



#### **PRESS RELEASE**

Biocon Q4FY22 Revenue at Rs 2,476 Cr, Up 21%; Core EBITDA at Rs 815 Cr, Up 37%; PBT(before Exceptional Items) at Rs 384 Cr, Up 9%

Biosimilars Up 48% at Rs 982 Cr; Generics Up 26% at Rs 717 Cr; Research Services Up 15% at Rs 758 Cr.

FY22 Revenue at Rs 8,397 Cr, Up 14%; Core EBITDA Up 18% at Rs 2,669 Cr;
PBT (before Exceptional Item) at Rs 1094 Cr, Up 4%

Bengaluru, Karnataka, India: April 28, 2022:

**Biocon Ltd** (BSE code: 532523, NSE: BIOCON), an innovation-led global biopharmaceuticals company, today announced its consolidated financial results for the fourth quarter and the fiscal year ended March 31, 2022.

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

"FY22 was a transformational year for Biocon. Key strategic moves in our Biosimilars business position us for long-term growth and value creation for our stakeholders.

"We believe that the two strategic transactions, with Viatris and Serum Institute Life Sciences, will position Biocon Biologics as a world leading, unique, fully integrated biologics company with a strong differentiated portfolio of biosimilars and vaccines.

"We reported a strong consolidated revenue growth of 21% for Q4FY22 at Rs 2,476 Crore driven by 48% growth in Biosimilars, 26% in Generics and 15% in Research Services, businesses. Our Gross R&D spends increased by 70% this quarter to Rs 232 Crore reflecting our advancing pipeline, that will drive our future growth. Core EBITDA was up by 37% at Rs 815 Crore, representing healthy operating margins of 33%. PBT before Exceptional Items stood at Rs 384 Crore, up by 9%.

"On a full- year basis, we delivered consolidated revenue of US\$ 1.1 billion (Rs 8,397 Crore) and reported a Core EBITDA growth of 18% at Rs 2,669 Crore with Core EBITDA margins at 32%."





## FINANCIAL HIGHLIGHTS (CONSOLIDATED): Q4 and Full Year FY22

#### In Rs Crore

Particulars	Q4FY22	Q4FY21	Change	FY22	FY21	Change
INCOME						
Generics	717	570	26%	2,341	2,363	-1%
Biosimilars	982	664	48%	3,464	2,800	24%
Novel Biologics	12	11	17%	51	11	386%
Research services	758	659	15%	2,604	2,184	19%
Inter-segment	(61)	(61)	0%	(276)	(215)	29%
Revenue from operations #	2,409	1,842	31%	8,184	7,143	15%
Other income	67	205	-67%	213	255	-16%
Total Revenue	2,476	2,048	21%	8,397	7,398	14%
EBITDA	659	641	3%	2,183	1,907	14%
PBT before Exceptional Items	384	353	9%	1,094	1,055	4%
Net Profit before Exceptional	262	257	2%	722	744	-3%
Items	202	257	2/0	122	744	-5%
Net Profit for the Period	239	253	-6%	648	740	-12%
R&D Expenses in P&L	191	127	50%	595	553	8%
Gross R&D Spend	232	136	70%	711	627	13%
EBITDA Margins	27%	31%		26%	26%	
Core EBITDA	815	594	37%	2,669	2,270	18%
Core EBITDA* Margins	33%	32%		32%	31%	
Net Profit Margin before	11%	13%		9%	10%	
Exceptional Items						

#Includes Licensing income. Figures above are rounded off to the nearest Crore; % based on absolute numbers.

# **PERFORMANCE REVIEW: Q4FY22**

- Consolidated Revenue grew 21% to Rs 2,476 Crore from Rs 2,048 Crore in Q4FY21
- EBITDA was at Rs 659 Crore (vs. Rs 641 Crore in Q4FY21) Up 3 %
- EBITDA Margins were at 27% (vs. 31% in Q4FY21)
- Core EBITDA was Rs 815 Crore (vs. Rs 594 Crore in Q4FY21) Up 37%
- Core EBITDA\* margins were at 33% (vs. 32% in Q4FY21)
- PBT before Exceptional Items was Rs 384 Crore (vs. Rs 353 Crore in Q4FY21) Up by 9%
- Net Profit before Exceptional Items was Rs 262 Crore (vs. Rs 257 Crore in Q4FY21) Up 2%
- Net Profit<sup>#</sup> was Rs 239 Crore (vs. Rs 253 Crore in Q4FY21)

<sup>\*</sup>Core EBITDA is EBITDA net of licensing, forex, gain on dilution in Bicara, mark-to-market loss on investments and R&D expense.





#### **PERFORMANCE REVIEW: FY22**

- Consolidated Revenue grew 14% to Rs 8,397 Crore from Rs 7,398 Crore in FY21
- FY22 EBITDA was Rs 2,183 Crore (vs. Rs 1,907 Crore in FY21) Up 14%
- FY22 EBITDA Margins were at 26%
- FY22 Core EBITDA was Rs 2669 Crore (vs. Rs 2270 Crore in Q4FY21) Up 18%
- FY22 Core EBITDA\* margins were at 32% (vs. 31% in FY21)
- FY22 PBT before Exceptional Items was Rs 1094 Crore (vs. Rs 1055 Crore in FY21) Up 4%
- FY22 Net Profit before Exceptional Items was Rs 722 Crore (vs. Rs 744 Crore in FY21)
- FY22 Net Profit<sup>#</sup> at Rs 648 Crore (vs. Rs 740 Crore in FY21)

\*Adjusted for dilution on Bicara, Mark-to-market loss on investments and exceptional items, **Net Profit grew by 145% and 23%** for the quarter and full year respectively.

## **CORPORATE UPDATES**

#### **Biocon Limited: Board Announcements:**

Naina Lal Kidwai joins Biocon Limited Board as Additional Director

Naina Lal Kidwai, an accomplished banker and business leader, has been appointed as Additional Director on the Board of Biocon Limited, with effect from April 28, 2022 for a period of three years till the conclusion of 47<sup>th</sup> AGM to be held in 2025.

Ms Kidwai serves as an Additional Director and Senior Advisor for Rothschild India, and Senior Advisor Advent International. She also serves as Non-Executive Director on the boards of many reputed companies like Holcim, Max Financial Services etc. She retired in 2015 as Chairman of HSBC India & Executive Director of HSBC Asia Pacific.

## **Dividend for FY22**

The Board of Directors has recommended a final dividend at the rate of 10% of the face value per share, for the financial year ended March 31, 2022.





## **BUSINESS SEGMENT REVIEW: Q4FY22**

**GENERICS: APIs & Generic Formulations** 

Q4FY22 Revenue at Rs 717 Crore, Up 26% YoY

#### **FULL YEAR FY22**

• FY22 Revenue at Rs 2,341 Crore

Commenting on the Generics segment performance, **Siddharth Mittal, CEO & Managing Director, Biocon Limited**, said, "The business saw robust sequential as well as YoY growth in Q4, on the back of contributions from new product launches in the U.S., particularly Everolimus, an uptick in our API business and a normalization of supply challenges that impacted us in the first half of the fiscal.

However, our FY22 performance was muted, largely due to supply and operational challenges earlier in the year, as well as headwinds in the form of pricing pressures, and escalating costs of solvents, raw material and logistics.

As we progress on our mission of providing high quality affordable medicines to patients around the globe, we will continue to focus on expediting our product pipeline, operationalizing new capacities, and accelerating projects that drive cost and operational efficiencies across the organization.

We will also commence work on important new projects in the current fiscal – a large scale synthetic facility in Hyderabad and an injectable facility in Bangalore; as well as expand our fermentation capacities in Bangalore, all of which will provide further impetus to our future growth."

# **Business Performance**

We received U.S. FDA approvals for Posaconazole, a vertically integrated anti-fungal drug and Dorzolamide, an ophthalmic product, both of which were launched during the quarter.

Our statin formulations portfolio in the U.S. held on to their market share, despite intense pricing pressure. We commenced our first MoW market supply of Tacrolimus capsules to Mexico.

We received our first approval in Singapore for Tacrolimus and in the UAE for Rosuvastatin and Tacrolimus. We also received Marketing Authorization (MA) for Everolimus tablets in Netherlands and Spain.

We received a 'Compliant' rating from Health Canada for a remote assessment conducted during the third quarter for our API manufacturing facility in Bangalore.





Our greenfield immunosuppressant API facility in Vizag remains on track with qualification and validation activities planned in FY23.

As a part of our sustainability initiative, we aim to increase the share of our renewable energy consumption through a combination of wind and solar power. Towards this objective, we commenced sourcing solar power during the quarter to add to the wind power.

## **BIOSIMILARS: Biocon Biologics Limited**

#### **Q4FY22**

- Revenue at Rs 982 Crore, Up 48% YoY
- Core EBITDA\* at Rs 382 Crore, Up 78% YoY
- Core EBITDA\* margins at 39%
- EBITDA at Rs 257 Crore, Up 56% YoY
- EBITDA margin at 26%
- PBT before exceptional items at Rs 144 Crore
- Net R&D Expenses at Rs 112 Crore, representing 11% of revenue

## **Full Year FY22**

- Revenue at Rs 3,464 Crore, Up 24% YoY
- Core EBITDA\* at Rs 1,320 Crore, Up 30% YoY
- Core EBITDA\* margins at 39%
- EBITDA at Rs 1,013 Crore, Up 35% YoY
- EBITDA margin at 29%
- PBT before exceptional items at Rs 543 Crore
- Net R&D Expenses at Rs 310 Crore, representing 9% of revenue

(\*Core EBITDA is EBITDA net of licensing, forex, mark- to- market loss on investments and R&D expense.)

## **Highlights:**

- Signed a **definitive agreement** to **acquire** partner **Viatris Inc.'s global biosimilars business** for up to **USD 3.335 billion in cash and stock**, creating a unique, global, fully integrated biosimilars leader.
- Won a 3-year, USD 90 million (MYR 370+ million) contract from the Ministry of Health, Malaysia to supply Insugen (rh-Insulin).
- Commercialized key biosimilars in several advanced markets, such as bGlargine in Germany and bPegfilgrastim in Italy.
- Received approval for bGlargine from Health Canada.
- Partner Celerity Pharmaceuticals received positive EU CHMP opinion for Inpremzia, a ready-to-use insulin for IV infusion, which uses Biocon Biologics' human insulin drug substance.





- Advanced two unpartnered Wave 2 molecules into the clinic backed by strong analytical similarity package.
- Patients reached: 5.3 million (MAT March 2022)##

# Commenting on the performance, Dr Arun Chandavarkar, Managing Director, Biocon Biologics Ltd. said:

"The 48% (Y-o-Y) growth in revenues this quarter was a result of improved performance across developed and emerging markets, driven by strong market share gains of our interchangeable bGlargine in the USA. The health of our operational and business performance is reflected in the Core EBITDA margins being at 39% of revenues and growing 78% Y-o-Y.

We have progressed well in the development of several next wave biosimilar programs, with two of our molecules entering the clinic. Whilst net R&D was at 9% of revenues in FY22, we expect this to ramp up in FY23 commensurate with the progress of our rich and diverse pipeline which provides Biocon Biologics a sustainable growth opportunity in the years ahead. The two strategic transactions with Serum and Viatris announced in FY22, upon likely closure in the second half of calendar year 2022, will propel us on our path to be a leading vertically integrated biosimilars company globally and will also support the higher investments in developing our pipeline."

## **Business Performance: Biocon Biologics**

#### **Q4FY22**

Revenue for Q4FY22 stood at Rs 982 Crore, reporting a growth of 48% YoY, driven by strong market share gains of Glargine in the U.S. and a robust performance of our commercial portfolio across multiple regions including India. EBITDA at Rs 257 Crore, was up 56%, and EBITDA margin stood at 26%. Core EBITDA margin increased to 39% for the quarter from 33% in Q4FY21, demonstrating improved operational profitability of the business. Profit Before Tax, before exceptional items, stood at Rs 144 Crore, up 109% year-on-year. Our Malaysia operations turned profitable this quarter.

#### **Full Year FY22**

**Revenue** for the full year stood at **Rs 3,464 Crore,** reporting a growth of **24%,** surpassing the growth of **21%** witnessed in FY21. There was a significant improvement in profitability at all levels in FY22. **EBITDA** for the year stood at **Rs 1,013** Crore, a year-on-year growth of **35%. Core EBITDA** grew by **30%** and **Profit Before Tax** before exceptional items, grew by **49%** year-on-year. Net R&D spend for the year was at **9%** of revenue. The growth in profits is driven by higher revenues and improved margins.

The two strategic transactions with Serum Institute Life Sciences (SILS) and Viatris announced in FY22 are progressing towards various regulatory approvals. The deals are expected to close in the second half of calendar year 2022.





## **Developed Markets**

In Q4FY22, the developed markets business reported a strong growth, led primarily by interchangeable bGlargine (Semglee), as well as improved sales of bTrastuzumab (Ogivri) and bPegfilgrastim (Fulphila). Additionally, bGlargine was commercialized in Germany and received approval in Canada, while bPegfilgrastim was introduced in Italy.

In the EU, our oncology biosimilars **bPegfilgrastim** (Fulphila) and **bTrastuzumab** (Ogivri) are gradually improving market shares and **bBevacizumab** (Abevmy) has been commercialized in select EU markets this year.

# **Emerging Markets**

During the quarter, Biocon Biologics-led commercial business recorded robust growth on the back of strong performance of key biosimilars in the AFMET and LATAM regions, as well as good business execution in India.

The **Branded Formulations** – **India** business reported double-digit growth for the quarter. The good performance came on the back of significant ramp-up in prescriptions for **Basalog** (bGlargine), improved patient acquisition and key account penetrations for oncology biosimilars such as **CANMAb** (bTrastuzumab) and **KRABEVA** (bBevacizumab), targeted engagement with HCPs and judicious use of both digital and physical marketing channels.

More recently, the Company's Malaysia subsidiary has won a 3-year tender worth **USD 90** million (MYR 370+ million) by the Ministry of Health, Malaysia for the supply of Insugen (rh-Insulin) products. This contract allows Biocon Sdn to consolidate its market leadership in insulins in Malaysia, one of its Top 5 Emerging Markets, where diabetes patients have been benefiting from the company's products since 2016.

The Company continues to see strong demand for its products in existing markets, and expects a greater play in emerging markets post integration of the biosimilars business of Viatris.

## **Development Updates**

During the year, Biocon Biologics made good progress on the development path of several biosimilar programs for the advanced markets. The Company also initiated clinical trials for two of its unpartnered assets, bDenosumab and bUstekinumab.

## **Biocon Biologics to Acquire Viatris' Global Biosimilars Business**

Biocon Biologics has taken a transformational step towards its long-term strategy to create a unique, fully integrated, world leading biosimilars enterprise by acquiring partner Viatris' global biosimilars business for up to USD 3.335 billion in cash and stock.





The combination of two businesses with complementary strengths and capabilities will enable full vertical integration across the biosimilars value chain, leading to operational and financial efficiencies, helping us maximize value from our biosimilars portfolio.

Under a Transition Services Agreement, Viatris will provide commercialization services and certain transition services to Biocon Biologics for an expected two-year period.

Full ownership of its current partnered biosimilar assets with Viatris will create a strong portfolio of biosimilars. This, along with a direct global commercial presence and value accretive revenues and profits, positions BBL to better leverage the evolving market dynamics.

# **Deal Financing**

The cash payment of USD 2 billion is to be funded by ~USD 800 million raised through equity infusion in BBL and the remainder to be funded by debt, additional equity or a combination thereof.

BBL has received firm commitment from financial institutions for debt financing. The debt assumed in this transaction will be supported by larger EBITDA base, as an outcome of the combination of BBL-Viatris business, vaccines income streams, and future equity infusion in BBL.

#### **NOVEL BIOLOGICS**

Equillium, our U.S. based partner has initiated a Phase 3 EQUATOR study of Itolizumab in patients with acute graft-versus-host disease (aGVHD). The randomized, double-blind study will assess the efficacy and safety of itolizumab versus placebo as a first-line therapy for aGVHD in combination with corticosteroids. The primary objective of the study is to achieve early disease response, with key secondary objectives to evaluate durability of response, corticosteroid use, survival outcomes, and chronic GVHD incidence.

## **RESEARCH SERVICES: Syngene**

## **Q4FY22**

- Q4FY22 revenue at Rs 758 Crore, up 15% YoY
- Q4FY22 PBT at Rs 179 Crore, up 14% YoY

#### **FULL YEAR FY22**

• FY22 revenue at Rs 2,604 Crore, up 19% YoY

Commenting on the performance, **Jonathan Hunt, CEO & Managing Director, Syngene** said: "I am pleased with the strong finish we had to the year and that we delivered results at the high end of our upgraded guidance range.





Reflecting on the last two years of the pandemic, I am extremely proud of our track record: we created more than 2000 new jobs — more than in any other two-year period of the company's history - and gained more than 100 new clients in the last year. We also extended and expanded our long-term partnership with Amgen Inc. and continued to invest in new capacity and technology to underpin future growth.

Looking ahead, we see growing demand for research, development and manufacturing services around the world and we are well-positioned to take advantage of these new opportunities."

#### **Business Performance**

Q4 growth was driven by solid delivery across all divisions, with a strong performance by Development Services.

Completed phase three of the Hyderabad research facility expansion plan, with 600 scientists accommodated and a further expansion being planned.

## **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. **Website: www.biocon.com; Follow-us on Twitter: @bioconlimited** for company updates.

**Biocon Biologics Ltd.**, a subsidiary of Biocon Ltd., is a unique, fully integrated global biosimilars organization. It is leveraging cutting-edge science, innovative tech platforms and advanced research & development capabilities to lower costs of biologics therapies while improving healthcare outcomes. It has a strong research pipeline of biosimilar molecules across diabetes, oncology, immunology and other non-communicable diseases. Seven molecules from Biocon Biologics' portfolio have been commercialized in key emerging markets and developed markets like U.S., EU, Australia, Canada, Japan. It has many firsts to its credit including the most recent U.S. FDA approval of the world's first interchangeable biosimilar, awarded to its Insulin Glargine, which has been commercialized in the U.S. in 2021. Biocon Biologics has signed a strategic alliance with Serum Institute Life Sciences (subject to certain closing conditions) to address the inequitable access to life saving vaccines and biologics globally. With a team of ~5,000 people, Biocon Biologics is committed to transforming healthcare and transforming lives by enabling affordable access to millions of patients' worldwide. **Website:** www.bioconbiologics.com; Follow us on **Twitter: @BioconBiologics** for company updates.





FOR MORE INFORMATION				
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## **Earnings Call**

The management of the Company will host an Earnings Call on 29<sup>st</sup> April, 2022 at 9:00 hrs, over a Zoom Webinar, where the senior management will discuss the company's performance and answer questions from participants. Details of the Zoom webinar are given below as well as on the company website <a href="www.biocon.com">www.biocon.com</a> under Investors>>Financial Calendar>>Earnings Call for period ended December 31, 2021. Transcript of the conference call will be uploaded on the company website in due course.

Zoom Webinar Details	
Date	29 <sup>th</sup> April, 2022
Time	9:00hrs -10:30hrs IST
Join Zoom Webinar	https://bit.ly/39bTN19 to attend earnings call

Or Copy this URL in your browser: <link>

#### **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.