Rating Rationale

March 09, 2022 | Mumbai

Biocon Limited

Long-term rating placed on 'Watch Developing'; short-term rating reaffirmed

Rating Action

Total Bank Loan Facilities Rated	**Rs.250 Crore**
Long Term Rating	**CRISIL AA+/Watch Developing (Placed on 'Rating Watch with Developing Implications')**
Short Term Rating	**CRISIL A1+ (Reaffirmed)**

1 crore = 10 million
Refer to Annexure for Details of Instruments & Bank Facilities

Detailed Rationale

CRISIL Ratings has placed its 'CRISIL AA+' rating on the long-term bank facilities of Biocon Ltd (Biocon) on **'Rating Watch with Developing Implications'**. The rating on the short-term bank facilities has been reaffirmed at 'CRISIL A1+'.

On February 28, 2022, Biocon Biologics Ltd (BBL ; a subsidiary of Biocon) announced that its Board of Directors, at a meeting held on February 27, 2022, approved the proposed acquisition of the biosimilar business of US-based Viatris Inc. Accordingly, BBL entered into a definitive agreement with Viatris Inc to acquire its biosimilars business for a total consideration of USD 3.335 billion, including cash up to USD 2.335 billion and compulsorily convertible preference shares (CCPS) in BBL of USD 1 billion. The upfront cash payment of USD 2 billion is expected to be funded by ~USD 800 million raised through equity infusion in BBL and the remainder is to be funded by debt. The transaction is expected to close in the second half of calendar year 2022, subject to satisfaction of closing conditions and certain regulatory approvals.

CRISIL Ratings will continue to monitor progress on the transaction and will remove the ratings from watch and take a final rating action once the regulatory approvals are in place and the transaction is concluded. While this transaction will enable BBL to attain commercialisation expertise in the developed markets and realize the higher revenue and associated profits from its partnered products, its debt protection metrics could moderate in the near-term due to the large debt expected to be taken for the acquisition. Nonetheless, CRISIL Ratings expects the debt protection metrics to improve back to almost current-levels by fiscal 2024.

CRISIL Ratings will remain in discussion with BBL's management to better understand the terms of debt funding for the transaction as well as the synergy benefits that may emerge post completion of the transaction. CRISIL Ratings also notes that the company may undertake an initial public offering (IPO) over the next two years depending on the market conditions.

Earlier, in September 2021, BBL and Serum Institute Life Sciences Pvt Ltd (SILS), announced a strategic alliance as part of which BBL will offer around 15% stake to SILS at a post-money valuation of around USD 4.9 billion, for which it will get committed access to 100 million doses of vaccines per annum for 15 years. This alliance is subject to regulatory approval and is on track to be implemented by October 1, 2022. CRISIL Ratings expects this alliance to strengthen BBL's business risk profile and product offerings over the medium term and will continue to monitor the developments in this regard.

The ratings continue to reflect the established position of Biocon in the biopharmaceutical (biopharma) segment, diversified revenue and healthy pipeline of biosimilar products. The ratings also factor in its strong financial risk profile, driven by healthy debt protection metrics. These strengths are partially offset by uncertainty regarding payoffs in the research and development (R&D)-driven model for development and commercialisation of biosimilars and novel molecules. The company is also susceptible to regulatory uncertainties and intense competition.

Analytical Approach

To arrive at its ratings, CRISIL Ratings has combined the business and financial risk profiles of Biocon and its subsidiaries as all the companies, collectively referred to as Biocon, primarily operate in the biopharma sector and are under a common management. The joint venture, Neo Biocon FZ-LLC, has been moderately consolidated. CRISIL Ratings has amortised goodwill on acquisition and intangibles (including products under development) over five years.

Please refer Annexure - List of Entities Consolidated, which captures the list of entities considered and their analytical treatment of consolidation.

Key Rating Drivers & Detailed Description

Strengths

Established position in the biopharma segment

Biocon is the leading biopharma company in India with a track record of 40 years. In the biopharma segment, the company has presence primarily in India and semi-regulated economies. In the domestic formulations market, it is a biosimilars-focused specialty products company, mainly in chronic therapy areas. The domestic business has multiple divisions such as metabolics, oncology, nephrology, immunotherapy and comprehensive care. Biocon has strong brands such as Insugen® (rh-insulin), BASALOG™ (insulin glargine), BIOMab-EFGR® (nimotuzumab), BLISTO® (glimepiride + metformin), CANMab (trastuzumab), KABEVA (bevacizumab), Evertor® (everolimus), TACROGRAF™ (tacrolimus), and ALZUMAb™ (itolizumab) across its biosimilar and novel biologic portfolio. It is among the leading players in insulin in Asia, with its global capacities making it a leading insulin producer globally. Biocon is also a leading supplier of complex, small molecule active pharmaceutical ingredients (APIs) across the cardiovascular, anti-obesity and immuno-suppressant therapeutic areas.

Strong and diversified revenue streams

Revenue is diversified primarily across generics (28% of revenue in the first nine months of fiscal 2022), biosimilars (43%), research services (32%), including the inter segment revenue (-4%).

Generics segment degrew by 9% in first nine months of fiscal 2022, due to a muted performance in the first half of the fiscal on account of operational and supply challenges posed by the Covid-19 pandemic, continued pricing pressure in the US for the formulations portfolio as well as slower-than-expected ramp up of demand for APIs. This was partially offset by a sequential growth in the third quarter driven by the launch of a complex generic, Everolimus, in the US market as well as uptick in the API business. Biocon has consolidated its position in this segment through its portfolio of differentiated API s, including fermentation based, synthetic, high potent and peptides as well as vertically integrated complex formulations and a moderate growth is expected in this segment over medium term.

Biocon's long-term growth potential is expected to be led by its biosimilar and novel biologics segments in both semi-regulated and regulated markets. While these segments continue to require large investment for R&D and capital expenditure (capex), the company is supported by steady cash flow from all its established business segments – generics, biosimilars and research services. As on December 31, 2021, the company had five approved biosimilar products in Europe and three in the US in partnership with Viatris. Semglee® (biosimilar insulin glargine) was launched in the US in August 2020 and is Biocon's third launch in that market after Fulphila® (biosimilar pegfilgrastin) and Ogivri® (biosimilar trastuzumab). Additionally, Biocon received the European Commission's approval for Abevmy® (biosimilar bevacizumab) and Kixelle® (biosimilar insulin aspart) in the second half of fiscal 2021. Further, the United States Food and Drug Administration (US FDA) intimation is awaited for site inspection of facilities for biosimilar bevacizumab. For biosimilar aspart, on-site pre-approval US FDA inspection for the company's Malaysian facility was carried out in September 2021 and commercialisation should happen in due course. The company will also continue to launch its products in other key geographies.

Syngene enhances revenue diversity with sustained healthy growth and profitability. For the first nine months of fiscal 2022, Syngene accounted for about one-third of the consolidated revenue and operating profit of Biocon. With commercialisation of the recently completed capex and expected ramp-up of operations, Syngene is expected to sustain its operating performance and revenue contribution over the medium term.

Healthy pipeline of biosimilar products

Biocon has strong R&D capability and has several biosimilars and novel biologic products in development in the diabetes, oncology and autoimmune therapeutic segments. In partnership with Viatris Inc, Biocon's biosimilar assets received approvals from various regulators and were launched in regulated and semi-regulated markets. The scaling up of revenue and market share of key biosimilar assets (trastuzumab, pegfilgrastin and insulin glargine) in the US and Europe and successful launch of biosimilars bevacizumab and insulin aspart will be key monitorables.

Strong financial risk profile

Adjusted gearing was healthy at 0.6 time as on December 31, 2021, and interest coverage and net cash accrual to total debt ratios were healthy at 26.7 times and 0.3 time, respectively, for the first nine months of fiscal 2022. The company completed a series of fundraising rounds at its subsidiary, BBL, in the past two fiscals and built up healthy cash and liquid investments of Rs 3,197 crore as on December 31, 2021, which will be utilised to partly fund capex and R&D. Biocon, BBL and Syngene each plan large annual capex of USD 80-100 million over the medium term. Biocon plans capex for operationalising its immunosuppressants and API facilities; BBL will undertake capex for commercialising a monoclonal antibodies facility and towards R&D for building a product pipeline; while Syngene will increase capacity of its research and API manufacturing facilities. Given the consolidated net cash accrual of over Rs 1,500 crore per fiscal, strong liquidity, and part funding of capex in biosimilars by Viatris Inc, the financial risk profile will likely remain healthy over the medium term. Debt protection metrics will nevertheless, moderate due to sizable debt addition by BBL to fund the proposed acquisition of the biosimilar business of Viatris. For instance, the debt to earnings before interest, tax, depreciation and amortisation (EBITDA) is seen moderating to 3.5-4 times in fiscal 2023 (from 2-2.5 times in fiscal 2022), before correcting back to 2-2.5 times in fiscal 2024.

Weaknesses

Uncertainty regarding payoffs in the R&D-driven model in biosimilars and novel biologic segments, especially for regulated markets

The company will continue to spend extensively on R&D for developing new molecules and biosimilars, particularly for the US and Europe. It remains exposed to long gestation period and uncertainty regarding timing and extent of returns on investments on new molecules given the nature of the drug discovery model. Gross R&D and net R&D (net of capitalisation) were 12% and 10%, respectively, of operating revenue, excluding Syngene, for the first nine months of fiscal 2022 (13% and 11%, respectively, in fiscal 2021). The R&D expenditure will increase over the medium term, driven by expenses on clinical trials and R&D to build a robust product pipeline. The uncertainty regarding revenue visibility and return on the R&D expense exposes the company to investment risk. However, it has achieved critical milestones in previous fiscals with approvals for biosimilars and launch in regulated and semi-regulated markets in partnership with Viatris Inc, leading to strong revenue growth. The extent of ramp up, particularly in the regulated markets, will be a key monitorable.

Susceptibility to regulatory uncertainties and intense competition

Regulatory risks are manifested in increasing scrutiny and inspections by regulatory authorities, including the US FDA, European Medical Agency, and those in Asian and Latin American markets.

The company faces intense competition in the regulated markets, which is characterised by aggressive defence tactics by innovator companies through introduction of authorised generics and the presence of several cost-competitive Indian players. In the branded formulations segment, additions to lists under Drug Price Control Order impact product pricing and profitability.

Liquidity: Strong

CRISIL Ratings expects Biocon to generate cash accrual of over Rs 1,500 crore, against term debt obligation of around Rs 800 crore (including Syngene and BBL) for fiscal 2022. Financial flexibility is high because of unencumbered cash and marketable securities of Rs 3,197 crore as on December 31, 2021. Biocon, BBL and Syngene each plan large annual capex of USD 80-100 million over the medium term, which is likely to be funded in a prudent mix of cash accrual and debt. Liquidity may moderate should Biocon use the cash surpluses to infuse funds into BBL for the proposed acquisition of the biosimilar business of Viatris, but still remain healthy. Repayment obligations should be sizeable in the medium term, post raising of the loans by BBL, but would be serviced mainly from accruals.

Environment, social and governance (ESG) profile

CRISIL Ratings believes Biocon's ESG profile supports its already strong credit risk profile.

The pharmaceutical sector can have a significant impact on the environment on account of greenhouse gas emissions, water use and waste generation. The sector's social impact is characterised by impact on the health and wellbeing of consumers on account of its products and on employees and local community on account of its operations.

Key ESG highlights

- Biocon has increased the share of green power in its total energy consumption to over 50% for fiscal 2021. It has also achieved 18% reduction in absolute Scope 1 and Scope 2 emissions in fiscal 2021 .
- Biocon has deployed water management practices and has recycled 100% of wastewater in fiscal 2021. All manufacturing sites are Zero Liquid Discharge facilities.
- Biocon has implemented gender diversity and inclusion policy, prevention of sexual harassment policy as well as zero tolerance for child labour. Gender diversity in Biocon is in line with industry peers with women employees comprising over 17% of the total workforce.
- Biocon's corporate social responsibility is focused on primary healthcare, environmental sustainability, rural development and Covid-19 relief.
- Biocon has adequate governance structure, with majority of its board comprising independent directors, presence of investor grievance redressal mechanism, whistle-blower policy and extensive disclosures.
- Biocon also has board-level ESG committee to provide oversight, direction and to monitor the ESG strategy and action plans.

There is growing importance of ESG among investors and lenders. Biocon's continued commitment to ESG principles will play a key role in enhancing stakeholder confidence and ensure ease of raising capital from markets where ESG compliance is a key factor.

Rating Sensitivity factors

Upward factors

- Significantly high revenue growth, driven by increased market share and improvement in profitability above 28%-30% on a sustained basis, leading to healthy annual cash accruals
- Faster-than-anticipated improvement in debt protection metrics, post the acquisition of Viatris' biosimilar business by BBL, supported by healthier accrual and equity raising at BBL

Downward factors

- Decline in revenue growth and drop in operating margin to below 20% on a sustained basis
- Delayed correction in debt protection metrics, due to further debt-funded capex or acquisitions or weaker cash generation; for instance, debt to earnings before interest, tax, depreciation and amortisation (EBITDA) ratio remaining above 2.5 times in fiscal 2024
- Any adverse US FDA regulatory action materially impacting the operating performance

About the Company

Founded in 1978, Biocon is India's leading biopharma company. It is fully integrated and delivers biopharma solutions, ranging from discovery to development and commercialisation. It has diversified revenue streams covering biologics (including branded formulations), contract research, and small molecules and APIs. As on December 31, 2021, the promoters held 60.64% stake in Biocon, foreign portfolio investors held 16.00%, and the balance was held by the public and others.

Key Financial Indicators

As on/for the period ended March 31		2021	2020
Revenue	Rs crore	7106	6301
Adjusted profit after tax (PAT)*	Rs crore	718	718
Adjusted PAT margin	%	10.1	11.4
Adjusted debt/adjusted networth	Times	0.56	0.37
Adjusted interest coverage	Times	30.1	26.7

**Adjusted for amortisation of goodwill and intangibles*

Any other information: Not applicable

Note on complexity levels of the rated instrument:
CRISIL Ratings' complexity levels are assigned to various types of financial instruments. The CRISIL Ratings' complexity levels are available on www.crisil.com/complexity-levels. Users are advised to refer to the CRISIL Ratings' complexity levels for instruments that they consider for investment. Users may also call the Customer Service Helpdesk with queries on specific instruments.

Annexure - Details of Instrument(s)

ISIN	Name of instrument	Date of allotment	Coupon rate (%)	Maturity date	Issue size (Rs crore)	Complexity level	Rating assigned with outlook
NA	Working capital facility	NA	NA	NA	100.0	NA	CRISIL AA+/Watch Developing
NA	Proposed working capital facility	NA	NA	NA	148.0	NA	CRISIL AA+/Watch Developing
NA	Proposed short-term bank loan facility	NA	NA	NA	2.0	NA	CRISIL A1+

Annexure – List of entities consolidated

Names of entities consolidated	Extent of consolidation	Rationale for consolidation
Syngene International Ltd	70.2%	Subsidiary
Biocon Biologics Ltd	93.5%	Subsidiary
Biocon Pharma Ltd	100.0%	Subsidiary
Biocon Academy	100.0%	Subsidiary
Biocon SA	100.0%	Subsidiary
Biocon SDN. BDH	93.5%	Step-down subsidiary
Biocon FZ LLC	100.0%	Subsidiary
Biocon Biologics UK Ltd	93.5%	Step-down subsidiary
Biocon Pharma Inc	100.0%	Step-down subsidiary
Biocon Biologics Healthcare SDN. BHD	93.5%	Step-down subsidiary
Biocon Pharma Ireland Ltd	100.0%	Step-down subsidiary
Biocon Pharma UK Ltd	100.0%	Step-down subsidiary
Biocon Biosphere Ltd	100.0%	Subsidiary
Biocon Biologics Inc	93.5%	Step-down subsidiary
Biocon Biologics Do Brasil Ltda	93.5%	Step-down subsidiary
Biocon Biologics FZ-LLC	93.5%	Step-down subsidiary
Biocon Pharma Malta Ltd	100.0%	Step-down subsidiary
Biocon Pharma Malta I Ltd	100.0%	Step-down subsidiary
Biofusion Therapeutics Ltd	100.0%	Subsidiary
Syngene USA Inc	70.2%	Step-down subsidiary
Bicara Therapeutics Inc (up to January 9, 2021)	87.0%	Associate
Neo Biocon FZ-LLC	49.0%	Joint venture

Annexure - Rating History for last 3 Years

	Current			2022 (History)		2021		2020		2019		Start of 2019
Instrument	Type	Outstanding Amount	Rating	Date	Rating	Date	Rating	Date	Rating	Date	Rating	Rating
Fund Based Facilities	LT/ST	250.0	CRISIL AA+/Watch Developing / CRISIL A1+	11-02-22	CRISIL AA+/Stable / CRISIL A1+	30-09-21	CRISIL AA+/Stable / CRISIL A1+	07-07-20	CRISIL AA+/Stable / CRISIL A1+	29-06-19	CRISIL AA+/Stable / CRISIL A1+	CRISIL AA+/Stable / CRISIL A1+
Short Term Debt	ST		--		--		--		--	29-06-19	Withdrawn	CRISIL A1+

All amounts are in Rs.Cr.

Annexure - Details of Bank Lenders & Facilities

Facility	Amount (Rs.Crore)	Rating
Proposed Short Term Bank Loan Facility	2	CRISIL A1+
Proposed Working Capital Facility	148	CRISIL AA+/Watch Developing
Working Capital Facility	100	CRISIL AA+/Watch Developing

Criteria Details

Links to related criteria
CRISILs Approach to Financial Ratios
Rating criteria for manufaturing and service sector companies
CRISILs Bank Loan Ratings - process, scale and default recognition
Rating Criteria for the Pharmaceutical Industry
CRISILs Criteria for Consolidation
Understanding CRISILs Ratings and Rating Scales

Media Relations	Analytical Contacts	Customer Service Helpdesk
Pankaj Rawat Media Relations **CRISIL Limited** B: +91 22 3342 3000 pankaj.rawat@crisil.com **Hiral Jani Vasani** Media Relations **CRISIL Limited** B: +91 22 3342 3000 hiral.vasani@crisil.com **Rutuja Gaikwad** Media Relations **CRISIL Limited** B: +91 22 3342 3000 Rutuja.Gaikwad@ext-crisil.com	Anuj Sethi Senior Director **CRISIL Ratings Limited** D:+91 44 6656 3100 anuj.sethi@crisil.com Tanvi Kumar Shah Associate Director **CRISIL Ratings Limited** D:+91 22 4097 8331 tanvi.shah@crisil.com Parth Shah Manager **CRISIL Ratings Limited** B:+91 22 3342 3000 Parth.Shah@crisil.com	Timings: 10.00 am to 7.00 pm Toll free Number:1800 267 1301 For a copy of Rationales / Rating Reports: CRISILratingdesk@crisil.com For Analytical queries: ratingsinvestordesk@crisil.com

About CRISIL Ratings Limited (A subsidiary of CRISIL Limited)

CRISIL Ratings pioneered the concept of credit rating in India in 1987. With a tradition of independence, analytical rigour and innovation, we set the standards in the credit rating business. We rate the entire range of debt instruments, such as bank loans, certificates of deposit, commercial paper, non-convertible/convertible/partially convertible bonds and debentures, perpetual bonds, bank hybrid capital instruments, asset-backed and mortgage-backed securities, partial guarantees and other structured debt instruments. We have rated over 33,000 large and mid-scale corporates and financial institutions. We have also instituted several innovations in India in the rating business, including ratings for municipal bonds, partially guaranteed instruments and infrastructure investment trusts (InvITs).

CRISIL Ratings Limited ('CRISIL Ratings') is a wholly-owned subsidiary of CRISIL Limited ('CRISIL'). CRISIL Ratings Limited is registered in India as a credit rating agency with the Securities and Exchange Board of India ("SEBI").

For more information, visit www.crisilratings.com

About CRISIL Limited

CRISIL is a global analytical company providing ratings, research, and risk and policy advisory services. We are India's leading ratings agency. We are also the foremost provider of high-end research to the world's largest banks and leading corporations.

CRISIL is majority owned by S&P Global Inc, a leading provider of transparent and independent ratings, benchmarks, analytics and data to the capital and commodity markets worldwide.

For more information, visit www.crisil.com

Connect with us: TWITTER | LINKEDIN | YOUTUBE | FACEBOOK

---

are available here: www.crisilratings.com.

CRISIL Ratings and its affiliates do not act as a fiduciary. While CRISIL Ratings has obtained information from sources it believes to be reliable, CRISIL Ratings does not perform an audit and undertakes no duty of due diligence or independent verification of any information it receives and/or relies on in its reports. CRISIL Ratings has established policies and procedures to maintain the confidentiality of certain non-public information received in connection with each analytical process. CRISIL Ratings has in place a ratings code of conduct and policies for managing conflict of interest. For details please refer to: https://www.crisil.com/en/home/our-businesses/ratings/regulatory-disclosures/highlighted-policies.html.

Rating criteria by CRISIL Ratings are generally available without charge to the public on the CRISIL Ratings public website, www.crisilratings.com. For latest rating information on any instrument of any company rated by CRISIL Ratings, you may contact the CRISIL Ratings desk at crisilratingdesk@crisil.com, or at (0091) 1800 267 1301.

CRISIL Ratings uses the prefix ‘PP-MLD’ for the ratings of principal-protected market-linked debentures (PPMLD) with effect from November 1, 2011, to comply with the SEBI circular, "Guidelines for Issue and Listing of Structured Products/Market Linked Debentures". The revision in rating symbols for PPMLDs should not be construed as a change in the rating of the subject instrument. For details on CRISIL Ratings' use of 'PP-MLD' please refer to the notes to Rating scale for Debt Instruments and Structured Finance Instruments at the following link: https://www.crisil.com/en/home/our-businesses/ratings/credit-ratings-scale.html