

August 04, 2023

Biocon Biologics 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	916.00	916.00	[ICRA]AA+(Stable); Reaffirmed and removed from Rating Watch with Developing Implications, and assigned Stable outlook
Working Capital Facilities	661.70	661.70	[ICRA]A1+; Reaffirmed
Unallocated Limits	22.30	22.30	[ICRA]AA+(Stable); Reaffirmed and removed from Rating Watch with Developing Implications, and assigned Stable outlook/[ICRA]A1+; Reaffirmed
Total	1,600.00	1,600.00	

*Instrument details are provided in Annexure-I

Rationale

The long-term rating of Biocon Biologics Limited (BBL/ the company) was placed on watch with developing implications, pending completion of its acquisition of the biosimilars assets of Viatrix Inc. (Viatrix) (hereafter referred to as acquisition), 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 from Viatrix was funded by \$1.33 billion of debt in Biocon Limited (Biocon; parent entity) 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 fund raise at BBL's level.

The sizeable debt-funded acquisition has led to moderation in BBL's and Biocon's debt and profitability metrics in FY2023. Biocon's adjusted net debt (net debt excluding structured debt¹)/OPBDITA moderated to 4.8x as of March 31, 2023, from 1.2x as of March 31, 2022. BBL's coverage metrics have also witnessed moderation with adjusted net debt (BBL net debt excluding inter-group and structured debt)/OPBDITA at 7.9x as on March 31, 2023, from 2.3x as on March 31, 2022. ICRA notes that Biocon and BBL have cumulatively raised structured debt of ~\$98 million in May 2023 from Edelweiss² 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 at Biocon level 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 Viatrix in FY2025, partially to acquire rights in one of the biosimilars. The funding of the same and the execution of deleveraging plans at consolidated level in a timely manner will be key credit monitorables. This acquisition has provided BBL with complete ownership of Viatrix' rights in biosimilars assets, enabling it to realise the full revenues and associated profits as against ~30% profits which was accrued to BBL as per previous arrangement with Viatrix

¹ Structured debt as of March 31, 2023, includes debentures issued to Goldman Sachs India AIF Scheme of ~\$170 million availed at BBL level and debentures issued to Kotak Special Situations Fund of ~\$130 million availed at Biocon standalone level.

² Edelweiss Alternative Asset Advisors and ESOF III Investment Fund investment of ~\$98 million in May 2023 (availed at Biocon level), which is also part of the structured debt from FY2024.

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 Viartis. 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 BBL's strong business profile, its established research and development (R&D) capabilities/early mover advantage in biosimilars, and its healthy revenues and margins. As a subsidiary of Biocon (rated [ICRA]AA+(Stable)/[ICRA]A1+), BBL also enjoys a strong parentage. 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 high, giving BBL the advantage of an early mover. During FY2023, BBL witnessed strong YoY revenue growth of 61% supported by consolidation of Viartis' biosimilar revenues of ~Rs. 2,200 crore from November 29, 2022. The operating profit margin (OPM) moderated to 27.3% in FY2023 from 30.2% mainly due to higher R&D cost incurred for the under-development product pipeline. However, the OPM is expected to remain healthy over the near term supported by ramp-up in revenues from new product launches and expansion of existing products across geographies.

BBL's core RoCE dipped to 5.1% in FY2023 from 14.3% in FY2022 due to the sizeable business acquisition of Viartis. However, despite the same, RoCE is expected to improve gradually over the medium to long-term with healthy accruals and launch of products. 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. 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 49% of its parent's consolidated revenues and 56% of its consolidated OPBIDTA in FY2023. BBL enjoys financial and operational flexibility by virtue of its parentage.

Strong business profile – BBL has a strong business profile backed by 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 Viartis deal, BBL has also acquired access to an ophthalmology biosimilar Aflibercept with a first-to-file status in FY2025, after payment of deferred consideration. BBL 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. The company recently launched its biosimilar, Adalimumab, in the US market in July 2023,

and expects to launch two more products (Bevacizumab and Insulin Aspart), which are under facility approval stage in the US market at present.

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 average net R&D expense was ~13% of its revenues in the last five years. Given the complexity the 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 revenue growth and profit margins – During FY2023, BBL witnessed strong YoY revenue growth of 61% supported by consolidation of Viatris' biosimilar revenues of ~Rs. 2,200 crore from November 29, 2022. The operating profit margin (OPM) moderated to 27.3% in FY2023 from 30.2% mainly due to higher R&D cost incurred for the under-development product pipeline. Given the healthy growth prospects for biosimilars, new product launches and expansion into new geographies for the existing products are expected to support margins, going forward.

Credit challenges

Significant increase in debt levels and low RoCE – BBL's adjusted net debt increased significantly to Rs. 11,995 crore in FY2023 from Rs. 2,410.9 crore in FY2022, following the sizeable debt funded acquisition of Viatris' biosimilar assets. BBL's coverage metrics have also witnessed moderation with adjusted net debt (BBL net debt excluding inter-group and structured debt)/OPBDITA at 7.9x as on March 31, 2023, from 2.3x as on March 31, 2022. The company's core RoCE dipped to 5.1% in FY2023 from 14.3% in FY2022. Despite incremental OPBDITA from the acquired entity, BBL's consolidated debt metrics and profitability (RoCE) has 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. Further, BBL expects to incur an annual capex of ~\$125-~\$150 million over the next two years to support business expansion. Although the capex may look 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 supported by its parentage.

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 BBL 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 ~90% of its revenues from overseas markets, the company's revenues and margins are susceptible to adverse forex movements including appreciation of the Rupee against the Dollar. However, the hedging mechanism adopted by BBL mitigates the risk to an extent.

Liquidity position: Adequate

As of March 31, 2023, the company had consolidated cash and liquid investments of ~Rs. 987 crore and unutilised working capital debt ~Rs.190crore. BBL's capex is expected to be ~\$125-\$150 million per annum for the next two years, part of which is likely to be debt funded. The repayment obligations (excluding lease liabilities) for FY2024 and FY2025 are Rs. 107 crore and Rs. 800 crore, respectively, on its existing loans. ICRA expects the capital commitments and debt obligations for the next two years to be met majorly 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, 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 and improvement in liquidity position while maintaining healthy profitability metrics on a sustained basis. The rating could also be upgraded upon the strengthening of the credit profile of the parent, Biocon.

Negative factors – Negative pressure on ratings could emerge if the company is unable to achieve material deleveraging in a timely manner and/or witnesses' inability to scale up earnings on a sustained basis. Impact of adverse regulatory developments, if any, would be evaluated on a case-by-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	Corporate Credit Rating Methodology Rating Methodology for Pharmaceutical Industry Rating Approach – Implicit Support from Parent or Group
Parent/Group support	Biocon currently holds ~70% stake on a fully diluted basis 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.

About the company

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. BBL has completed the acquisition of the biosimilar business from Viartis with effect from November 29, 2022, which has led to annualised revenues of ~\$1 billion from Q4 FY2023. Also, it has strategic partnerships with a global player, Sandoz, for commercialisation of its biosimilars.

Key financial indicators (audited)

BBL Consolidated	FY2021	FY2022	FY2023
Operating income	2,797.2	3,464.3	5,583.8
PAT	267.5	382.5	133.5
OPBDIT/OI	27.0%	30.2%	27.3%
PAT/OI	9.6%	11.0%	2.4%
Total outside liabilities/Tangible net worth (times)	4.0	3.3	1.3
Total debt/OPBDIT (times)	6.7	5.0	9.6
Adjusted net debt/OPBDIT (times)	2.5	2.3	7.9
Interest coverage (times)	20.3	15.7	5.1

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	Jun 30, 2022	Mar 10, 2022	Jan 11, 2022	-	
1 Term Loans	Long Term	916.00	916.00	[ICRA]AA+ (Stable)	[ICRA]AA+&	[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+&	[ICRA]A1+&	[ICRA]A1+	-
3 Unallocated Limits	Short Term/Long Term	22.30	--	[ICRA]AA+ (Stable)/ [ICRA]A1+	[ICRA]AA+&/ [ICRA]A1+	[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
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	3 Months T-bill + 2.39% p.a.	April 2026	350.00	[ICRA]AA+(Stable)
NA	Term Loans*	FY2021	LIBOR + 1% p.a.	April 2025	566.00	[ICRA]AA+(Stable)
NA	Working Capital Facilities	NA	NA	-	661.70	[ICRA]A1+
NA	Unallocated 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 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.	100% by Biocon Biologics UK Limited	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

Note: Company Annual Report FY2023

ANALYST CONTACTS

Shamsher Dewan

+91 124 4545 5328

shamsherd@icraindia.com

Mythri Macherla

+91 22 6114 3435

mythri.macherla@icraindia.com

Kinjal Shah

+91 22 6114 3442

kinjal.shah@icraindia.com

Seetha Pillai

+91 80 4332 6411

seetha.pillai@icraindia.com

RELATIONSHIP CONTACT

L. Shivakumar

+91 22 6169 3304

shivakumar@icraindia.com

MEDIA AND PUBLIC RELATIONS CONTACT

Ms. Naznin Prodhani

Tel: +91 124 4545 860

communications@icraindia.com

Helpline for business queries

+91-9354738909 (open Monday to Friday, from 9:30 am to 6 pm)

info@icraindia.com

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ICRA Limited



Registered Office

B-710, Statesman House, 148, Barakhamba Road, New Delhi-110001

Tel: +91 11 23357940-45



Branches



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