

# Press Release

# Biocon Q4FY19 Revenue Rs 1,557 Cr, Up 26%; EBITDA Up 43% at Rs 431 Cr; Net Profit Up 64% at Rs 214 Cr FY19 Revenue Up 31% at Rs 5,659 Cr; Net Profit Up 143% at Rs 905 Cr Board Recommends 1: 1 Bonus Shares

Bengaluru, Karnataka, India: April 25, 2019:

**Biocon Ltd** (BSE code: 532523, NSE: BIOCON), Asia's premier biopharmaceuticals company, today announced its consolidated financial results for the fourth quarter and fiscal year ended March 31<sup>st</sup>, 2019.

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

"Our Q4 FY19 performance was led by robust growth in our Biologics and Research Services business segments, supported by a significant growth in the Small Molecules business.

"On an annual basis, our Revenue grew 31% to Rs 5,659 Crore, and Net Profit soared 143% to Rs 905 Crore. FY19 was a landmark year for the Biologics business, which reported a growth of 97%, thus emerging as a key driver for Biocon's incremental growth. Our three strategic business segments Small Molecules, Biologics and Research Services have reported a top-line of over Rs 1,500 Crore each this fiscal. A higher share of Biologics revenue boosted profitability as reflected in the consolidated EBITDA margin of 27% for the full year despite a 34% increase in Net R&D expenses.

"Looking ahead in FY20, we expect to sustain the growth momentum across our business segments led by biosimilars. We expect to sustain core EBITDA margins despite higher R&D investments to fuel our future growth."

# **Highlights: Q4FY19**

- ➤ **Biologics** revenue nearly doubled, led by biosimilars portfolio performance in developed and emerging markets.
- > Branded Formulations India business reported a strong double digit growth which was offset by a decline in UAE.
- ➤ **Generic Formulations** business grew multi-fold off a low base, reflecting our focus on vertical integration in the Small Molecules business
- ➤ **Research Services** subsidiary **Syngene** crossed the **Rs 500 Crore** Revenue milestone with a Net Profit milestone of **Rs 100 Crore** in Q4 on a standalone basis.
- To commemorate the 40<sup>th</sup> anniversary of Biocon Limited the **Board** recommended the issue of 1 bonus share for every 1 share held in Biocon.



# FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q4 & FULL YEAR FY19

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

Post los	O 4EV4C	O 4 EV4 C		FV10	FY18	
Particulars	Q4FY19	Q4FY18	Growth	FY19	FA18	Growth
INCOME						
Small Molecules	472	426	11%	1773	1508	18%
Biologics	451	241	87%	1517	770	97%
Branded Formulations	133	149	-11%	656	612	7%
Research Services	534	409	30%	1826	1423	28%
Inter-segment	-61	-55	11%	-257	-183	41%
Revenue from Operations#	1529	1170	31%	5514	4130	34%
Other Income	28	67	-58%	144	206	-30%
TOTAL REVENUE	1557	1237	26%	5659	4336	31%
EBITDA	431	300	43%	1538	1035	49%
<b>PBT</b> (Before exceptional items)	284	193	47%	1020	610	67%
РВТ	284	193	47%	1215	610	99%
Net Profit*	214	130	64%	905	372	143%
Net Profit (excl. exceptional income)	214	130	64%	729	372	96%
R&D Expenses in P&L	92	51	81%	290	216	34%
Gross R&D Spends	166	98	70%	480	380	26%
EBITDA Margin	28%	24%		27%	24%	
Core EBITDA Margin	34%	26%		32%	27%	
Net Profit Margin	1.40/	110/		13%	9%	
(excl. exceptional income )	14%	11%				
Net Profit Margin*	14%	11%		16%	9%	
#includes Licensing Income	7	2		25	23	
**includes exceptional income ,				176		
net of tax						

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

# **EXECUTIVE COMMENTARY:**

# **PERFORMANCE REVIEW: Q4FY19**

- Biocon's **Total Revenue** for Q4FY19 at Rs 1,557 Crore grew by 26% year-on-year (YoY) with **Revenue from Operations** at Rs 1,529 Crore increasing by 31%.
- **EBITDA** grew 43% YoY at Rs 431 Crore, with an **EBITDA** margin of 28% for Q4FY19. **Core EBITDA** margin for Q4FY19 (net of licensing, impact of forex and R&D) stood at 34%
- **Net Profit** for the quarter jumped 64% YoY to Rs 214 Crore, which represents a **Net Profit margin** of 14%.
- Net R&D expenses for the quarter increased 81% to Rs 92 Crore while Gross R&D expenses stood at Rs 166 Crore, corresponding to 17% of our revenue (excluding Syngene).



# **Business Segment Review: Q4FY19**

The **Q4FY19** revenue growth was largely led by a robust performance by **Biologics** and **Research Services**, supported by a double digit growth in **Small Molecules**. The **Biologics** segment revenue grew 87% to Rs 451 Crore driven by strong sales of our biosimilars **Pegfilgrastim** and **Trastuzumab** in developed and emerging markets. **Ogivri®** (*biosimilar Trastuzumab*) was launched by our partner Mylan in Europe in Q4. We also launched our biosimilar **Trastuzumab** in a few more emerging markets this quarter. The product continues to gain traction in key markets of Latin America and AFMET regions.

The **Small Molecules** business reported a growth of 11% led by a robust performance by **Generic Formulations** and steady sales of **APIs**. The strong performance of Generic Formulations was driven by increased traction in **Statins** sales in the U.S.

The **Branded Formulations** business, which includes sales in **India** and **UAE**, was adversely impacted due to headwinds in UAE. However, the business in India reported a strong performance led by double-digit growth in **Metabolics**, **Critical Care**, **Immunotherapy** and **Market Access** divisions.

**Research Services** reported a robust growth of 30% YoY with revenue at Rs 534 Crore on account of sustained growth in the Discovery and Development Services segments. On a standalone basis **Syngene** crossed the **Rs 500 Crore Revenue milestone** with a **Net Profit milestone of Rs 100 Crore** in Q4.

During the quarter, Syngene and the Government of India's Biotechnology Industry Research Assistance Council (BIRAC) collaborated to set up a **Centre for Advanced Protein Studies** (CAPS). The 2000 sq. ft. centre at Syngene's Bengaluru Campus hosts a state-of-the-art, GLP-accredited analytical laboratory which will be available to BIRAC-funded start-ups, SMEs/MMEs and academia in India at an affordable cost.

## PERFORMANCE REVIEW: FULL YEAR FY19

- Biocon's Total Revenue for FY19 rose 31% to Rs 5,659 Crore with Revenue from Operations growing 34% at Rs 5,514 Crore.
- EBITDA expanded 49% to Rs 1,538 Crore, with an EBITDA margin of 27% for FY19.
- Core EBITDA margin for the year (net of licensing, impact of forex and R&D) stood at 32%.
- Net Profit (including exceptional income\*) for the year climbed 143% to Rs 905 Crore.
- **Net Profit** (excluding exceptional income\*) stood at Rs 729 Crore reflecting a stellar growth of 96%.
- Net Profit Margin stood at 16% in FY19 versus 9% in FY18. Net Profit Margin (excluding net exceptional income) was 13% in FY19.
- Net R&D expenses for FY19 grew by 34% to Rs 290 Crore while Gross R&D expenses
  were

Rs 480 Crore, representing 13% of our revenue (excluding Syngene).

<sup>\*</sup> A net exceptional income of Rs 176 Crore related to change in the fair value of our investment in U.S.-based Equillium Inc. was reported in earlier quarters during FY19.



# **Business Segment Review: FY19**

#### **SMALL MOLECULES: APIs & Generic Formulations**

**Small Molecules** revenue at Rs 1,773 Crore in FY19 reported a growth of 18% on the back of steady **API** sales in global markets and robust sales in the **Generic Formulations** business in the U.S.

Sales of our core APIs including Statins & Immunosuppressants to customers in India, Latin America and Europe contributed significantly to the overall performance. Our **Generic Formulations** business in the U.S. recorded a multi-fold growth off a low base, in its first full year of commercial operations, reflecting the success of our vertical integration strategy in the Small Molecules business. We successfully commercialized **Atorvastatin** and **Simvastatin** formulations in the U.S. in FY19 and recorded market share gains in the previously launched **Rosuvastatin** formulations.

#### **BIOLOGICS: Biosimilars & Novels**

The **Biologics** segment was the strongest performing segment in FY19, reporting a stellar 97% revenue growth at Rs 1,517 Crore in FY19. It has been a landmark year for the biosimilars business with revenues doubling this year led by the launch of our key biosimilars in the U.S. and Europe and ramp up of sales in the emerging markets. Inclusive of inter-segment transfers, the Biologics business crossed the US\$ 200 million revenue milestone in FY19.

The launch of **Fulphila**® (biosimilar Pegfilgrastim) in the U.S. by our partner Mylan contributed significantly to the Biologics segment's performance in FY19. Mylan also launched **Semglee**® (biosimilar Insulin Glargine) and **Ogivri**® (biosimilar Trastuzumab) in Europe along with the in-licensed biosimilar **Adalimumab**, where Biocon retains its economic interest.

Significant growth in biosimilars sales was reported from emerging markets in LATAM, APAC and MENA regions. Biocon-supplied products hold dominant shares for **Trastuzumab**, **rh-Insulin** and **Insulin Glargine** in many of these markets.

Strong realizations on biosimilars sales in both developed and emerging markets led to the **Profit Before Interest and Tax** (PBIT) margin for the Biologics segment improving from -2% in FY18 to 26% in FY19.

In keeping with our commitment to make our biosimilars affordable and hence accessible to a large global population, our **Biologics business addressed the needs of nearly 2 million patients in FY19**.

Till end of FY19, three of our biosimilars have been commercialized in developed markets, viz., **Pegfilgrastim** in U.S., **Trastuzumab** in Europe and **Insulin Glargine** in Europe and Japan. Additionally, our **Trastuzumab** has marketing approvals in U.S. and Australia, **Pegfilgrastim** has approvals in EU, Canada and Australia, and **Insulin Glargine** has approval in Australia. The global development programs for biosimilar **Bevacizumab** and **Insulin Aspart** are progressing well in Phase III clinical studies.

## **Novel Biologics**

**Itolizumab:** A Phase 1b/2 trial in acute graft-versus-host disease (aGVHD) with our novel asset Itolizumab (EQ001) was initiated by our partner Equillium, who has licensed our novel anti-CD6 monoclonal antibody for development in U.S. and Canada. Equillium has been awarded 'Fast



Track' and 'Orphan Drug' designations for the molecule in both prevention and treatment of aGVHD by the U.S. FDA.

We have incorporated **Bicara Therapeutics** based in Boston, U.S., as a wholly owned subsidiary of Biocon to focus on developing Immuno-oncology assets.

## **BRANDED FORMULATIONS**

In FY19, the **Branded Formulations** business reported growth of 7% at a revenue of Rs 656 Crore led by a strong performance by business in India which was offset by a decline in the UAE business.

The Metabolics, Nephrology, Critical Care and Market Access divisions were the key growth drivers for the **Branded Formulations** - **India** (BFI) business. The Top 10 brands in our BFI portfolio grew by 17% and accounted for 80% of total sales in FY19. As a specialty products company, 70% of our overall India business is now accounted for by biologics / biosimilars products. Key brands **Insugen®** and **Basalog®** reported a combined sales of over Rs 200 Crore in FY19.

In **UAE**, business performance for the year was impacted by uncertainty in the local market including delays in product registrations with the local health authorities and repricing of branded generic products by the Ministry of Health.

On the positive side, we launched **Canhera™**, as the first *biosimilar Trastuzumab* in UAE this year to enable affordable access to this therapy for breast cancer patients. **Glaricon™**, our *Insulin Glargine* introduced earlier, is continuing to gain traction and along with some of the novel in-licensed products has improved Biocon's position in the Top 10 companies in the diabetes segment in UAE.

## **RESEARCH SERVICES – SYNGENE**

During FY19, **Research Services** revenue grew 28% to Rs 1,826 Crore driven by robust performances in both Discovery Services and Dedicated R&D Centre business. During the year, Syngene further expanded its customer base as well as extended its existing client relationships taking the total active client base to over 330. The expansion of ongoing strategic collaboration with Baxter Inc. led to the commissioning of additional infrastructure for Baxter.

# **CORPORATE SOCIAL RESPONSIBILITY**

As a part of its Lake Revival Mission, **Biocon Foundation** has brought back to life the 35 acre dying **Hebbagodi Lake** in Bengaluru, using a 3- step eco-friendly bioremediation process and dedicated the lake to the community in FY19. The Project has won several awards including a place in the Limca Book of Records for introducing the largest artificial floating wetlands. Biocon Foundation has further expanded its initiative to take up the revival of **Yarandahalli** and **Kammasandra Lakes** in the same area.

# RECENT KEY APPOINTMENTS

In line with our aspiration of transforming Biocon into a major global player in biologics, we appointed **Dr. Christiane Hamacher as CEO of Biocon Biologics**, in March 2019. Dr. Hamacher brings more than 20 years of leadership experience in both strategic and operational roles across the value chain in the global pharma sector, spanning Asia, Europe and the U.S. with leading multinational pharma companies. She holds a Ph.D. in Molecular Biology (Oncology) from the University Clinic Bergmannsheil / University of Bochum, Germany.



**Dr. Gopal Krishna Dasika** has also been appointed as **Head of R&D at Biocon Biologics**, in February 2019. Dr Dasika comes with over 20 years of experience in biologics R&D. He holds a Ph.D. from the University of Wisconsin, U.S. and a post-doctoral fellowship from the University of Texas Health Sciences Center at Saint Antonio, Texas.

# **DECLARATION OF BONUS SHARES & FINAL DIVIDEND**

To commemorate the 40<sup>th</sup> anniversary of Biocon the Board of Directors of the Company at the meeting held on April 25, 2019 recommended the **issue of 1 bonus share for every 1 share held in Biocon.** 

The Board also recommended a **Final Dividend** of Re 1/- per share (pre-bonus) for FY19.

## **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. 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

#### Earninas Cal

The company will conduct a call at 9.00 AM IST on April 26, 2019 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 60 minutes post the conclusion of the call till May 3, 2019 on +91 22 7194 5757 Playback Code: 91385. Transcript of the conference call will be uploaded on the company website in due course.

FOR MORE INFORMATION	
MEDIA RELATIONS	INVESTOR RELATIONS
Seema Ahuja	Saurabh Paliwal
VP & Global Head of Communications	Head, Investor Relations
<b>≅</b> +91 80 2808 2222; <b>)</b> +91 99723 17792	<b>2</b> +91 80 6775 2040
oxtimes seema.ahuja@biocon.com	☐ investor.relations@biocon.com
Alternate	
Rumman Ahmed	
Sr.Manager, Corporate Communications	
<b>2</b> +91 80 2808 2223; <b>3</b> +91 98451 04173	
□ rumman.ahmed@biocon.com	

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.