November 17, 2022

Biocon Limited: Long-term rating continues to be on watch with developing implications; short-term rating removed from watch with developing implications and reaffirmed; Rating assigned for CP programme

Summary of rating action

Instrument*	Previous Rated Amount (Rs. crore)	Current Rated Amount (Rs. crore)	Rating Action
Long-term term loans	183.83	205.00	[ICRA]AA+&; Rating continues to be on watch with developing implications
Long-term unallocated	6.17	0.00	-
Long-term/short-term fund based/non-fund based	260.00	245.00	[ICRA]AA+&/[ICRA]A1+; Long term rating continues to be on watch with developing implications; short term rating removed from watch with developing implications and reaffirmed
Commercial Paper Programme (CP)	0.00	2,250.00	[ICRA]A1+; assigned
Total	**450.00**	**2,700.00**	

**Instrument details are provided in Annexure-I; &: Under watch with developing implications*

Rationale

On February 28, 2022, Biocon Limited (Biocon) announced that its subsidiary, Biocon Biologics Limited ('BBL'), has approved the proposed acquisition of biosimilars assets of Viatris Inc. (Viatris) for a consideration of up to $3.335 billion in stock and cash, subject to necessary regulatory and other approvals. ICRA had placed the ratings on watch with developing implications pending clarity on the funding plan, completion of transaction and greater clarity on integration of operations of BBL and the acquired entity.

Through the acquisition, BBL will acquire Viatris' global biosimilars business with estimated revenues and OPBDITA of $1.1 billion and $250 million respectively for CY2023, along with its portfolio of in-licensed biosimilar assets. The consideration was expected to be a mix of cash and stock, and BBL will be paying an upfront cash consideration of $2 billion on closing of the transaction and up to $335 million as additional payments in CY2024. Additionally, upon closing of the transaction, BBL will issue $1 billion of Compulsorily Convertible Preference Shares (CCPS) to Viatris, equivalent to an equity stake of ~13% in BBL, on a fully diluted basis.

ICRA now understands that the cash payment of $2 billion to Viatris is expected to be funded by $1.62 billion of debt in Biocon at the consolidated level ($1.2 billion at Biocon Biologics and $420 million at Biocon standalone through commercial paper and short term borrowings), while the remaining is expected to be funded through internal cash flows and equity fund raise[1]. ICRA also understands that ~$200 million which forms part of $1.62 billion debt will be refinanced through equity funds in the near term, while another ~$225 million will be refinanced through issuance of NCD. The transaction is expected to close in Q3 FY2023, subject to satisfaction of closing conditions (including certain regulatory approvals).

Accordingly, ICRA has removed the watch on the short-term rating and reaffirmed it at [ICRA]A1+ as it believes that Biocon's liquidity profile will continue to be healthy, upon receiving reasonable clarity on the company's funding plan for Viatris'

[1] The current equity/internal cash flow portion of $380 million (of the $2 billion) is expected to be funded through proceeds of $150 million received from the stake sale in Syngene International Limited, proposed infusion of $150 million from Serum Institute Life Sciences and $80 million of internal accruals.

acquisition and the incremental borrowings that are likely for Biocon at a consolidated level post the transaction. However, the long-term rating continues to be on watch with developing implications, pending completion of the acquisition and will be resolved once greater clarity emerges on the integration of operations between BBL and the acquired entity with regards to successful launch of biosimilars pipeline in regulated markets. In addition, earnings potential from BBL's recent business collaboration with Serum Institute Life Sciences for marketing a portfolio of vaccines for global markets will also be critical to evaluate group's financial profile. That said, downward pressure on long-term rating could arise from any delay in integration of operations including proposed product launches leading to sharp deterioration in the group's financial profile. Given the debt-funded acquisition, material deleveraging in a timely manner will be a key credit monitorable.

In ICRA's opinion, the acquisition is expected to accelerate BBL's direct market strategy for its biosimilars portfolio in the regulated markets including USA and Europe. BBL will also acquire complete ownership of Viatris' rights in biosimilars assets, enabling it to realise the full revenues and associated profits from its partnered products, thereby expanding its operating profits. These are step-ups from its previous arrangement with Viatris. The deal is also expected to provide other advantages, including strategic agility and operational efficiencies, which could aid BBL in mitigating pricing pressures in a competitive global biosimilars landscape to an extent. However, obtaining new product approvals in a timely manner and extent of performance improvement in the light of increasing competition and pricing pressures, remain to be seen.

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 through the pharma value chain, across Research & Development (R&D), manufacturing and marketing and has a global presence with revenues from India, USA, Europe and most of the world (MoW) markets. The company derived 26.2% of consolidated revenues from generics (Active Pharmaceutical Ingredients - APIs/formulations) in H1 FY2023, while 43.0% and 30.8% of the operating income came from biosimilars and research services respectively in H1 FY2023. Biocon also has presence in novel biologics. The diverse business mix and geographic presence lend stability to revenues to an extent.

Established R&D capabilities; relatively high entry barriers in biosimilar space - Akin to other players in the industry, Biocon periodically invests in R&D for clinical trials and development. Its R&D expense was around 10-15% of operating income in the last three years. Further, given the complexity, long development cycle and high costs involved, the entry barriers for biosimilars are relatively high, giving BBL an advantage as an early mover.

Healthy market position, periodic new product launches/development pipeline and new research contracts provides revenue visibility over the medium term – Biocon has a healthy biosimilar portfolio in oncology, diabetes and autoimmune segments, with three oncology biosimilars (biosimilar Trastuzumab, biosimilar Pegfilgrastim and biosimilar Bevacizumab) and three diabetes biosimilars (Insulin Glargine, Insulin Aspart and Insulin rHI), commercialised as on date. Further, the company also has economic interest in two marketed in-licensed autoimmune biosimilars (biosimilar Adalimumab and biosimilar Etanercept) and has seven undisclosed and four disclosed biosimilars (biosimilar Pertuzumab, biosimilar Ustekinumab and biosimilar Denosumab - oncology and bone health) under various stages of development. With the Viatris deal, BBL will also acquire complete ownership of Viatris' rights in biosimilars assets. The company is a reputed global player in statins and immunosuppressants in the generics space and has established market position/client relationships for more than 40 APIs, which are catered to over 700 pharma companies. Also, Biocon has low-mid teens market share for its finished dosage formulations in the USA. Further, the company has strong presence across discovery and development research and contract manufacturing services for small and large molecules with established clients. For H1 FY2023, Biocon reported a consolidated revenue YoY growth of 23.8% and its revenues stood at Rs. 4,459.2 crore while its operating margins remained healthy at 22.2%. Given the healthy growth prospects for biosimilars, robust demand for services from contract research organisations (CROs) and new business additions/scope enhancements in the research segment and Biocon's formulation/API pipeline, ICRA expects the company to witness healthy consolidated revenue growth over the medium term.

Credit challenges

Moderate coverage metrics – Biocon's consolidated net debt is expected to increase significantly from Rs. 1,882.4 crore[2] in H1 FY2023, following the acquisition of Viatris' biosimilar assets. Despite incremental operating profits from the acquired entity, Biocon's consolidated debt metrics and profitability (return on capital employed, RoCE) could weaken because of the additional borrowings. Further, Biocon expects to incur an annual capex of Rs. 2,400 crore at the consolidated level over the next few years to support business expansion. Although the capex is relatively high, ICRA draws comfort from the anticipated healthy accruals from the business over the medium term and Biocon's exceptional financial flexibility.

Relatively high competition in generics and growing competition in the biosimilar space – The generic segment witnesses high competition and pricing pressure because of the presence of a large number of players. However, periodic product launches, expansion in new geographies and sizeable revenues from other segments where competitive intensity is relatively lower mitigates 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, the company's 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 including appreciation of rupee against the dollar. 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 with regard to breach of the waste and pollution norms, which can lead to an increase in operating costs and new capacity instalment 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/control also remains a social risk faced by entities in the pharmaceutical industry.

Liquidity position: Strong

Biocon's liquidity position is expected to remain strong over the medium term, supported by its strong operational profile and margins and exceptional financial flexibility and lender/investor comfort. As on September 30, 2022, the company had consolidated cash and liquid investments of Rs. 3,977.4 crore and adequate unutilised working capital debt. Biocon has an annual tangible capex plan of ~Rs. 2,400 crore (~Rs. 1,600 crore ex-Syngene) per year for FY2023 to FY2025s, and part of it is expected to be debt-funded. Also, Biocon has consolidated repayment obligations of Rs. 38.0 crore in FY2023, Rs. 117.7 crore in FY2024 and Rs. 761.2 crore in FY2025, on its existing loans.

[2] The total debt of Rs. 5,859.4 crore includes lease liabilities of Rs. 244.0 crore as on September 30, 2022. Net debt excluding cash & liquid investments stood at Rs. 1,8824 crore as on September 30, 2022.

Rating sensitivities

Positive factors – An upgrade in long term rating is unlikely as it is currently on watch with developing implications.

Negative factors – Pressure on ratings could emerge in the absence of significant deleveraging, post completion of the Viatris' biosimilar business acquisition. Further, any delay in integration of operations, resulting in weaker than expected group's financial profile could result in a downgrade. 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	NA
Consolidation/Standalone	For arriving at the ratings, ICRA has considered the consolidated financials of Biocon Limited.

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 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. In 2000, the company commissioned its first fully automated submerged fermentation plant to produce specialty biopharmaceuticals and received 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 proprietary products and offering research services to global pharmaceutical majors. Biocon, through its subsidiary BBL, recently entered into a collaboration with Adagio Therapeutics for a novel Covid antibody therapy and a strategic alliance with Serum Institute Life Sciences (SILS) for vaccines and infectious diseases antibodies. The alliance with SILS for vaccines enables BBL to generate a committed revenue stream and related margins, commencing H2 FY2023. BBL is also in the process of acquiring biosimilar assets of Viatris Inc., and the transaction is expected to be concluded by Q3 FY2023.

Key financial indicators (audited)

Biocon Consolidated	FY2021	FY2022	H1 FY2023*
Operating income	7,143.1	8,184.0	4,459.2
PAT	925.6	978.5	320.5
OPBDIT/OI	23.4%	24.4%	22.2%
PAT/OI	13.0%	12.0%	7.2%
Total outside liabilities/Tangible net worth (times)	1.1	1.1	1.1
Total debt/OPBDIT (times)	2.7	2.6	3.0
Interest coverage (times)	28.9	29.6	19.8

*Amount in Rs crore; Source: Company, ICRA Research; Financial ratios in this document are ICRA adjusted figures and may not be directly comparable with results reported by the company in some instances; PAT: Profit after Tax; OPBDIT: Operating Profit before Depreciation, Interest, Taxes and Amortisation; total debt includes lease liabilities; *unaudited*

Status of non-cooperation with previous CRA: Not applicable

Any other information: None

Rating history for past three years

	Instrument	Current rating (FY2023) Type	Amount rated (Rs. crore)	Amount Outstanding as of June 30, 2022 (Rs. crore)	Date & rating in FY2023 Nov 17, 2022	Date & rating in FY2023 June 30, 2022	Chronology of rating history for the past 3 years: Date & rating in FY2022 Mar 10, 2022	Date & rating in FY2021 Jan 29, 2021	Date & rating in FY2020 Oct 10, 2019
1	Long-term term loans	Long Term	205.00	189.80	[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+& / [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+	-	-	-	-

*&: Under Watch with Developing Implications; *yet to be placed*

Complexity level of the rated instruments

Instrument	Complexity Indicator
Long-term term loans	Simple
Long-term/short-term fund based/non-fund based	Simple/Very 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+&
NA	Long-term/short-term fund based/non-fund based	-	-	-	245.00	[ICRA]AA+& / [ICRA]A1+
NA	Commercial Paper Programme (CP)*	-	-	-	2,250.00	[ICRA]A1+

*Source: Company; &: Under watch with developing implications; *yet to be placed*

Annexure II: List of entities considered for consolidated analysis

Company Name	Biocon's Ownership	Consolidation Approach
Syngene International Limited	64.56%	Full Consolidation
Syngene USA Inc.	100% by Syngene International Limited	Full Consolidation
Biocon Biologics Limited	93.47%	Full Consolidation
Biocon Pharma Limited	100%	Full Consolidation
Biocon Academy	100%	Full Consolidation
Biocon SA	100%	Full Consolidation
Biocon FZ LLC	100%	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 Pharma Malta I Limited	100% by Biocon Pharma Malta Limited	Full Consolidation
Biocon Biosphere Limited	100%	Full Consolidation
Biofusion Therapeutics Limited	100%	Full Consolidation
Biocon Biologics UK Limited (formerly Biocon Biologics Limited)	100% by Biocon Biologics Limited	Full Consolidation
Biocon SDN BHD	100% by Biocon Biologics UK Limited	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
Neo Biocon FZ LLC, UAE (JV)	49%	Equity Method
Bicara Therapeutics Inc.	74%	Equity Method

Source: Company's Annual Report for FY2022

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ICRA Limited was set up in 1991 by leading financial/investment institutions, commercial banks and financial services companies as an independent and professional investment Information and Credit Rating Agency.

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