

August 30, 2024

## Biocon Biologics Limited: Ratings 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+ (Stable); Reaffirmed
Short-term Working Capital Facilities	1566.70	1566.70	[ICRA]A1+; Reaffirmed
Long-term/ Short-term Unallocated Limits	117.30	117.30	[ICRA]AA+ (Stable)/[ICRA]A1+; Reaffirmed
<b>Total</b>	<b>2,600.00</b>	<b>2,600.00</b>	

\*Instrument details are provided in Annexure-I

### Rationale

The reaffirmed ratings consider Biocon Biologics Limited's (BBL) strong business profile, its established research and development (R&D) capabilities/early-mover advantage in biosimilars and its healthy revenue growth over the past two to three years, partly owing to the consolidation of the biosimilar business of Viatris acquired in November 2022. ICRA expects the company's revenues to continue to grow at a healthy rate, supported by new product launches and further growth in market share of its biosimilars launched in different geographies. BBL also benefits from the financial support available to it from its parent, Biocon Limited (Biocon, rated [ICRA]AA+ (Stable)/[ICRA]A1+) and ICRA expects Biocon to continue providing need-based funding support whenever required. ICRA further derives comfort from the management's intention of deleveraging its balance sheet in the near term.

As on date, BBL has commercialised eight biosimilars and has a strong product pipeline. Given the product and manufacturing complexity, the long development cycle and the high costs involved, the entry barriers for biosimilars are high, giving BBL the advantage of an early mover. In FY2024, BBL witnessed strong YoY growth of ~58% in revenues, partly supported by the consolidation of Viatris' biosimilars business. The operating profit margin (OPM) moderated to 22.8% in FY2024 from 27.3% in FY2023, mainly due to one-time integration-related costs, which BBL completed in 120+ countries one year ahead of its planned schedule. Additionally, slower traction in some of the molecules across geographies constrained the margins, although the company reported Rs. 350 crore as a gain on divestiture of its non-core nephrology and dermatology branded formulations India (BFI) business to Eris Lifesciences Limited in FY2024. In Q1 FY2025, the slowdown in US biotech funding further impacted the OPM, which was, in turn, compensated by the gain of Rs. 1,057 crore on the sale of metabolics, oncology, and critical care diagnostic divisions to Eris Lifesciences Limited. Obtaining new product approvals in a timely manner and the extent of performance improvement through the launch of products across geographies remain key monitorables.

BBL prepaid \$250 million of acquisition-related debt in FY2024, which reduced its total debt and improved the debt metrics for the fiscal. BBL's adjusted net debt (net debt excluding intra-group and structured debt<sup>1</sup>)/OPBDITA improved to 5.7 times as on March 31, 2024 from 7.8 times as on March 31, 2023. After the payment of the first tranche of the deferred consideration of \$175 million in April 2024 to Viatris, BBL has to pay the balance \$160 million in November 2024. This apart, it has significant repayment obligations for acquisition-related debt of \$950 million, which commences from FY2026. The funding for the deferred consideration and the execution of deleveraging plans in a timely manner are key credit monitorables. BBL's core return on capital employed (RoCE) dipped to 3.3% in FY2024 from 5.1% in FY2022 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,

<sup>1</sup> Structured debt as of March 31, 2024 included debentures issued to Goldman Sachs India AIF Scheme Fund of ~\$150 million

supported by the launch of new products. Given the industry's growth prospects, several players are expanding their presence in the biosimilars space. This is likely to increase competition and pricing pressure for BBL going forward. However, the company's robust product portfolio and global footprint are likely to mitigate competitive threats to a large extent. Further, BBL is also exposed to increasing regulatory scrutiny and uncertainties in the approval pathway for molecules under development and the consequent volatility in launch timelines and revenues.

The Stable outlook on the long-term rating reflects ICRA's expectation that the company will continue to benefit from its strong business profile, supported by established R&D capabilities. That said, material deleveraging will be one of the key monitorables.

## Key rating drivers and their description

### Credit strengths

**Strong parentage** – BBL is a ~70% subsidiary (on a fully diluted basis) of Biocon and generated ~60% of its parent's consolidated revenues and ~60% of its consolidated OPBIDTA in FY2024. BBL enjoys financial and operational flexibility by virtue of its parentage. It also benefits from the financial support available to it from its parent, Biocon, and ICRA expects Biocon to continue providing need-based funding support whenever required.

**Strong business profile owing to established R&D capabilities; relatively high entry barriers in biosimilars space** – BBL 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. In FY2024, Biocon also received the USFDA<sup>2</sup>, UK MHRA<sup>3</sup>, 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 biosimilars Pertuzumab, Ustekinumab and Denosumab for oncology and bone health and five other undisclosed biosimilars under various stages of development. Going forward, BBL's revenue growth is expected to be supported by new launches, expansion in new geographies and increase in the market share of its existing products.

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 average net R&D expense was ~12% of its revenues in the last five years. Given the complexity, the long development cycle and high costs involved, entry barriers for the biosimilar segment are relatively higher compared to generics, giving BBL the advantage of an early mover.

**Healthy scale-up of operations** – In FY2024, BBL witnessed strong YoY revenue growth of ~58% supported by full fiscal year consolidation of Viatrix' biosimilar revenues. The revenues in FY2024 were also supported by Rs. 350 crore gain from the divestiture of the nephrology and dermatology branded formulations of the India (BFI) business to Eris Lifesciences Limited on a slump-sale basis. Subsequently, BBL sold its BFI business consisting of metabolics, oncology, and critical care diagnostic 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, which is expected to support the revenue growth in the current fiscal year. Despite a healthy scale-up in revenues, BBL's OPM moderated to 22.8% in FY2024 from 27.3% in FY2023, mainly due to one-off expenses incurred towards the integration of the Viatrix operations across 120+ countries, which took place a year earlier than scheduled. The healthy growth prospects for biosimilars, new product launches and the expansion into new geographies for the existing products are expected to support BBL's margins going forward.

<sup>2</sup> USFDA: The United States Food and Drug Administration is a federal agency of the Department of Health and Human Services

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

## Credit challenges

**High leverage and low RoCE** – BBL's total debt remained high at Rs. 14,092.7 crore as on March 31, 2024. BBL prepaid \$250 million of acquisition-related debt in FY2024, which improved the company's debt metrics for the fiscal. The company's adjusted net debt (net debt excluding intra-group and structured debt)/OPBDITA was at 5.7 times as on March 31, 2024 from 7.8 times as on March 31, 2023, although leverage remained high. However, RoCE is expected to improve gradually over the medium-to-long term with healthy accruals, supported by the launch of new products. ICRA further derives comfort from the management's intention of deleveraging its balance sheet in the near term.

**Growing competition in the biosimilar space and lower traction in one of the key products in the US market** – 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 pressures for BBL going forward. However, the company's robust product portfolio and global footprint are likely to mitigate competitive threats to an extent.

In FY2024, the company also launched its biosimilar, Adalimumab, in the US market, which experienced slower-than-expected traction. The originator (brand name Humira) retained a preferred or exclusive status on payor formularies and offered high rebates, providing no incentive for prescribers or pharmacies to switch to biosimilars. As a result, the originator retained over 98% of the market by volume. The management expects an improvement in market share from CY2025, which remains monitorable.

**Regulatory risks** – 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 ~90% of its revenues from overseas markets, the company's revenues and margins are susceptible to adverse forex movements. However, the hedging mechanism adopted by BBL mitigates the risk to an extent.

### Liquidity position: Adequate

As on March 31, 2024, the company had consolidated free cash and bank balance and liquid investments of ~Rs. 917 crore and unutilised working capital limits of ~Rs. 420 crore. BBL's capex is expected to be ~\$100 million per annum for the next two to three years. The repayment obligations (excluding lease liabilities) for FY2025 and FY2026 are Rs. 607 crore and Rs. 4,163 crore, respectively, on its existing loans, which is sizeable. BBL also has an additional obligation to pay a deferred consideration of \$160 million to Viatrix in November 2024. ICRA expects the capital commitments and debt obligations for FY2025 and FY2026 to be met through a mix of internal accruals, existing cash reserves and equity raise. Overall, BBL'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** – The long-term rating could be upgraded if BBL demonstrates significantly higher-than-expected deleveraging, coupled with improvement in profitability and liquidity position on a sustained basis. The rating could also be upgraded with the strengthening of the parent company's (Biocon) credit profile.

**Negative factors** – Pressure on ratings could emerge if the company is unable to achieve timely material deleveraging and/or is unable to scale up earnings on a sustained basis. The impact of adverse regulatory developments, if any, would be evaluated on a case-to-case basis. 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	<a href="#">Corporate Credit Rating Methodology Pharmaceuticals</a>
Parent/Group support	The ratings assigned to BBL factor in the high likelihood of its parent, Biocon, (rated [ICRA]AA+ (Stable) / [ICRA]A1+) extending financial support to it because of close business linkages between them. ICRA also expects Biocon to be willing to extend financial support to BBL to protect its reputation from the consequences of a Group entity's distress.
Consolidation/Standalone	For arriving at the ratings, ICRA has considered the consolidated financials of BBL. As on March 31, 2024, the company had 22 subsidiaries, which are enlisted in Annexure II.

## About the company

Biocon Biologics Limited (formerly Biocon Biologics India Limited) (BBL/the company), a subsidiary of Biocon, was incorporated on June 8, 2016. BBL acquired the business related to the manufacturing and commercialisation of biosimilars, insulins and drug substances on a going-concern basis by way of slump sale from Biocon, as on May 01, 2019. The company also acquired branded formulations Indian business on a going concern basis on a slump-sale basis from Biocon on August 01, 2019. BBL acquired the biosimilar assets of Viartis Inc. in November 2022, and the operations were fully integrated by December 2023.

### Key financial indicators (audited)

BBL Consolidated	FY2023	FY2024
Operating income	5,583.8	8,824.2
PAT	133.5	218.2
OPBDIT/OI	27.3%	22.8%
PAT/OI	2.4%	2.5%
Total outside liabilities/Tangible net worth (times)	1.3	1.3
Total debt/OPBDIT (times)	9.6	7.0
Interest coverage (times)	5.1	2.3

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	916.00	[ICRA]AA+ (Stable)	09-Oct-23	[ICRA]AA+ (Stable)	17-Nov-22	[ICRA]AA+ Rating Watch with Developing Implications	10-Mar-22	[ICRA]AA+ Rating Watch with Developing Implications
				04-Aug-23		30-Jun-22		11-Jan-22	[ICRA]AA+ (Stable)
Working Capital Facilities	Short term	1566.70	[ICRA]A1+	09-Oct-23	[ICRA]A1+	17-Nov-22	[ICRA]A1+	10-Mar-22	[ICRA]A1+ Rating Watch with Developing Implications
				04-Aug-23		30-Jun-22	11-Jan-22	[ICRA]A1+	
Unallocated Limits	Long Term/ Short Term	117.30	[ICRA]AA+ (Stable)/ [ICRA]A1+	09-Oct-23	[ICRA]AA+ (Stable)/ [ICRA]A1+	17-Nov-22	[ICRA]AA+ Rating Watch with Developing Implications / [ICRA]A1+	10-Mar-22	[ICRA]AA+ / [ICRA]A1+; Rating Watch with Developing Implications
				04-Aug-23		30-Jun-22	11-Jan-22	[ICRA]AA+ (Stable) / [ICRA]A1+	

## Complexity level of the rated instruments

Instrument	Complexity Indicator
Long-term term loans	Simple
Short-term 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	NA	April 2026	350.00	[ICRA]AA+ (Stable)
NA	Term loans*	FY2021	NA	April 2025	566.00	[ICRA]AA+ (Stable)
NA	Working Capital Facilities	NA	NA	-	1566.70	[ICRA]A1+
NA	Unallocated Limits	NA	NA	-	117.30	[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 II: List of entities considered for consolidated analysis**

Company Name	BBL Ownership	Consolidation Approach
Biocon Biologics UK Limited	100%	Full Consolidation
Biosimilars Newco Limited	100% by Biocon Biologics Limited and Biocon Biologics UK Limited	Full Consolidation
Biosimilar Collaborations Ireland 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.	100% by Biocon Biologics UK Limited	Full Consolidation
Biocon Biologics Belgium BV		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
Biocon Biologics Croatia LLC		Full Consolidation

Note: Company Annual Report FY2024

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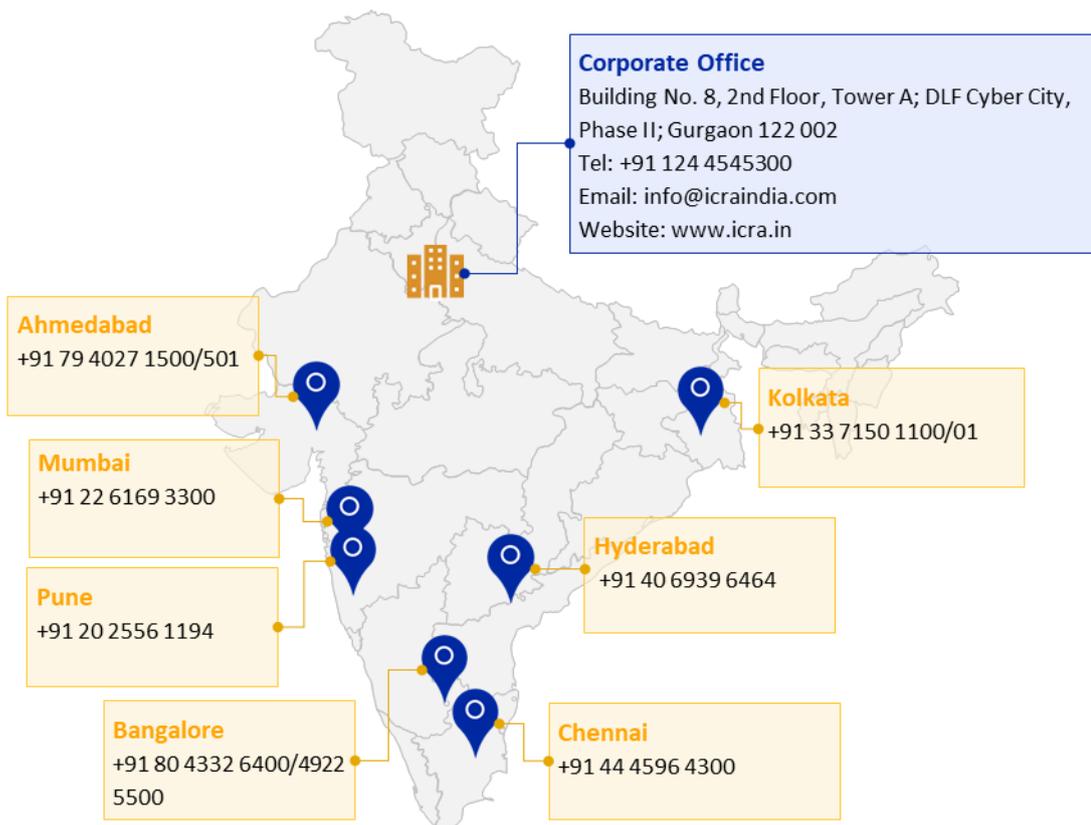
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### Branches



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