocon Biologics’ Biosimilars (YTD): 538,000

The **Biologics** segment reported a strong revenue growth of **40%** at **Rs 516 Crore** for Q2FY20, led by a robust performance by key biosimilars portfolio in developed and emerging markets. The business is well placed for even stronger performance in the second half of the year. For H1FY20, **PBIT margins** were strong at **31%**.

Commenting on the performance, **Dr Christiane Hamacher, CEO, Biocon Biologics**, said, *“We are extremely excited to Cross the Rs 1000 Cr revenue milestone in H1 FY20 and are committed to pursue the path of innovation to enable affordable access to patients across the world. Biocon Biologics aspires to be a global leader in high quality biosimilars with a revenue target of US\$ 1 billion by FY 2022. Together with a team of over 4000 people we have embarked on a journey of transforming healthcare and transforming lives.”*

Biosimilars

Biocon Biologics **reaffirmed its commitment to enable universal access to high quality insulin** by offering recombinant human Insulin (**rh-Insulin**) at **less than 10 US cents / day** for direct procurement by governments in low and middle-income countries (LMICs). The announcement was made at a UNAIDS Health Innovation Exchange event held on the sidelines of the 74th session of the UN General Assembly in New York. UNAIDS welcomed the announcement by Biocon.

Another significant development is the **U.S. Food and Drug Administration (FDA) approval** of our partner Mylan's **supplemental Biologics License Application (sBLA)** for the **additional capacity for manufacturing Ogivri® 150 mg / vial drug product**. This follows the pre-approval Inspection (PAI) of Biocon's New Drug Product (DP) filling line at B-2 Biologics Facility, conducted between Sept 10 and Sept 19, 2019. This approval will expand Biocon Biologics' capacity to supply Trastuzumab and ensure the **flexibility of offering both 420 mg and 150 mg** presentations of Ogivri® to patients in the U.S.

The Q2FY20 revenue was fuelled by sales of **Fulphila®** (*biosimilar Pegfilgrastim*) in U.S., **Hulio®** (*biosimilar Adalimumab*) in EU and our biosimilar Trastuzumab in several emerging markets like Brazil, Turkey and Algeria. Furthermore, two of our biosimilars co-developed with Mylan were commercialized in **Australia**. **Semglee®** and **Ogivri®** are the first biosimilar Insulin Glargine and biosimilar Trastuzumab, respectively, to be made available in Australia through the Pharmaceutical Benefits Scheme.

Insulin sales remain strong in most of the world markets including APAC and LATAM regions, Biocon Biologics is a leading global insulins player with over 15 years of experience in addressing the needs of patients with diabetes, having provided over 2 billion doses of human insulin worldwide, thus far.

Biocon Biologics undertook **strategic partnerships** and **acquisitions** during the quarter to rapidly expand its biosimilars portfolio which increases the addressable market opportunity for Biocon Biologics, quite significantly.

We in-licensed an **early-stage, pre-clinical biosimilar asset** from **Just – Evotec Biologics**, wholly owned by Evotec SE. We will **develop, manufacture and commercialize the biosimilar under the Biocon Biologics label** in global markets. Just – Evotec has received an undisclosed license fee and will receive milestone payments.

We also **expanded our R&D footprint** in the quarter by acquiring Pfizer Healthcare India Ltd.'s **R&D capital assets** to set up a 60,000 sq. ft. **world-class integrated R&D facility** at TICEL Bio Park in Chennai. The high-end facility will enable Biocon Biologics to expand its R&D capability and **fast-forward development of its biosimilars from lab to pilot scale**. The facility is expected to be operational in a few months post qualification and will house over 250 scientists.

Product Portfolio

Biocon Biologics has a product pipeline of 28 molecules, including 11 with Mylan, several with Sandoz, and is developing many independently. The Company's therapeutic basket includes molecules from diabetes, oncology, immunology, dermatology, ophthalmology, neurology, rheumatology and inflammatory diseases.

Regulatory Updates

Biocon's **Malaysia Insulin Glargine manufacturing facility** received the **Certificate of GMP compliance** from the **European Medicines Agency**. This approval expands Biocon Biologics' capacities multi-fold with the **new large-scale devices facility coming up to speed** to serve the needs of people with diabetes in EU.

BRANDED FORMULATIONS

- Q2 FY20 Revenue at **Rs 128 Crore**, down 22% (YoY)
- H1 FY20 Revenue **Rs 262 Crore**, down 16% (YoY)

The **Branded Formulations** business reported a **revenue of Rs 128 Crore** for Q2FY20. The business in India registered a single digit growth but overall performance was impacted due to subdued performance in UAE.

In **India**, the **Market Access** and **Immunotherapy** divisions reported a double-digit growth, but it was offset by the muted performance of other divisions. Key Brands like **Basalog®**, **BIOMAb EGFR®** and **Psorid®** reported double digit growth.

Our **Branded Formulations** business in **UAE** continued to be under pressure due to lower offtake of our branded generics post the price revision by the Ministry of Health. However, our biosimilar portfolio continues to do well with **CANHERA** (*biosimilar Trastuzumab*) capturing 29% volume market share and **Glaricon** (*biosimilar Insulin Glargine*) growing at 21% is one of the fastest growing brands with a double digit volume market share. (*Source: IMS YTD Aug 2019*).

NOVEL BIOLOGICS

Our partner **Equillium** initiated a **Phase 1b proof-of-concept trial** of **Itolizumab** (EQ001) in patients with **Lupus Nephritis in U.S. this quarter**.

RESEARCH SERVICES – SYNGENE

- Q2 FY20 Revenue at **Rs 465 Crore**, up 11% (YoY)
- H1 FY20 Revenue at **Rs 886 Crore**, up 7% (YoY)

Revenue from the **Research Services** business this quarter stood at **Rs 465 Crore**, a growth of **11%**, driven by continued growth in the **Discovery Services** business and consistent performances in the **Dedicated R&D Centres** and **Development Services** business.

Syngene operationalized the **first phase of new 50,000 sq. ft. research facility** in Hyderabad, which will house a team of **nearly 150 discovery research scientists**.

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 an innovation-led global biopharmaceuticals company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune. It is a leading global player for APIs including statins, immunosuppressants and specialty molecules. **Biocon** has developed and commercialized novel biologics, biosimilars, and complex small molecule APIs in India and several key global markets as well as generic formulations in the US and Europe. It also has a pipeline of promising novel assets in immunotherapy under development. Biocon is committed to pursue the path of innovation to develop products that have the potential to benefit a billion lives.

Biocon Biologics is a subsidiary of Biocon Ltd. It is uniquely positioned as a fully integrated ‘pure play’ biosimilars organization in the world and aspires to transform patient lives through innovative and inclusive healthcare solutions. The Company has a large portfolio of biosimilars under global clinical development with three of these commercialized in developed markets like EU, U.S. Australia and Japan.

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Earnings Call

The company will conduct a call at 9.00 AM IST on October 24, 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 October 31, 2019 on +91 22 7194 5757 or +91 22 6663 5757, Playback Code: 99244. Transcript of the conference call will be uploaded on the company website in due course.

FOR MORE INFORMATION	
MEDIA RELATIONS Seema Ahuja Sr. VP & Global Head, Corporate Communications ☎ +91 80 2808 2222 📠 +91 99723 17792 ✉ seema.ahuja@biocon.com	INVESTOR RELATIONS Saurabh Paliwal Head, Investor Relations ☎ +91 80 6775 2040 📠 +91 95383 80801 ✉ investor.relations@biocon.com

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