August 30, 2024

Biocon Limited: Ratings reaffirmed for bank facilities; rating reaffirmed and withdrawn for commercial paper programme

Summary of rating action

Instrument*	Previous Rated Amount (Rs. crore)	Current Rated Amount (Rs. crore)	Rating Action
Long-term - term loans	205.00	205.00	[ICRA]AA+ (Stable); reaffirmed
Long-term/ Short-term fund-based/ non-fund based	245.00	245.00	[ICRA]AA+ (Stable)/ [ICRA]A1+; reaffirmed
Commercial Paper Programme	2,250.00	2,250.00	[ICRA]A1+; reaffirmed and withdrawn
Total	**2,700.00**	**2,700.00**	

**Instrument details are provided in Annexure-I*

Rationale

The reaffirmed ratings of Biocon Limited (Biocon/ the company) consider ICRA's expectations that the company's credit profile will continue to improve. This is supported by its diversified business mix, established market position across segments, integrated operations in the pharmaceutical value chain and geographically diversified presence across several countries. ICRA further derives comfort from the management's intention of deleveraging its balance sheet in the near term.

Biocon, through its subsidiary Biocon Biologics Limited (BBL), has a healthy portfolio of biosimilars in the oncology, diabetes and autoimmune segments, with eight products commercialised and a strong product pipeline. Given the complexity, long development cycle and high costs involved, the entry barriers for the biosimilar segment are relatively higher compared to generics, giving BBL the advantage of an early mover. The company is also a reputed global player in statins and immunosuppressants in the generic space and has an established market position in the active pharmaceutical ingredients (APIs) segment.

It also has an improving presence in the finished dosage formulations segment in the US and EU markets. ICRA expects the company to benefit from the UK launch of Liraglutide in FY2025, for which approvals have been recently received. Biocon's research services segment (operating under a subsidiary, Syngene International Limited or Syngene) has a strong presence across discovery and development research and contract manufacturing services for small and large molecules. In FY2024, Biocon reported strong YoY growth of ~32% in revenues, partly supported by the consolidation of Viatris' biosimilars business acquired in November 2022.

However, the operating profit margin (OPM) moderated to 22.6% in FY2024 compared to 24.5% in FY2023, owing to one-off integration costs pertaining to Viatris. ICRA also notes that the pricing pressures in the API business, the slowdown in the US biotech funding and lower traction in sales of Adalimumab in the US impacted the OPM in Q1 FY2025, which was compensated by the gain of Rs. 1,057 crore on the sale of metabolics, oncology and critical care brands of BBL to Eris Lifesciences Limited. However, the company expects the OPM to improve in H2 FY2025, led by new generic formulation launches across multiple markets including its GLP product i.e., Liraglutide and an improved performance expectation from Syngene. Obtaining new product approvals in a timely manner and the extent of performance improvement in light of increasing competition and pricing pressures remain key monitorables.

Biocon prepaid $250 million of acquisition-related debt in FY2024, which reduced the total debt and improved the company's debt metrics in FY2024. The company's consolidated adjusted net debt (net debt excluding structured debt[1])/OPBDITA improved to 3.5 times as on March 31, 2024 from 4.6 times as on March 31, 2023. Following the payment of the first tranche of the deferred consideration of $175 million to Viatris in April 2024, BBL has to pay the balance $160 million in November 2024. In addition, Biocon must provide an exit to other investors (totalling Rs. 1,479.8 crore as on March 31, 2024), who invested in BBL over a period of time for an equity stake. The funding for the deferred consideration, providing an exit to the investors and the timely execution of deleveraging plans are key credit monitorables.

However, the ratings remain constrained due to the company's weak core return on capital employed (RoCE), which dipped to 5% in FY2024 from 7.4% in FY2023 due to the sizeable acquisition of Viatris' biosimilars portfolio. However, RoCE is expected to improve gradually over the medium-to-long term with healthy accruals, supported by the launch of new products. Further, akin to other industry players, Biocon is also exposed to increasing regulatory scrutiny and uncertainties in the approval pathway for molecules under development and consequent volatility in launch timelines and revenues. Additionally, with a significant share of its revenues coming from overseas markets, the company's revenues and margins are susceptible to risks of fluctuations in foreign exchange rates. However, ICRA notes that the company enjoys significant natural hedge, supported by its prudent hedging mechanism in place.

The Stable outlook on the long-term rating reflects ICRA's expectation that Biocon will continue to benefit from its position as an integrated global pharmaceutical major with a diversified business mix. However, material deleveraging will be a key monitorable. Further, ICRA has withdrawn the rating assigned to the commercial paper programme of Biocon based on the company's request and in accordance with ICRA's policy on withdrawal.

Key rating drivers and their description

Credit strengths

Integrated global pharmaceutical major with capabilities across the value chain and diversified business mix – Biocon is present across the pharmaceutical value chain. It is engaged in research and development (R&D), manufacturing, and marketing activities. The company is also geographically diversified with revenues coming from the US, the EU, India, and most of the world (MoW) markets. In terms of its business profile, the company's revenues are diversified across generics - APIs, and formulations (16% of revenues in FY2024), biosimilars (60%), and research services (24%). Presence across various businesses and geographies mitigates revenue risks arising from competition and slowdown in a segment/region and lends stability to revenues.

Established R&D capabilities; relatively high entry barriers in biosimilars space – Biocon periodically invests in R&D for clinical trials and development. Its R&D expenses were ~12-15% of its revenues in the last five years, although declined to ~10% in FY2024. The company is expected to incur R&D expenses of ~8-9% of its generics business revenues and ~8-9% of its biosimilars revenues in FY2025 to support its product pipeline. Further, given the complexity, long development cycle and high costs involved, the entry barriers for biosimilars are relatively higher compared to generics, providing BBL with the advantage of an early mover.

Healthy market position, new product launches, development pipeline and research contracts provide revenue visibility over medium term – Biocon has a healthy biosimilar portfolio within oncology, diabetes, and autoimmune segments. Three oncology biosimilars (biosimilars Trastuzumab, Pegfilgrastim, Bevacizumab), two immunology biosimilars (biosimilar Etanercept and Adalimumab) and three diabetes biosimilars (Insulin Glargine, Insulin Aspart and Insulin rHI), have been

[1] *Structured debt as of March 31, 2024, included debentures issued to Goldman Sachs India AIF Scheme and Kotak Special Situations Fund of ~$300 million. In addition, ~$98 million in May 2024 has been raised from Edelweiss Alternative Asset Advisors and ESOF III Investment Fund*

commercialised as on date. In FY2024, Biocon also received the USFDA[2], UK MHRA[3], and the European Medicines Agency (EMA) approvals and provisional approval from Health Canada, for its ophthalmology biosimilar, Aflibercept, which is yet to be launched. Further, the company has biosimilar Pertuzumab and Denosumab for oncology and Ustekinumab for Immunology and five other undisclosed biosimilars under various stages of development. Moreover, the company is a reputed global player in statins and immunosuppressants in the generics space with an established market position/client relationships for more than 50 APIs, which it supplies to over 750 pharma companies across 100+ countries. It also has an improving presence in the finished dosage formulations segment in the US and other markets. The company is expanding its global footprint beyond its direct presence in the US into other geographies including the UK, Europe, Latin America, Asia and Australia either through a direct presence or Strategic partnerships. Biocon, in its generic segment, has also received UK approval for its GLP product i.e., Liraglutide which is expected to be launched in H2 FY2025 and will contribute to the overall revenues going forward.

Further, the company through its subsidiary, Syngene, has a strong presence across discovery and development research and contract manufacturing services for small and large molecules with established clients. Syngene has over 400 established clients, including long-term contracts with Bristol Myers Squibb (BMS), Baxter International and Amgen Inc. In FY2023, Syngene also signed a 10-year biologics manufacturing agreement with Zoetis amounting to ~$500 million, which supported its contract development and manufacturing (CDMO) business in FY2024. Going forward, given the healthy growth prospects for biosimilars, strong demand for services from contract research, CDMO and Biocon's formulations/ API pipeline, ICRA expects the company to witness healthy consolidated revenue growth over the medium term.

Healthy revenue growth and margins – In FY2024, Biocon reported strong YoY revenue growth of ~32% to Rs. 14,755.7 crore from Rs. 11,174.2 crore in FY2023, supported by full-year consolidation of Viatris' biosimilar revenues, which also increased by 58%, coupled with moderate growth in research segments. The generics segment revenue growth remained flat in FY2024, where ~36% growth in the formulation business was compensated by the decline in the API business, which was impacted by pricing and demand pressures. The research services witnessed ~9% YoY growth in revenues in FY2024. The consolidated revenues in FY2024 were also supported by Rs. 350 crore of gain from BBL's divestiture of the nephrology and dermatology BFI business to Eris Lifesciences Limited on a slump-sale basis. Subsequently, BBL sold its BFI business constituting metabolics, oncology and critical care divisions to Eris Lifesciences on a slump-sale basis for Rs. 1,242 crore in Q1 FY2025, resulting in a gain of Rs. 1,057 crore.

While the OPM remained healthy at 22.6% in FY2024 it moderated from 24.5% in FY2023, primarily due to one-off expenses incurred for the complete integration of Viatris operations in 120+ countries.

Credit challenges

Moderate coverage metrics and low RoCE – Biocon's consolidated debt increased significantly following the debt-funded acquisition of Viatris' biosimilar assets in November 2022. Although the company prepaid $250 million of this debt in FY2024, the total debt remains high at Rs. 18,078.5 crore as on March 31, 2024. Biocon's consolidated adjusted net debt (net debt excluding structured debt)/OPBDITA improved to 3.5 times as on March 31, 2024 against 4.6 times as on March 31, 2023, however, remains moderately stretched. The funding for the deferred consideration and for providing an exit to the investors, along with the execution of deleveraging plans in a timely manner, are key credit monitorables. The company's core RoCE dipped to 5% in FY2024 from 7.4% in FY2023. However, it is expected to improve gradually over the medium-to-long term with healthy accruals, supported by the launch of new products and limited capex of $200-$250 million per annum.

High competition in generics and growing competition in the biosimilars space – The pharmaceutical generics segment typically encounters high competition and pricing pressures due to the presence of a large number of players in the field. However, periodic product launches, expansion into new geographies and sizeable revenues from other segments where competitive intensity is relatively low, mitigate the risk to a large extent. With the biosimilar industry poised for healthy growth

[2] *USFDA: The United States Food and Drug Administration is a federal agency of the Department of Health and Human Services*

3 MHRA: The Medicines and Healthcare products Regulatory Agency is an executive agency of the Department of Health and Social Care in the United Kingdom

over the next few years, several players are expanding their presence in this space. This is likely to increase competition and pricing pressure for Biocon going forward. However, its robust biosimilar product portfolio and global footprint are likely to mitigate competitive threats to an extent.

Regulatory risks and vulnerability to unfavourable forex movement - Akin to other industry players, Biocon is also exposed to increasing regulatory scrutiny and uncertainties in the approval pathway for molecules under development and consequent volatility in launch timelines and revenues. Also, Syngene is bound by strict regulations for clinical trials for regulated markets. Further, with a significant portion of its revenues from overseas markets, the company's revenues and margins are susceptible to risks arising from adverse forex movements. However, the partial hedging mechanisms adopted by the company mitigate the risk to an extent

Environment and social risk

Environmental considerations – The company does not face any major physical climate risk. However, it remains exposed to tightening environmental regulations about breaches of the waste and pollution norms, which can lead to an increase in operating costs and new capacity installation costs. This can also require capital investments to upgrade its effluent treatment infrastructure to reduce the carbon footprint and waste generation. However, the company has constantly been making efforts to minimise the impact of environmental risks on its operations. Also, it remains focused on reducing its carbon footprint by constantly monitoring and reducing its emission levels and has enhanced the consumption level of energy generated through renewable resources.

Social considerations – The company faces high industry-wide social risks related to product safety and the associated litigation risks, access to qualified personnel for R&D and process engineering, and maintenance of high manufacturing compliance standards. Further, Government intervention related to price caps/controls also remains a social risk faced by entities in the pharmaceutical industry.

Liquidity position: Adequate

Biocon had consolidated free cash and bank balance and liquid investments of ~Rs. 3,100 crore as on March 31, 2024. Biocon, at the consolidated level, has capex plans of $200-250 million annually in FY2025 and FY2026, which is expected to be mainly funded by internal accruals and existing reserves, coupled with some portion of debt if required. Also, Biocon has consolidated repayment obligations of Rs. 648 crore and ~Rs. 4,400 crore in FY2025 and FY2026, respectively, on its existing loans (excluding lease liabilities), which also include the expected payment to equity-linked liabilities of the company. BBL had an obligation to pay a deferred consideration of $335 million to Viatris in FY2025. The first tranche has already been paid, while the second tranche of $160 million is due to be paid in November 2024. ICRA expects the capital commitments and debt obligations for the next two years to be funded through a mix of internal accruals, existing cash reserves and fund raise. Overall, Biocon's liquidity position is expected to remain adequate over the medium term, supported by its healthy accruals, exceptional financial flexibility, and lender/investor comfort.

Rating sensitivities

Positive factors – ICRA could upgrade the long-term rating if Biocon demonstrates significantly higher-than-expected deleveraging, coupled with improvement in profitability and liquidity position, on a sustained basis.

Negative factors – Pressure on Biocon's ratings could emerge if the company is unable to achieve material deleveraging and/or is unable to scale up earnings, leading to net debt (excluding structured debt) / OPBDITA exceeding 3.5 times on a sustained basis. The impact of adverse regulatory developments, if any, would be evaluated on a case-to-case basis.

Analytical approach

Analytical Approach	Comments
Applicable rating methodologies	Corporate Credit Rating Methodology Pharmaceuticals
Parent/Group support	Not applicable
Consolidation/Standalone	For arriving at the ratings, ICRA has considered the consolidated financials of Biocon. As on March 31, 2024, the company had 38 subsidiaries, which are enlisted in Annexure-II.

About the company

Biocon Limited was initially set up as a joint venture between Biocon Biochemicals Limited of Ireland and Indian entrepreneur Ms. Kiran Mazumdar Shaw in 1978 to manufacture and export enzymes. After the JV partner was acquired by Unilever and businesses were restructured, Biocon became an independent entity, and the Indian promoters bought the entire stake in 1998. In 2000, the company commissioned its first fully automated submerged fermentation plant to produce speciality biopharmaceuticals and received the USFDA approval for lovastatin in 2001. From being a predominantly fermentation-based APIs and enzymes manufacturer, the company has emerged as an R&D-based biotechnology company, having developed its own proprietary products as well as offering research services to global pharmaceutical majors.

Key financial indicators (audited)

Biocon Consolidated	FY2023	FY2024
Operating income	11,174.2	14,755.7
PAT	810.0	1,382.0
OPBDIT/OI	24.5%	22.6%
PAT/OI	7.2%	9.4%
Total outside liabilities/Tangible net worth (times)	1.3	1.2
Total debt/OPBDIT (times)	7.1	5.4
Interest coverage (times)	6.5	3.4

Source: Company, ICRA Research; All ratios as per ICRA's calculations; Amount in Rs. crore, PAT: Profit after tax; OPBDIT: Operating profit before depreciation, interest, taxes and amortisation

Status of non-cooperation with previous CRA: Not applicable

Any other information: None

Rating history for past three years

	Current (FY2025)			Chronology of rating history for the past 3 years					
	FY2025			FY2024		FY2023		FY2022	
Instrument	Type	Amount Rated (Rs Crore)	Aug 30, 2024	Date	Rating	Date	Rating	Date	Rating
Term loans	Long term	205.0	[ICRA]AA+ (Stable)	04-Aug-23	[ICRA]AA+ (Stable)	17-Nov-22 30-Jun-22	[ICRA]AA+ Rating Watch with Developing Implications	10-Mar-22	[ICRA]AA+ Rating Watch with Developing Implications
Unallocated	Long term	-	-	04-Aug-23	-	17-Nov-22 30-Jun-22	[ICRA]AA+ Rating Watch with Developing Implications	10-Mar-22	[ICRA]AA+ Rating Watch with Developing Implications
Fund based/non-fund based	Long Term/Short Term	245.0	[ICRA]AA+ (Stable)/ [ICRA]A1+	04-Aug-23	[ICRA]AA+ (Stable)/ [ICRA]A1+	17-Nov-22	[ICRA]AA+ Rating Watch with Developing Implications /[ICRA]A1+ Rating Watch with Developing Implications	10-Mar-22	[ICRA]AA+ Rating Watch with Developing Implications /[ICRA]A1+ Rating Watch with Developing Implications

	Current (FY2025)			Chronology of rating history for the past 3 years					
	FY2025			FY2024		FY2023		FY2022	
Instrument	Type	Amount Rated (Rs Crore)	Aug 30, 2024	Date	Rating	Date	Rating	Date	Rating
						30-Jun-22	[ICRA]AA+ Rating Watch with Developing Implications /[ICRA]A1+ Rating Watch with Developing Implications		
Commercial Paper Programme	Short term	2,250.00	[ICRA]A1+; Withdrawn	04-Aug-23	[ICRA]A1+	17-Nov-22	[ICRA]A1+	10-Mar-22	-
						30-Jun-22	-		

Complexity level of the rated instruments

Instrument	Complexity Indicator
Long-term term loans	Simple
Long-term/short-term fund based/non-fund based	Simple
Commercial Paper Programme (CP)	Very simple

The Complexity Indicator refers to the ease with which the returns associated with the rated instrument could be estimated. It does not indicate the risk related to the timely payments on the instrument, which is rather indicated by the instrument's credit rating. It also does not indicate the complexity associated with analysing an entity's financial, business, industry risks or complexity related to the structural, transactional or legal aspects. Details on the complexity levels of the instruments are available on ICRA's website: Click Here

Annexure I: Instrument details

ISIN	Instrument Name	Date of Issuance	Coupon Rate	Maturity	Amount Rated (Rs. crore)	Current Rating and Outlook
NA	Long-term term loans	May 2020	NA	FY2028	205.00	[ICRA]AA+ (Stable)
NA	Long-term/short-term fund based/non-fund based	NA	NA	NA	245.00	[ICRA]AA+ (Stable)/ [ICRA]A1+
NA*	Commercial Paper Programme (CP)	NA	NA	NA	2,250.00	[ICRA]A1+; withdrawn

*Source: Company; *CP not placed*

Annexure II: List of entities considered for consolidated analysis

Company Name	Biocon Ownership	Consolidation Approach
Syngene International Limited	54.52%	Full Consolidation
Syngene USA Inc.	100% by Syngene International Limited	Full Consolidation
Syngene Manufacturing Solutions Limited		Full Consolidation
Syngene Scientific Solutions Limited		Full Consolidation
Biocon Biologics Limited	88.70%	Full Consolidation
Biocon Biologics UK Limited	100% by Biocon Biologics Limited	Full Consolidation
Biosimilars Newco Limited	100% by Biocon Biologics Limited and Biocon Biologics UK Limited	Full Consolidation
Biosimilar Collaborations Ireland Limited	100% by Biocon Biologics UK Limited	Full Consolidation
Biocon SDN BHD		Full Consolidation
Biocon Biologics Inc.		Full Consolidation
Biocon Biologics Healthcare Malaysia SDN BHD		Full Consolidation
Biocon Biologics Do Brasil Ltda, Brazil		Full Consolidation
Biocon Biologics FZ LLC, UAE		Full Consolidation
Biocon Biologics Canada Inc.		Full Consolidation
Biocon Biologics Germany GmbH		Full Consolidation
Biocon Biologics Spain S L U, Sapin		Full Consolidation
Biocon Biologics Finland O.Y.		Full Consolidation
Biocon Biologics Belgium BV		Full Consolidation
Biocon Biologics Inc. USA		Full Consolidation
Biocon Biologics France S.A.S		Full Consolidation
Biocon Biologics Switzerland A.G.		Full Consolidation
Biocon Biologics Morocco, S.A.R.L.A.U. Morocco		Full Consolidation
Biocon Biologics Greece		Full Consolidation
Biocon Biologics South Africa (PTY) Ltd.		Full Consolidation
Biocon Biologics (Thailand) Co. Ltd.		Full Consolidation
Biocon Biologics Philippines Inc.		Full Consolidation
Biocon Biologics Italy SRL		Full Consolidation

Company Name	Biocon Ownership	Consolidation Approach
Biocon Biologics Croatia LLC		Full Consolidation
Biocon Pharma Limited	100.00%	Full Consolidation
Biocon Academy	100.00%	Full Consolidation
Biocon SA, Switzerland	100.00%	Full Consolidation
Biocon FZ LLC, Dubai	100.00%	Full Consolidation
Biocon Pharma Inc.	100% by Biocon Pharma Limited	Full Consolidation
Biocon Pharma Ireland Limited		Full Consolidation
Biocon Pharma UK Limited		Full Consolidation
Biocon Pharma Malta Limited		Full Consolidation
Biocon Generics Inc. USA		Full Consolidation
Biocon Pharma Malta I Limited	100% by Biocon Pharma Malta Limited	Full Consolidation

Note: Company Annual Report FY2024

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