August 04, 2023

Biocon Limited: Ratings reaffirmed; removed from rating watch with developing implications; assigned Stable outlook for the long-term rating; short term rating reaffirmed

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 and removed from rating Watch with developing implications, and assigned Stable outlook
Long-term/ Short-term fund-based/ non-fund based	245.00	245.00	[ICRA]AA+(Stable); Reaffirmed and removed from rating Watch with developing implications, and assigned Stable outlook/[ICRA]A1+; Reaffirmed
Commercial Paper Programme (CP)	2,250.00	2,250.00	[ICRA]A1+; Reaffirmed
Total	**2,700.00**	**2,700.00**	

**Instrument details are provided in Annexure-I*

Rationale

The long-term rating of Biocon Limited (Biocon/ the company) was placed on watch with developing implications, pending completion of the acquisition of the biosimilars assets of Viatris Inc. (Viatris) (hereafter referred to as acquisition) by its subsidiary, Biocon Biologics Limited (BBL), and was expected to be resolved once greater clarity emerged on the integration of operations between BBL and the acquired entity. ICRA has now removed the long-term rating from watch, following completion of the acquisition and consolidation of revenues from the acquired business in BBL with effect from November 29, 2022. ICRA notes that the upfront cash consideration of $2 billion for the acquisition of Viatris biosimilars business was funded by $1.33 billion of debt in Biocon at the consolidated level ($1.2 billion at BBL and ~$130 million at Biocon standalone through non-convertible debentures), while the remaining was funded through internal cash flows, Biocon's subsidiary stake sale proceeds and equity fundraise at BBL's level.

The sizeable debt-funded acquisition has led to moderation in the company's debt and profitability metrics in FY2023. Adjusted net debt (net debt excluding structured debt[1])/OPBDITA moderated to 4.8x as of March 31, 2023, from 1.2x as of March 31, 2022. ICRA notes that the company and BBL have cumulatively raised structured debt of ~$98 million in May 2023 from Edelweiss[2] and is expected to raise further equity at BBL level to deleverage its balance sheet over the near term. Consequently, the adjusted net debt/OPBDITA is expected to improve to ~3-3.5x as of March 31, 2024. ICRA also notes that BBL has an obligation to pay deferred consideration of $335 million to Viatris in FY2025, partially to acquire rights in one of the biosimilars. The funding of the same and the execution of deleveraging plans in a timely manner will be key credit monitorables.

This acquisition has provided BBL with complete ownership of Viatris' rights in biosimilars assets, enabling it to realise the full revenues and associated profits as against a portion of the profits which was accrued to BBL as per previous arrangement with

[1] *Structured debt as of March 31, 2023, includes debentures issued to Goldman Sachs India AIF Scheme and Kotak Special Situations Fund of ~$300 million.*

[2] *Edelweiss Alternative Asset Advisors and ESOF III Investment Fund investment of ~$98 million in May 2023, which is also part of the structured debt from FY2024.*

Viatris from its partnered products, thereby expanding its earnings. It will also accelerate BBL's direct market strategy for its biosimilars portfolio in the regulated markets, including USA and Europe. These are step-ups from its previous arrangement with Viatris. However, obtaining new product approvals in a timely manner and extent of performance improvement in the light of increasing competition and pricing pressures over the medium term remain to be seen.

During September 2021, BBL and Serum Institute Life Sciences (SILS), entered a strategic collaboration wherein BBL was to issue ~15% equity stake to SILS, against which it was to receive access to 100 million doses of vaccines per annum for 15 years. This was expected to generate ~$300 million of committed annualised revenues from Q3 FY2023 with operating margins of ~30%. However, due to delay in receipt of certain regulatory approvals, the deal was withdrawn in May 2023. This collaboration was expected to strengthen BBL's business risk profile in vaccines segment over the medium term. ICRA notes that while the expected earning potential has reduced over the near term due to the deal withdrawal, BBL has received total equity infusion of $300 million from SILS for a total equity stake of ~5%.

The reaffirmation of ratings considers Biocon's diversified business mix with established market position across segments, integrated operations in the pharmaceutical value chain, and geographically diversified presence across various countries. Biocon has a healthy biosimilar portfolio in oncology, diabetes, and autoimmune segments with eight products commercialised, and a strong product pipeline. The company is also a reputed global player in statins and immunosuppressants in the generics space and has an established market position in the active pharmaceutical ingredients (APIs) segment. Also, it is improving its presence in the finished dosage formulations in the US and EU markets. Biocon's research services segment (which operates under a subsidiary, Syngene International Limited, or Syngene) has strong presence across discovery and development research and contract manufacturing services for small and large molecules. During FY2023, Biocon reported strong YoY revenue growth of 36.5% supported by consolidation of Viatris' biosimilar revenues of ~Rs. 2,200 crore coupled with healthy growth across generics and research segments. Further, the operating profit margin (OPM) remained healthy at 24.5%. ICRA positively factors in Biocon's consolidated financial profile characterised by healthy revenue growth and profit margins.

The company's core RoCE dipped to 7.4% in FY2023 from 13.7% in FY2022 due to the sizeable acquisition of Viatris. However, despite the same, RoCE is expected to improve gradually over the medium to long-term with healthy accruals and launch of 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. Further, with a significant share of its revenues coming from overseas markets, the company's revenues and margins are susceptible to forex risks.

The Stable outlook on the long-term rating reflects ICRA's expectation that the company will continue to benefit from being an integrated global pharmaceutical major with a diversified business mix. However, material deleveraging will be a key monitorable.

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 pharma 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 European Union (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 (23% of revenues in FY2023), biosimilars (49%), and research services (28%). Presence across various businesses and geographies mitigates revenue risks arising from competition, slowdown in a segment/region and lends stability to revenues.

Established R&D capabilities; relatively high entry barriers in biosimilar space - Biocon periodically invests in R&D for clinical trials and development. Its R&D expense was around 12-15% of operating income in the last five years. The company is expected to incur R&D expense of ~9-10% of its generics business revenues and ~12% of its biosimilar revenues during FY2024 to support its product pipeline. Further, given the complexity, long development cycle and high costs involved, the entry barriers for biosimilars are relatively high as compared to generics, giving BBL the advantage of an early mover.

Healthy market position, periodic new product launches/development pipeline and new research contracts provide revenue visibility over medium term – Biocon has a healthy biosimilar portfolio in 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 commercialised as on date. Further, the company also has seven undisclosed and three disclosed biosimilars (biosimilar Pertuzumab, Ustekinumab and Denosumab for oncology and bone health) under various stages of development. With the Viatris deal, BBL will also acquire access to an ophthalmology biosimilar, Aflibercept, with a first-to-file status in FY2025 after payment of deferred consideration. 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. Also, Biocon has been improving its presence for its finished dosage formulations in the US, EU and MoW markets. 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 450 established clients, including long-term contracts with Bristol Myers Squibb (BMS), Baxter International and Amgen Inc. Syngene has also signed a 10-year biologics manufacturing agreement with Zoetis amounting to ~$500 million (subject to regulatory approvals and market demand), which will support its contract development and manufacturing (CDMO) business. Going forward, given the healthy growth prospects for biosimilars, strong demand for services from contract research, CDMO and Biocon's formulation/API pipeline, ICRA expects the company to witness healthy consolidated revenue growth and OPM over the medium term.

Healthy revenue growth and margins – During FY2023, Biocon reported strong YoY revenue growth of 36.5% supported majorly by consolidation of Viatris' biosimilar revenues of ~Rs. 2,200 crore, coupled with healthy growth across generics and research segments. The generics segment witnessed YoY revenue growth of 13% in FY2023 largely backed by increasing volume share in the new product launches under immunosuppressant APIs and generic formulations. Its research services witnessed broad based growth across its business segments, which led to strong growth of 23% in FY2023. Further, the consolidated operating profit margin (OPM) remained healthy at 24.5%. Going forward, Biocon's financial profile is characterised by anticipated healthy revenue growth and profit margins.

Credit challenges

Moderate coverage metrics and low RoCE – Biocon's consolidated adjusted net debt[3] increased significantly from Rs. 2,461.2 crore in FY2022 to Rs. 13,204.4 crore in FY2023, following the debt-funded acquisition of Viatris' biosimilar assets. Adjusted net debt (net debt excluding structured debt)/OPBDITA moderated to 4.8x as of March 31, 2023, from 1.2x as of March 31, 2022. ICRA notes that the company has raised structured debt of ~$98 million in May 2023 from Edelweiss and is also expected to raise further equity at BBL's level to deleverage its balance sheet over the near term. Despite incremental operating profits from the acquired entity, Biocon's consolidated debt metrics and profitability (return on capital employed, RoCE) weakened because of the additional borrowings to fund the acquisition. ICRA notes that the OPBDITA from the acquired entity is consolidated for the period November 29, 2022, to March 31, 2023. The company's core RoCE dipped to 7.4% in FY2023 from 13.7% in FY2022. Further, Biocon expects to incur a capex of ~Rs. 5,000-5,600 crore at the consolidated level over the next two years to support business expansion. Although the capex is high, ICRA draws comfort from the anticipated healthy accruals and Biocon's exceptional financial flexibility, which will support the improvement in debt metrics and RoCE over the medium term.

High competition in generics and growing competition in the biosimilar space – The generic segment typically witnesses high competition and pricing pressure because of a large number of players in the field. However, periodic product launches,

[3] *Net debt is calculated as total debt (less structured debt) minus cash and liquid investments.*

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 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 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 breach 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

The company had consolidated free cash and liquid investments of Rs. 3,723.1 crore as on March 31, 2023. Biocon has capex plans of ~Rs. 3,000-3,200 crore and ~Rs. 2,000-2,400 crore in FY2024 and FY2025, respectively, which is expected to be mainly funded by internal accruals and existing reserves, coupled with some portion of debt. Also, Biocon has consolidated repayment obligations of Rs. 193.3 crore and Rs. 943.8 crore in FY2024 and FY2025, respectively, on its existing loans (excluding lease liabilities). ICRA expects the capital commitments and debt obligations for the next two years to be met mainly through internal accruals and existing cash reserves. BBL has an obligation to pay deferred consideration of $335 million to Viatris in FY2025, partially to acquire rights in one of the biosimilars. The company is expected to fund the same through internal cash accruals and equity infusion, which remains one of the key monitorables. Overall, Biocon's liquidity position is expected to remain adequate over the medium term, supported by its heathy accruals, exceptional financial flexibility, and lender/investor comfort.

Rating sensitivities

Positive factors – ICRA could upgrade the ratings if Biocon demonstrates significantly higher-than-expected deleveraging and improvement in liquidity position while maintaining healthy profitability metrics on a sustained basis.

Negative factors – Negative pressure on Biocon's rating 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. Impact of adverse regulatory developments, if any, would be evaluated on a case-by-case basis.

Analytical approach

Analytical Approach	Comments
Applicable rating methodologies	[Corporate Credit Rating Methodology](#) [Rating Methodology for Pharmaceutical Industry](#)
Parent/Group support	Not Applicable
Consolidation/Standalone	For arriving at the ratings, ICRA has considered the consolidated financials of Biocon.

About the company

Biocon Limited was initially set up as a joint venture in 1978 between Biocon Biochemicals Limited of Ireland and the Indian entrepreneur, Ms. Kiran Mazumdar Shaw, to manufacture and export enzymes. After Unilever acquired the JV partner and the businesses were restructured, Biocon became an independent entity, and the Indian promoters bought the entire stake in 1998. From a predominantly fermentation-based APIs and enzymes manufacturer, the company emerged as an R&D-based biotechnology company having developed its proprietary products and offering research services to global pharmaceutical majors. Currently, Biocon is present in the entire pharma value chain, across R&D, manufacturing and marketing, with a global presence with revenues from India, USA, Europe and MoW markets.

Key financial indicators (audited)

Biocon Consolidated	FY2021	FY2022	FY2023
Operating income	7,143.1	8,184.0	11,174.2
PAT	925.6	978.5	810.0
OPBDIT/OI	23.4%	24.4%	24.5%
PAT/OI	13.0%	12.0%	7.2%
Total outside liabilities/Tangible net worth (times)	1.1	1.1	1.3
Total debt/OPBDIT (times)	3.6	3.3	7.1
Adjusted net debt/OPBDIT (times)	1.0	1.2	4.8
Interest coverage (times)	28.9	29.6	6.5

PAT: Profit after tax; OPBDIT: Operating profit before depreciation, interest, taxes, and amortisation; Amount in Rs. crore; All amounts as per ICRA calculations

Status of non-cooperation with previous CRA: Not applicable

Any other information: None

Rating history for past three years

	Instrument	Current rating (FY2024)				Chronology of rating history for the past 3 years				
		Type	Amount rated (Rs. crore)	Amount Outstanding as of Mar 31, 2023 (Rs. crore)	Date & rating in FY2024	Date & rating in FY2023		Date & rating in FY2022		Date & rating in FY2021
					Aug 04, 2023	Nov 17, 2022	June 30, 2022	Mar 10, 2022	Jan 29, 2021	Oct 10, 2019
1	Long-term term loans	Long Term	205.00	205.00	[ICRA]AA+ (Stable)	[ICRA]AA+&	[ICRA]AA+&	[ICRA]AA+&	[ICRA]AA+ (Stable)	-
2	Long-term fund based	Long Term	-	-	-	-	-	-	-	[ICRA]AA+ (Stable)
3	Long-term non-fund based	Long Term	-	-	-	-	-	-	-	[ICRA]AA+ (Stable)
4	Long-term unallocated	Long Term	-	-	-	[ICRA]AA+&	[ICRA]AA+&	[ICRA]AA+&	[ICRA]AA+ (Stable)	[ICRA]AA+ (Stable)
5	Long-term/short-term fund based/non-fund based	Long Term/Short Term	245.00	-	[ICRA]AA+ (Stable)/ [ICRA]A1+	[ICRA]AA+& / [ICRA]A1+	[ICRA]AA+& / [ICRA]A1+&	[ICRA]AA+& / [ICRA]A1+&	[ICRA]AA+ (Stable)/ [ICRA]A1+	[ICRA]AA+ (Stable)/ [ICRA]A1+
6	Short-term non-fund based	Short Term	-	-	-	-	-		-	[ICRA]A1+
7	Commercial Paper Programme (CP)	Short Term	2,250.00	-	[ICRA]A1+	[ICRA]A1+	-		-	-

&: Under Watch with Developing Implications

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	3 Months LIBOR + 1.75% p.a.	FY2028	205.00	[ICRA]AA+(Stable)
NA	Long-term/short-term fund based/non-fund based	-	-	-	245.00	[ICRA]AA+(Stable) / [ICRA]A1+
NA*	Commercial Paper Programme (CP)	-	-	-	2,250.00	[ICRA]A1+

Source: Company; CP yet to be placed

Annexure II: List of entities considered for consolidated analysis

Company Name	Biocon Ownership	Consolidation Approach
Syngene International Limited	54.60%	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	92.04%	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		Full Consolidation
Biocon Biologics Canada Inc.		Full Consolidation
Biocon Biologics Germany GmbH		Full Consolidation
Biocon Biologics Spain S L		Full Consolidation
Biocon Biologics Finland O.Y.		Full Consolidation
Biocon Biologics Belgium BV		Full Consolidation
Biocon Biologics France S.A.S		Full Consolidation
Biocon Biologics Switzerland A.G.		Full Consolidation
Biocon Pharma Limited	100.00%	Full Consolidation
Biocon Academy	100.00%	Full Consolidation
Biocon SA	100.00%	Full Consolidation
Biocon FZ LLC	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

Company Name	Biocon Ownership	Consolidation Approach
Biocon Pharma Malta Limited		Full Consolidation
Biocon Pharma Malta I Limited	100% by Biocon Pharma Malta Limited	Full Consolidation
Biocon Biosphere Limited	100%	Full Consolidation
Biofusion Therapeutics Limited	100%	Full Consolidation
Neo Biocon FZ LLC, UAE (JV)	49%	Equity Method
Bicara Therapeutics Inc. (fully diluted basis)	39%	Equity Method

Note: Company Annual Report FY2023

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