January 11, 2022

Biocon Biologics Limited: [ICRA]AA+ (Stable)/[ICRA]A1+ assigned

Summary of rating action

Instrument*	Current Rated Amount (Rs. crore)	Rating Action
Term Loans	916.00	[ICRA]AA+ (Stable); Assigned
Working Capital Facilities	661.70	[ICRA]A1+; Assigned
Untied Limits	22.30	[ICRA]AA+ (Stable) / [ICRA]A1+; Assigned
Total	**1,600.00**	

**Instrument details are provided in Annexure-1*

Rationale

The ratings draw comfort from Biocon Biologics Limited's (BBL) strong business profile, its established research and development (R&D) capabilities/early mover advantage in biosimilars, and its healthy revenues and margins. The company also has strong parentage as it is a subsidiary of Biocon Limited (rated [ICRA]AA+ (Stable)/[ICRA]A1+). As on date, BBL has commercialised eight biosimilars and has a strong product pipeline. Given the complexity, the long development cycle and high costs involved, the entry barriers for biosimilars are relatively high, giving BBL advantage as an early mover.

BBL's revenues increased at a healthy compound annual growth rate (CAGR) of 16.6% between FY2018 and H1 FY2022, supported by product launches and expansion across geographies. Further, the company had a healthy operating profit margin of over 30% during FY2019 – H1 FY2022, except in FY2021, when it moderated to 27% impacted primarily by the delay in some product launches because of the Covid-19 pandemic. BBL also has strong liquidity and lender/investor comfort. However, the significant R&D requirements and the relatively long gestation period have resulted in a low core return on capital employed (RoCE; 10.6% in FY2021). Also, BBL's coverage metrics are moderate[1] with Net Debt/OPBDITA at 3.8x and net gearing at 1.6x as on March 31, 2021, because of the relatively high debt level for the scale of operations.

BBL has entered into a collaboration with Serum Institute Life Science Private Limited (SILS) for 100 million vaccine doses per annum for the next 15 years. The healthy growth prospects for biosimilars, the company's product pipeline and diversification into vaccines are likely to support revenues and margins going forward. Given the industry's growth prospects, several players are expanding their presence in the biosimilar space. This is likely to increase competition and pricing pressure for BBL going forward. However, the company's robust biosimilar product portfolio and global footprint are likely to mitigate competitive threats to a large extent. 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. To support business expansion, the company has Rs. 700.0-750.0-crore annual capital expenditure (capex) plans over the medium term. Acquisitions or a material increase in the capex shall remain event risks and will be evaluated on a case-by-case basis. BBL has also received fund infusion of Rs 2,442.2 crore between January 2020 and January 2021 from four private equity (PE) investors in the form of equity and redeemable optionally convertible debentures.

[1] Debt excludes cash and liquid investments, non-convertible redeemable preference shares, optionally convertible redeemable preference shares and non-cumulative redeemable preference shares issued to Group companies. If the funds received in the form of redeemable optionally convertible debentures from Goldman Sachs are excluded from debt apart from debt from group entities, Net Debt/OPBDITA stood at 2.5x and net gearing at 1.0x as on March 31, 2021.

Key rating drivers and their description

Credit strengths

Strong business profile – BBL has a strong business profile backed by several launched and in-pipeline biosimilar products for developed and emerging markets, all of which are in partnership with Viatris (formerly Mylan) or Sandoz. As on date, it has commercialised three oncology biosimilars (trastuzumab, pegfilgrastim and bevacizumab) and three diabetes biosimilars (insulin glargine, insulin aspart and recombinant human insulin). 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. Apart from this, BBL has economic interest in two marketed in-licensed autoimmune biosimilars (adalimumab and etanercept) and has strong product pipeline. 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 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 at ~12-15% of revenues in the last three years and is expected to remain in similar range going forward. 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 16.6% between FY2018 and H1 FY2022, supported by product launches and expansion across geographies. The healthy growth prospects for biosimilars, 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-H1 FY2022, except FY2021, when it moderated to 27% impacted primarily by the delay in some product launches because of the pandemic. New product launches and stabilisation of existing products are expected to support margins going forward.

Strong parentage – BBL is a 93.5%-subsidiary[2] of Biocon Limited (rated [ICRA]AA+ (Stable)/[ICRA]A1+) and contributed 39% to the latter's consolidated revenues and 47% to its consolidated OPBIDTA in FY2021. BBL enjoys financial and operational flexibility by virtue of its parentage. As of September 30, 2021, the company had Rs. 1,286.4 crore of non-convertible and optionally convertible preference shares from Biocon Limited.

Credit challenges

Moderate coverage metrics and low core RoCE; significant capex plans – The company has significant R&D requirements and a relatively long gestation period compared to other generic pharma players because of the complexity of biosimilars. This had led to a low core RoCE (10.6% in FY2021). Further, the debt levels are relatively high, at Rs. 3,680.8[3] crore as of March 31, 2021, resulting in moderate coverage metrics (Net debt/OPBDITA at 3.8x and net gearing at 1.6x as on March 31, 2021). Going forward, BBL expects to incur annual capex of ~Rs. 700.0-750.0 crore 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 strong financial flexibility.

Growing global competition in biosimilar space – With the industry poised for healthy growth over the next few years, several players are expanding their presence in the biosimilar space. This is likely to increase competition and pricing pressure for BBL

[2] BBL shall offer a 15% stake to SILS, subject to necessary approvals; Biocon Limited's stake to reduce to 78.5% post completion of this transaction

[3] 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 2,651.5 crore at March 31, 2021

going forward. However, the company's robust biosimilar product portfolio and global footprint are likely to mitigate competitive threats to a large extent.

Exposed to regulatory risks and vulnerable 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 unfavourable forex movements. However, the hedging mechanism adopted by BBL mitigates the risk to an extent.

Liquidity position: Strong

BBL's liquidity profile is strong, with the company having cash and bank balances of Rs. 343.0 crore and undrawn working capital limits of Rs. 287.0 crore as on September 30, 2021. The average working capital utilisation remained at ~50% during the 12 month-period ended September 2021. The company has consolidated debt repayment obligations of ~Rs 740.0 crore in FY2022 (excluding lease liabilities of Rs. 43 crore), which are payable between December 2021 and March 2022, for which refinancing tie-ups are in place at present. Over the medium term, it has consolidated repayment obligations of ~Rs 200.0 crore and ~Rs 300.0 crore for FY2023 and FY2024 respectively, on its existing loans. BBL's capex is expected to be ~Rs. 700-750 crore per annum for the next two to three years, part of which is likely to be debt-funded. Despite this, the company's liquidity position is expected to remain strong over the medium term, supported by its strong operational profile and margins, strong financial flexibility and lender/investor comfort.

Rating sensitivities

Positive factors – The rating could be upgraded a) if there is a significant improvement in the profitability (RoCE) and debt coverage metrics on a sustained basis, aided by the continued healthy momentum in the biosimilars business and the successful ramp-up of the vaccine business; and b) upon the strengthening of the credit profile of the parent, Biocon Limited.

Negative factors – Pressure could emerge with the sustained deterioration in earnings leading to pressure on the profitability or a significant rise in the net debt. Weakening in the parent's (Biocon Limited, [ICRA]AA+(Stable)/[ICRA]A1+) 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 Limited (rated [ICRA]AA+(Stable)/[ICRA]A1+) currently holds a 93.5% stake[4] in BBL. It enjoys financial and operational flexibility by virtue of its parentage.
Consolidation/Standalone	For arriving at the ratings, ICRA has considered the consolidated financials of BBL. As on March 31, 2021, the company had one subsidiary and five stepdown subsidiaries which are listed in Annexure-2.

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

[4] *BBL shall offer a 15% stake to SILS, subject to necessary approvals; Biocon Limited's stake to reduce to 78.5% post completion of this transaction*

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 15% equity stake to SILS for the recent vaccine collaboration subject to the receipt of regulatory approvals.

Key financial indicators (audited)

BBL Consolidated	FY2020	FY2021
Operating Income (Rs. crore)	2,305.5	2,797.2
PAT (Rs. crore)	317.3	267.5
OPBDITA/OI (%)	32.2%	27.0%
PAT/OI (%)	13.8%	9.6%
Total Outside Liabilities/Tangible Net Worth (times)	8.3	4.0
Total Debt/OPBDITA (times)	5.8	6.7
Interest Coverage (times)	9.0	20.3

**Provisional; PAT: Profit after Tax; OPBDITA: Operating Profit before Depreciation, Interest, Taxes and Amortisation; All ratios are as per ICRA calculations*

Source: Company and ICRA Research

Status of non-cooperation with previous CRA: Not applicable

Any other information: None

Rating history for past three years

	Instrument	Current Rating (FY2022)				Chronology of Rating History for the Past 3 Years			
		Type	Amount Rated (Rs. crore)	Amount Outstanding as of Sep 30, 2021 (Rs. crore)	Date & Rating in FY2022	Date & Rating in FY2020		Date & Rating in FY2019	Date & Rating in FY2018
					Jan 11, 2022	-	-	-	-
1	Term Loans	Long Term	916.00	916.00	[ICRA]AA+ (Stable)	-	-	-	-
2	Working Capital Facilities	Short Term	661.70	--	[ICRA]A1+	-	-	-	-
3	Untied Limits	Short Term/Long Term	22.30	--	[ICRA]AA+ (Stable)/ [ICRA]A1+				

Complexity level of the rated instruments

Instrument	Complexity Indicator
Term Loans	Simple
Working Capital Facilities	Simple

Untied 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: www.icra.in

Annexure-1: 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+ (Stable)
	Term Loans*	FY2021	LIBOR + 1% p.a.	April 2025	566.00	[ICRA]AA+ (Stable)
	Working Capital Facilities	NA	NA	-	661.70	[ICRA]A1+
	Untied Limits	NA	NA	-	22.30	[ICRA]AA+ (Stable)/ [ICRA]A1+

Source: *Company; * in the form of External Commercial Borrowings*

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

Annexure-2: List of entities considered for consolidated analysis

Company Name	BBL 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: *BBL's annual report FY2021*

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