



PRESS RELEASE

Biocon Q2FY21 Revenue at Rs 1,760 Cr, Up 10%;
EBITDA at Rs 407 Cr;
Net Profit *(before exceptional item & discontinuing operations)* **at Rs 174 Cr;**
Generics Up 8% at Rs 599 Cr; Biosimilars Up 11% at Rs 676 Cr;
Research Services Up 12% at Rs 520 Cr.

Bengaluru, Karnataka, India: October 22, 2020:

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, 2020.

Commenting on the results, **Kiran Mazumdar-Shaw, Executive Chairperson, Biocon**, said:

*“Consolidated revenue for Q2FY21 increased 10% to **Rs 1,760 Crore** driven by 11% growth in **Biosimilars**, 12% in **Research Services** and 8% in **Generics**, businesses. **EBITDA** for the quarter stood at **Rs 407 Crore** and **Net Profit** *(before exceptional item & discontinuing operations)* was at **Rs 174 Crore**. Our profitability was impacted on account of higher R&D expenses, staff costs, other expenses and forex losses. However, our **Core EBITDA margins** stood at a healthy **32%**, indicating sound operational performance.”*

*“Our **Insulin Glargine, Semglee®**, was commercialized in the U.S. by our partner Mylan, during the quarter, thus heralding our entry into the US Insulins market. With this launch, we have expanded our portfolio of Biosimilars and occupy a position of impactful influence in the Biosimilars segment.”*

*“As a part of our commitment to address the novel coronavirus pandemic in India, the Biocon Group is working on a comprehensive portfolio of products for treating mild to severely ill COVID-19 patients. We have introduced **ARAFLU®** (Favipiravir) in addition to **Cytosorb®** and **ALZUMAB-L™**, and Syngene has started manufacturing **Remdesivir** under a voluntary licensing agreement with Gilead.” she added.*

BUSINESS HIGHLIGHTS

BIOSIMILARS: Biocon Biologics

- Insulin Glargine, Semglee®, commercialized in the U.S., making it the third product under the Biocon Biologics / Mylan collaboration to be launched in the U.S.
- Expanded business in Europe with the launch of Semglee in Spain, the third largest market among the EU5, by value.

- Mission 10 cents rolled out in Philippines to unlock universal access to quality insulins; MoU signed with 2 municipal governments for long-term, integrated diabetes management program.
- Phase IV clinical trials with Itolizumab for COVID-19, initiated in India.
- Tata Capital Growth Fund invested ~USD 30 million (Rs 225 Crore) in Biocon Biologics for an equity stake of 0.85%, valuing the entity at USD 3.5 billion.

NOVEL BIOLOGICS

- Steady progress towards deploying **Itolizumab, our first-in-class anti-CD6 monoclonal antibody, to treat Covid-19, globally**. Our US-based partner, Equillum, has received positive feedback from their pre-IND (Investigational New Drug) meeting with the USFDA and is advancing along the regulatory pathway in preparation for initiating a global Phase III, randomized, double-blind, placebo-controlled clinical trial in Q4 CY20.

RESEARCH SERVICES: Syngene

- Commenced manufacturing Remdesivir in Bengaluru as part of the voluntary licensing agreement with Gilead.

BIOCON FOUNDATION

- Signed an MoU with the Bengaluru Metro Rail Corporation Limited to contribute Rs 65 Cr towards building the metro station at Hebbagodi.

EXECUTIVE COMMENTARY:

PERFORMANCE REVIEW: Q2FY21

- **Q2FY21 Consolidated Revenue** grew **10%** to **Rs 1,760 Crore** from Rs 1,606 Crore in Q2FY20.
- **Q2FY21 Earnings before Interest, Depreciation and Amortization (EBITDA)** was **Rs 407 Crore** (vs. Rs 441 Crore in Q2FY20)
- **Q2FY21 Net Profit** (before exceptional item and discontinuing operations) was at **Rs 174 Crore** (vs. Rs 198 Crore in Q2FY20) was down (12%)
- **Q2FY21 Net Profit** at **Rs 169 Crore** (vs. Rs 216 Crore in Q2FY20) was down (22%)
- **Net Profit** for Q2FY21 was impacted due to higher R&D expenses at **Rs 148 Crore** (Vs Rs 104 Crore in Q2FY20) up by 42%, forex losses and higher staff & other expenses.
- **Our Core EBITDA margins were at a healthy 32%**

FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q2FY21

In Rs Crore

Particulars	Q2FY21	Q2FY20	Growth
INCOME			
Generics	599	553	8%
Biosimilars	676	607	11%
Novel Biologics	-	-	-
Research Services	520	465	12%
Inter-segment	(50)	(57)	(13%)
Revenue from Operations[#]	1745	1567	11%
Other Income	16	38	(60%)
TOTAL REVENUE	1760	1606	10%
EBITDA	407	441	(8%)
PBT (before exceptional item)	223	296	(25%)
Net Profit (before exceptional item and discontinuing operation)	174	198	(12%)
Loss from discontinuing operation	5	9	(47%)
Exceptional item, net of taxes	-	27	(100%)
Net Profit	169	216	(22%)
R&D Expenses in P&L	148	104	42%
Gross R&D Spends	165	123	35%
EBITDA Margin	23%	27%	
Core EBITDA Margin	32%	33%	
Net Profit Margin	10%	13%	
<i>[#]includes Licensing Income</i>			

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

BUSINESS SEGMENT REVIEW: Q2FY21

GENERICS: APIs & Generic Formulations

- Q2FY21 revenue at Rs 599 Crore, up 8 percent (YoY) from Rs 553 Crore in Q2FY20.
- H1 FY21 revenue at Rs 1,198 Crore; up 12%

The Generics business reported revenue growth of 8% YoY, driven by a strong performance in our generic formulations business in the US, where our products continued to hold mid to high teens market share. In the API business, growth was largely driven by immunosuppressants and other speciality APIs.

Commenting on the performance, **Siddharth Mittal, CEO and Managing Director, Biocon Limited**, said, *“Our Q2 performance was in line with expectations. I am pleased that we were able to ensure business continuity and serve patients across the world despite the challenges that Covid-19 brought with it.*

Looking ahead, we expect the generic formulations business to continue to drive growth, based on new launches in the US for products which are currently under regulatory review. We also plan to commercialise Remdesivir in India as part of our commitment towards providing treatment for Covid-19.”

During the quarter, we received a Complete Response Letter (CRL) from the US FDA for gCopaxone (40mg and 20mg), primarily relating to queries on drug substance. We are working expeditiously to address the queries and expect to respond to the CRL within the next few months.

We submitted Drug Master Files for three APIs in the US and seven APIs in other markets. We also received licenses from MHRA, UK, to import and distribute products there. This is in line with our plans to commercialise our formulations directly in the UK.

The construction of a greenfield facility in Visakhapatnam for immunosuppressant APIs has been slightly impacted due to delays by our vendors on account of Covid-19. We expect this facility to be commissioned by CY 2022. Our existing facility in Visakhapatnam, where we manufacture high-potent APIs, has received ISO 14001-2015 and ISO 45001-2018 certifications for its environmental management and occupational health & safety management systems, respectively.

BIOSIMILARS: Biocon Biologics

- **Q2FY21 revenue at Rs 676 Crore up 11 % (YoY) from Rs 607 crore in Q2FY20**
- **H1 FY21 revenue at Rs 1368 Crore; up 15%**
- **Segment EBITDA for Q2FY21 at Rs 176 crore**
- **Patients benefited through Biocon Biologics’ biosimilars in Q2FY21 (MAT Oct 19- Sep 2020) 3.3 million[#]**

The Biosimilars segment reported a revenue **growth of 11%** to **Rs 676 Crore** in Q2FY21 driven by sales of our key biosimilars in developed as well as Most of the World (MoW) markets.

Commenting on the performance, **Dr Christiane Hamacher, CEO & Managing Director, Biocon Biologics Ltd**, said, *“Our Biosimilars business recorded a quarterly revenue of Rs 676 Crore with a growth of 11% year-on-year, led by biosimilars Trastuzumab and Pegfilgrastim in developed markets including US. We also launched Insulin Glargine, our third product in the US, to address the needs of patients with diabetes. As a part of our commitment to enable universal access to affordable insulins in low- and middle-income countries we also rolled out our ‘Mission 10 cents’ in the Philippines. While we continue to see strong demand for our products globally, we are experiencing some operational challenges which have prevented us from*

achieving our full potential. However, we are confident of addressing these, going forward, as a part of our commitment to expand access to life-saving, quality biosimilars including monoclonal antibodies and insulin analogs, for millions of patients across the globe.”

“Our value unlocking plans for Biocon Biologics progressed further with a private equity investment of Rs 225 Crore by Tata Capital pushing up Biocon Biologics’ equity valuation to USD 3.5 billion.”, she added.

Commercial Update

Our biosimilar **Trastuzumab, Ogivri®**, co-developed with Mylan, is holding ground in the U.S., with a 6% share of the overall Trastuzumab market and 4% and 10% in the 150 mg and 420 mg segments, respectively, in Q2FY21. Our biosimilar **Pegfilgrastim, Fulphila®**, co-developed with Mylan, held 15% of the prefilled syringe market in the U.S. for Q2FY21. (Source: Market share July-Sep 2020: IQVIA WSP). **Ogivri** continues to be the leading biosimilar Trastuzumab in Australia and Canada and it has a double-digit share in 3 markets in Europe.

For **Semglee®**, our biosimilar **Insulin Glargine**, co-developed with Mylan, we are witnessing encouraging market penetration in certain markets such as Slovakia and Croatia.

Product Launches

We continued to expand our commercial presence with the launch of our key biosimilars in developed and some Most of the World (MoW) markets.

We expanded our portfolio in the U.S. with the commercial launch of **Semglee, Insulin Glargine** injection in vial and pre-filled pen presentations by our partner Mylan this quarter. In order to broaden patient access to this critical life-saving therapy for people with diabetes, Mylan has made Semglee available at a 65% discounted list price, which is the lowest price for a long-acting Insulin Glargine in the market and represents real value to the U.S. healthcare system.

Semglee is the third product under the Biocon Biologics-Mylan collaboration to be commercialized in the U.S. **With the launch of Semglee, Biocon Biologics becomes the only company from India to have a biosimilar monoclonal antibody, a therapeutic protein and an insulin analog commercialized in the U.S.**

We also further expanded business in Europe with the launch of **Semglee** in **Spain**, which is the third largest market among the EU5 by value (after Germany and France). Our partner Mylan has also launched **biosimilar Etanercept** in Europe where we have economic interest.

We continue to build momentum in MoW markets. During the quarter, **we had 5 product launches and 3 new market entries with our key biosimilars Trastuzumab, rh- Insulin and Insulin Glargine.**

We are further **expanding our global footprint** through a direct presence and have set up commercial offices in Brazil, Malaysia, UAE and Saudi Arabia which would enable us to expand our business in MoW markets.

In-development Biosimilars Update

We continue to advance our pipeline of in-development biosimilars. We are in the process of completing the integration of our R&D site in Chennai, which is currently undergoing qualification, and will expand our R&D capabilities significantly once completed.

The **Biologics License Application (BLA)** for **biosimilar Insulin Aspart** under the 351(k) pathway has been submitted to the U.S. Food and Drug Administration (FDA) and is currently under review.

Our **BLA for Insulin Glargine** has also been submitted to the U.S. FDA under the 351(k) pathway for interchangeability status, and is currently under review.

'Mission 10 cents' Rollout

As a part of '**Mission 10 cents**' program aimed at making our high quality recombinant human insulin (rh-insulin) available for less than 10 U.S. cents per day, in low- and middle-income countries (LMICs), a Memorandum of Understanding (MoU) has been signed with two municipalities in the Philippines.

Itolizumab: Update

We have commenced enrolment for a **300-patient, Phase IV clinical study across 15 centres** in India in order to generate a larger body of scientific evidence to support the safety, efficacy and usefulness of Itolizumab in prevention and treatment of Cytokine Release Syndrome (CRS) in COVID-19 patients with moderate to severe Acute Respiratory Distress Syndrome (ARDS).

Biocon Biologics' Comprehensive COVID-19 Portfolio in India

ALZUMAb-L™, a new 100 mg/vial formulation of **Itolizumab**, has been approved by the Drugs Controller General of India (DCGI) for treating *CRS* in moderate to severe ARDS due to COVID-19, this quarter. This is a global specification product being used by our partners for global trials. This will now be available to patients in India. ALZUMAb-L will replace the need to buy four vials of the previous ALZUMAb 25 mg formulation, increasing patient convenience.

We have further expanded our portfolio for COVID-19 with the introduction of **ARAFLU® (Favipiravir)** for the treatment of patients with mild to moderate COVID-19 infection.

Value Unlocking

During the quarter, **Tata Capital Growth Fund** has made a primary equity investment of **Rs 225 Crore** for a 0.85% minority stake in the biosimilar business, valuing **Biocon Biologics** at an **equity valuation** of Rs 26,250 Crore, or **~USD 3.5 billion**, and an enterprise valuation of Rs 30,400 Crore, or **~USD 4.0 billion**.

This investment will enable Biocon Biologics' future growth through prudent capital allocation, while it continues to invest in R&D and manufacturing to meet the growing demands of patients worldwide. Having reputed investors as our partners in the journey of establishing Biocon Biologics as a leading global player in biosimilars is reflective of the confidence they have in the company's current and future prospects, aimed at benefiting patients, partners and healthcare systems across the world.

Name Change

We have renamed Biocon Biologics India Limited as **Biocon Biologics Limited** and our subsidiary Biocon Biologics Limited, based in UK, has been renamed as **Biocon Biologics UK Limited**. As a global organization, headquartered in India, we are in the process of expanding our commercial footprint in many geographies and the change in name reflects that commitment.

RESEARCH SERVICES: Syngene

- Q2FY21 revenue at Rs 520 Crore, up 12% (YoY) from Rs 465 Crore in Q2FY20.
- H1 FY21 revenue at 941 Crore; up 6%

Research Services revenue was driven by good performances in the **Discovery Services and Dedicated R&D Centre businesses**.

As a part of the voluntary licensing agreement with Gilead, Syngene has started manufacturing Remdesivir in Bengaluru. The company has also joined a global consortium, led by Bristol Myers Squibb (BMS), to support research on Covid-19. The consortium will work towards developing new approaches to Covid-19 testing, apart from acting as a knowledge repository on the virus.

Commenting on the performance, **Jonathan Hunt, CEO & Managing Director, Syngene** said: *"The second quarter saw a positive return to growth following a muted first quarter that was impacted by COVID-19. This result reflects a robust operating performance as we have adapted to the COVID-19 situation. We are at near normal operating levels with all our scientists working on site with proper protective measures."*

New Appointments

Mr Anupam Jindal has joined as the **Chief Financial Officer (CFO)** of Biocon Limited. He will head the finance function and will be a part of the Executive Leadership Team. Prior to joining Biocon, Anupam worked with the Vedanta Group of companies for 22 years, where he held the position of Group Chief Financial Officer at Sterlite Technologies Limited since 2006.

Mr. Atanu Roy has joined as the **Chief Information Officer (CIO)** for Biocon Group of Companies. Atanu will lead the combined IT teams across all group companies, Biocon, Biocon Biologics and Syngene. As the Group CIO, he will be driving digital transformation at Biocon Group. He comes with over 27 years of vast experience in the Pharma and Technology sectors that include Dr Reddy's, HP and PwC. Prior to joining Biocon Atanu was the Global CIO at Sun Pharmaceuticals and was a member of the Core Management team.

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

About Biocon Limited:

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 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. www.biocon.com
Follow-us on Twitter: [@bioconlimited](https://twitter.com/bioconlimited)

Biocon Biologics Limited, a subsidiary of Biocon Limited is uniquely positioned as a fully integrated 'pure play' biosimilars organization in the world. Building on the four pillars of Patients, People, Partners and Business, Biocon Biologics is committed to transforming healthcare and transforming lives. Biocon Biologics is leveraging cutting-edge science, innovative tech platforms and advanced research & development capabilities to lower treatment costs while improving healthcare outcomes. It has a platform of 28 biosimilar molecules across diabetes, oncology, immunology, dermatology, ophthalmology, neurology, rheumatology and inflammatory diseases. Five molecules from Biocon Biologics' portfolio have been taken from lab to market, of which three have been commercialized in developed markets like United States, EU, Australia, Canada and Japan. It aspires to benefit 5 million patient lives with its biosimilars and attain a revenue milestone of USD 1 billion in FY22. www.biocon.com/businesses/biosimilars/ Follow-us on Twitter: [@BioconBiologics](https://twitter.com/BioconBiologics)

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Earnings Call

The company will conduct a call at 9.00 AM IST on October 23, 2020 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 under Investors>>Financial Calendar>>Earnings Call for period ended September 30, 2020. The operator will provide instructions on asking questions before the start of the call. A replay of this call will also be available 60 minutes from the conclusion of the call till **October 30, 2020 on +91 22 7194 5757**, Playback Code: **89647**. Transcript of the conference call will be uploaded on the company website in due course.

Forward-Looking Statements: Biocon

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.