November 17, 2022(Revised)

Biocon Biologics Limited: Long-term rating continues to be on watch with developing implications; short-term rating removed from watch with developing implications and reaffirmed

Summary of rating action

Instrument*	Previous Rated Amount (Rs. crore)	Current Rated Amount (Rs. crore)	Rating Action
Long-term term loans	916.00	916.00	[ICRA]AA+&; rating continues to be on watch with developing implications
Working Capital Facilities	661.70	661.70	[ICRA]A1+; rating removed from watch with developing implications and reaffirmed
Unallocated limits	22.30	22.30	[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
Total	**1,600.00**	**1,600.00**	

**Instrument details are provided in Annexure-I*

&: under rating 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 non-convertible debentures. 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 and BBL’s liquidity profile will continue to be healthy, upon receiving reasonable clarity on the company’s funding plan for Viatris’ 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

[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.

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 Private Limited (SILS) 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

Strong parentage – BBL is a 93.5%-subsidiary[2] of Biocon and contributed ~43% to the latter's consolidated revenues and ~50% to its consolidated OPBIDTA in H1 FY2023. BBL enjoys financial and operational flexibility by virtue of its parentage. As of March 31, 2022, the company had Rs. 1,286.4 crore of non-convertible and optionally convertible preference shares from Biocon.

Strong business profile – BBL has a strong business profile backed by healthy biosimilar portfolio in oncology, diabetes, and autoimmune segments, with three oncology biosimilars (biosimilar Trastuzumab, biosimilar Pegfilgrastim and biosimilar Bevacizumab) and three diabetes biosimilar (Insulin Glargine, Insulin Aspart and Insulin rHI), commercialized 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 4 disclosed (biosimilar Pertuzumab, biosimilar Ustekinumab and biosimilar Denosumab - oncology and bone health) biosimilars under various stages of development. With the Viatris deal, BBL will also acquire complete ownership of Viatris' rights in biosimilars assets. BBL also received the world's first interchangeability designation for insulin glargine from the US Food and Drug Administration (FDA) in July 2021, which was subsequently launched in November 2021 with a 12-month exclusivity period. It has also collaborated with SILS for a committed vaccine business of 100 million doses per annum for the next 15 years. The vaccine segment, along with existing biosimilars, would augur well for the company.

Established research and development (R&D) capabilities; relatively high entry barriers in biosimilar space – The company has two R&D facilities in Bengaluru and Chennai. Akin to other players in the industry, BBL periodically invests in R&D for clinical trials and development. Its R&D expense was ~12-16% of revenues in the last three years till H1 FY2023. Given the complexity the long development cycle and high costs involved, the entry barriers for biosimilars are relatively high, giving BBL an advantage as an early mover.

Healthy revenue growth and profit margins – BBL's revenue increased at a CAGR of 22% between FY2019 and FY2022 and witnessed YoY revenue growth of 31.5% in H1 FY2023 supported by product launches and expansion across geographies. The healthy growth prospects for biosimilars (along with Viatris acquisition), the company's product pipeline and diversification into vaccines are likely to support revenues going forward. Further, BBL had a healthy operating profit margin of over 30% during FY2019 - FY2022, except FY2021, when it moderated to 27% impacted primarily by the delay in some product launches because of the pandemic. During H1 FY2023, the company's operating margin[3] remained healthy at 24.4%, though witnessing contraction from 30% in H1 FY2022, mainly due to increase in R&D investments for the current product pipeline. New product launches and stabilisation of existing products are expected to support margins going forward.

[2] *Biocon shareholding in BBL to be ~68% on fully diluted basis, post completion of Viatris acquisition and SILS collaboration*

[3] Adjusting for Adagio revaluation gains, non-cash foreign currency translational loss pertaining to Goldman Sachs' OCD investment and other income

Credit challenges

Significant increase in debt levels expected by end of FY2023 – BBL's net debt is expected to increase significantly from Rs.3,638.9[4] crore as of March 31, 2022, following the acquisition of Viatris' biosimilar assets. Despite incremental OPBDITA from the acquired entity, BBL's consolidated debt metrics and profitability (RoCE) will deteriorate because of the additional borrowings. Further, BBL expects to incur annual capex of ~$100 million over the next few years to support business expansion. Although the capex is relatively high for BBL's scale, ICRA draws comfort from the anticipated healthy accruals from the business over the medium term and BBL's exceptional financial flexibility.

Growing competition in the biosimilar space – 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, BBL is exposed to increasing regulatory scrutiny and uncertainties in the approval pathway for molecules under development and the consequent volatility in launch timelines and revenues. Also, with about 80% of its revenues from overseas markets, the company's revenues and margins are susceptible to adverse forex movements including appreciation of rupee against the dollar. However. However, the hedging mechanism adopted by BBL mitigates the risk to an extent.

Liquidity position: Strong

BBL'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 of March 31, 2022, the company had consolidated cash and liquid investments of ~Rs. 280 crore and adequate unutilized working capital debt. BBL's capex is expected to be ~$100 million per annum for the next two to three years, part of which is likely to be debt-funded. While repayment obligations (excluding lease liabilities of Rs. 43 crore) for FY2023 and FY2024 is low at Rs 38 crore, the company has long-term debt obligations of Rs 602 crore in FY2025 on its existing loans.

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. Further, any delay in integration, resulting in weaker-than-expected financial profile of the merged entity could result in a downgrade. Deterioration in the parent's (Biocon) credit profile or BBL's operational/financial linkages with the parent could also impact the ratings.

Analytical approach

Analytical Approach	Comments
Applicable rating methodologies	Corporate Credit Rating Methodology Rating Methodology for Pharmaceutical Industry Rating Approach – Implicit Support from Parent or Group
Parent/Group support	Biocon currently holds a 93.5% stake[5] in BBL. It enjoys financial and operational flexibility by virtue of its parentage.

[4] Debt excludes cash and liquid investments, non-convertible redeemable preference shares, optionally convertible redeemable preference shares and non-cumulative redeemable preference shares issued to the group entities. If the fund infusion received in the form of redeemable optionally convertible debentures from Goldman Sachs are also excluded, the debt level stood at Rs 2,404 crore as of March 31, 2022

[5] *Biocon shareholding in BBL to be ~68% on fully diluted basis, post completion of Viatris acquisition and SILS collaboration*

Consolidation/Standalone	For arriving at the ratings, ICRA has considered the consolidated financials of BBL. As on March 31, 2022, the company had one subsidiary and five stepdown subsidiaries which are listed in Annexure-II.

About the company

Biocon Biologics Limited (BBL), a subsidiary of Biocon Limited, manufactures and commercialises biosimilar products. As on date, the company has commercialised eight products in developed and emerging markets primarily in the oncology, diabetes and immunology segments. It has strategic partnerships with global players like Viatris and Sandoz for commercialisation of its biosimilars. BBL recently entered into a collaboration with Adagio Therapeutics for a novel Covid antibody therapy and a strategic alliance with SILS for vaccines and infectious diseases antibodies.

BBL currently has four PE investors, including Activ Pine LLP (affiliate of True North Fund), Tata Capital Growth Fund II, Goldman Sachs and Beta Oryx Limited (affiliate of Abu Dhabi-based ADQ). The PEs have invested Rs. 2,442.2 crore in the company during January 2020 to January 2021 in the form of equity (combined stake of 5.09%) and redeemable optionally convertible debentures. Also, BBL will offer a ~13% equity stake to SILS for the recent vaccine collaboration subject to the receipt of regulatory approvals. The alliance with SILS for vaccines enables BBL to generate a committed revenue stream and related margins, commencing H2 FY2023. BBL acquisition of biosimilar assets of Viatris Inc. is expected to be concluded by Q3 FY2023.

Key financial indicators (audited)

BBL Consolidated	FY2021	FY2022	H1 FY2023*
Operating income	2,797.2	3,464.3	1,974.0
PAT	267.5	382.5	NA
OPBDIT/OI	27.0%	30.2%	24.4%
PAT/OI	9.6%	11.0%	NA
Total outside liabilities/Tangible net worth (times)	4.0	3.3	NA
Total debt/OPBDITA (times)	6.7	5.0	NA
Interest coverage (times)	20.3	15.7	NA

*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; NA: Not Available*

Status of non-cooperation with previous CRA: Not applicable

Any other information: None

Rating history for past three years

	Instrument	Current rating (FY2023)					Chronology of rating history for the past 3 years			
		Type	Amount rated (Rs. crore)	Amount Outstanding as of Mar 31, 2022 (Rs. crore)	Date & rating in FY2023		Date & rating in FY2022		Date & rating in FY2021	Date & rating in FY2020
					Nov 17, 2022	Jun 30, 2022	Mar 10, 2022	Jan 11, 2022	-	-
1	Term Loans	Long Term	916.00	916.00	**[ICRA]AA+&**	**[ICRA]AA+&**	**[ICRA]AA+&**	**[ICRA]AA+ (Stable)**	-	-
2	Working Capital Facilities	Short Term	661.70	--	**[ICRA]A1+**	**[ICRA]A1+&**	**[ICRA]A1+&**	**[ICRA]A1+**	-	-
3	Unallocated Limits	Short Term/Long Term	22.30	--	**[ICRA]AA+&/ [ICRA]A1+**	**[ICRA]AA+&/ [ICRA]A1+&**	**[ICRA]AA+&/ [ICRA]A1+&**	**[ICRA]AA+ (Stable)/ [ICRA]A1+**	-	-

&= Under Watch with Developing Implications

Complexity level of the rated instruments

Instrument	Complexity Indicator
Term Loans	Simple
Working Capital Facilities	Simple
Unallocated Limits	NA

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	Term Loans	FY2019	3 Months T-bill + 2.39% p.a.	April 2026	350.00	[ICRA]AA+&
NA	Term Loans*	FY2021	LIBOR + 1% p.a.	April 2025	566.00	[ICRA]AA+&
NA	Working Capital Facilities	NA	NA	-	661.70	[ICRA]A1+
NA	Unallocated Limits	NA	NA	-	22.30	[ICRA]AA+&/ [ICRA]A1+

*Source: Company; * in the form of External Commercial Borrowings; &: under rating watch with developing implications*

[Please click here to view details of lender-wise facilities rated by ICRA]

Annexure II: List of entities considered for consolidated analysis

Company Name	Biocon's Ownership	Consolidation Approach
Biocon Biologics UK Limited (formerly Biocon Biologics Limited)	100%	Full Consolidation
Biocon SDN BHD, Malaysia	100% by Biocon Biologics UK Limited	Full Consolidation
Biocon Biologics Inc, USA		Full Consolidation
Biocon Biologics Healthcare Malaysia SDN BHD, Malaysia		Full Consolidation
Biocon Biologics Do Brasil Ltda, Brazil		Full Consolidation
Biocon Biologics FZ LLC, UAE		Full Consolidation

Source: Company's Annual Report for FY2022

Corrigendum

Document dated November 17, 2022, has been corrected with revisions as detailed below:

The rating methodology on implicit support from parent or group is captured in the applicable rating methodology section.

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