September 21, 2023 (Revised)

Stelis Biopharma Limited: Rating downgraded to [ICRA]BBB (CE) (Negative)/[ICRA]BB- (Negative)

Summary of rating action

Instrument*	Previous Rated Amount (Rs. crore)	Current Rated Amount (Rs. crore)	Rating Action
Long-term, Fund-based – Term loan	475.90	258.80	[ICRA]BBB (CE) (Negative); downgraded from [ICRA]A- (CE) (Negative)
Long-term, Fund-based – Term loan	318.40	183.70	[ICRA]BB- (Negative); downgraded from [ICRA]BB+ (Negative)
Long term, Fund-based/ non-fund based – Working capital facilities	200.00	96.50	[ICRA]BB- (Negative); downgraded from [ICRA]BB+ (Negative)
Unallocated limits	34.40	-	-
Total	**1,028.70**	**539.00**	

**Instrument details are provided in Annexure I*

Rating Without Explicit Credit Enhancement	[ICRA]BB-

Note: The (CE) suffix mentioned alongside the rating symbol indicates that the rated instrument/facility is backed by some form of explicit credit enhancement. This rating is specific to the rated instrument/facility, its terms and its structure and does not represent ICRA's opinion on the general credit quality of the entity concerned. The last row in the table above also captures ICRA's opinion on the rating without factoring in the explicit credit enhancement.

Rationale

The rating of Stelis Biopharma Limited (Stelis/the company) is based on its credit profile as well as on its parent's, Strides Pharma Science Limited (Strides; rated [ICRA]A- (Negative)/[ICRA]A2+). Further, ICRA's assessment of the strength of the linkages between Stelis and Strides, including the corporate guarantee furnished by Strides to Stelis for the rated facilities, is also a key driver of the rating.

The rating downgrade considers the continuing operating losses being incurred by the company in its contract development and manufacturing (CDMO) segment. The low recognition of revenues, coupled with high unabsorbed costs of the greenfield facility (which commenced during December 2021), resulted in operating losses of ~Rs. 225 crore in FY2023. Further, the net loss was impacted by interest cost on the debt availed for capex (of Unit 2 and Unit 3 facilities) and exceptional loss of ~Rs. 345 crore (towards write-off of Sputnik inventory and impairment provisioning), resulting in net loss of ~Rs. 800 crore in FY2023 against ~Rs. 236 crore in FY2022. During Q1 FY2024, the company reported ~Rs. 9 crore of revenues in its CDMO operations, which reduced sequentially from ~Rs. 22 crore in Q4 FY2023, due to spillover of order executions/billings to subsequent months. This, coupled with fixed costs for the manufacturing facilities, led to operating and net losses of ~Rs 43 crore and ~Rs. 107 crore, respectively, in Q1 FY2024. ICRA notes that Stelis resorted to writing off portion of its vaccine inventory of ~Rs. 200 crore in FY2023 and is expected to write-off its balance inventory of ~Rs. 125 crore during FY2024 due to limited shelf life. While Stelis has initiated legal actions against RDIF for recovering its costs, the enforceability of the same remains uncertain. Going forward, the company's ability to recognise revenues and improve profitability in the CDMO segment (based on its order pipeline) remains a key monitorable. ICRA notes that the company has secured commercial service (CSA) orders worth ~$350 million to be executed between FY2024-FY2028; however, timely execution of the same remains a key monitorable.

On July 04, 2023, Stelis announced that it had entered into a binding term sheet with Syngene International Limited (Syngene) for sale of its Unit-3 biologics manufacturing facility (multi-modal facility) in Bengaluru, India. The transaction will be on a slump sale basis for a gross cash consideration of Rs. 702 crore ($86 million). Additionally, security deposits and advances of ~Rs. 23 crore pertaining to the facility are also expected to be received from Syngene. The company is expected to utilise the proceeds from the sale of its facility for repaying its Covid-19 vaccine-segment loans, outstanding capital creditors and for meeting the repayment obligations of its CDMO loans and operational creditors of the company in FY2024.

In addition to the sizeable quantum of debt raised by Stelis to partially fund the greenfield manufacturing plant, the company had also availed Rs. 200-crore working capital loan during January 2022, to fund its working capital requirements for manufacturing the Sputnik vaccine. Stelis has repaid Rs. 100 crore and needs to repay the balance working capital loan in FY2024, in addition to the scheduled repayments of its term loans, resulting in total principal repayment (external debt) of ~Rs. 411 crore during FY2024. The company has availed interim high-cost unsecured loans to meet its debt obligations and operational requirements in FY2024, as the sale proceeds of the transaction are expected to be accessible to Stelis by October-November 2023. As of August 31, 2023, the unsecured loans (partially backed by corporate guarantee of Strides) amounted to ~Rs. 390 crore (including loan of ~Rs 125 crore from its shareholders[1]). In addition, the company is expected to avail incremental net unsecured loan of Rs. 65 crore during September 2023. A portion of the unsecured loans raised thus far, is expected to be repaid with the sale proceeds and the balance is expected to be repaid in FY2025. While the sale transaction is expected to reduce the overall outstanding debt, given the continued losses in the company's CDMO business, refinancing of balance loans, if any to meet its sizeable debt repayment commitments on a timely basis remains extremely critical.

ICRA notes the company's financial flexibility is aided by equity raise of $155 million and rights issue of Rs. 160 crore, of which $90 million was received over FY2021 and FY2022 and Rs. 586 crore was received during FY2023, which was utilised for partially funding the vaccine project and meeting its repayment obligations and funding the ongoing losses. The company has balance equity to be received of ~Rs 80 crore, which is expected to be adjusted towards the inter-group deposit outstanding as of August 31, 2023. Any additional equity infusion in the company, will support the cash flows to a certain extent.

The rating also factors in the various regulatory and market risks associated with the products being manufactured by the company. However, ICRA notes that the drug product capabilities in the company's flagship manufacturing facility in Bengaluru have received the European Union Good Manufacturing Practices (EU-GMP) and the US Food and Drug Administration (US FDA) approvals during June 2022 and September 2022, respectively. While the company is expected to witness ramp-up in its CDMO business, backed by the regulatory approvals from the US FDA and the EU-GMP, the same will remain a monitorable.

ICRA maintains its Negative outlook on the long-term rating of Stelis due to the continued losses under its CDMO operations and its weak debt metrics and cash flows, despite significant debt reduction from the proceeds of its Unit-3 sale. The revenue and margin trajectory of the company over the near term will be key monitorables.

Adequacy of credit enhancement for ratings of the Rs. 258.80-crore term loan facilities

For the above-mentioned rating, ICRA has assessed the attributes of the corporate guarantee provided by Strides for the rated bank facilities of Stelis. The guarantee is legally enforceable, irrevocable, unconditional, covers the entire amount and tenor of the rated instruments, it does not have a well-defined invocation and payment mechanism (except for corporate guarantee for a Rs. 120-crore facility, which has a well-defined payment mechanism). Given these attributes, the guarantee provided by Strides is adequately strong to result in an enhancement in the rating of the said instruments to [ICRA]BBB(CE)(Negative), against the rating of [ICRA]BB- (Negative) without explicit credit enhancement. In case the rating of the guarantor undergoes a change in the future, the same would reflect in the rating of the aforesaid instruments. The ratings of the instruments may also undergo a change in a scenario, where, in ICRA's assessment, there is a change in the strength of the business linkages between the guarantor and the rated entity; or a change in the reputation sensitivity of the guarantor to a default by the rated entity; or a change in the strategic importance of the rated entity for the guarantor.

Salient covenants of the rated facility

» *Main promoter and sponsor shall not pledge the shares held beyond 30% of borrower stake for raising any loan or for securitising any loans or advances availed/ to be availed by them from any bank/ FI/ lender.*

[1] Arcolab Private Limited – ~Rs 50 crore and Tenshi Life Sciences Private Limited – ~Rs 75 crore

- *The borrower to seek prior approval from the lender before any amalgamation/ merger/ change in management control.*
- *No dividend/ interest payment to promoter/ promoter Group by the borrower to be done without prior written approval from the lender, in an event of default.*

Key rating drivers and their description

Credit strengths

Explicit support with corporate guarantee – The rating for the bank facilities of Rs. 258.80 crore derives comfort from the irrevocable and unconditional corporate guarantee extended by the guarantor, Strides.

Equity funding support from existing and external investors; sale of Unit-3 facility to support cash flows – Since its inception, Stelis has enjoyed regular equity infusion from its promoters (Strides, GMS Pharma Singapore (Pte) Ltd., or GMS, and Tenshi Life Sciences Private Limited, or Tenshi) to fund its capital expenditure (capex), research and development (R&D) expenses and losses. The company raised $195 million via Series B and C funding in March 2021, which includes partial exit of GMS ($40 million). In addition to existing investors, external investors such as TPG Growth, Route One, Think Investments and the Mankekar family participated in this funding round. The company received equity of ~$143 million from the latest funding round till August 2023. Further, the company also received Rs. 160 crore from TPG Growth and its promoter Group entity, Karuna Business Solutions LLP, as part of its rights issue during November 2022. The equity was utilised for partially funding the vaccine project, meeting the company's operational requirements and debt repayment obligations. The sale of its Unit-3 facility will result in cash inflow of ~Rs. 725 crore during FY2024. The company is expected to utilise the proceeds from the sale of its facility for repaying its Covid-19 vaccine-segment loans (~Rs. 225 crore), outstanding capital creditors (~Rs. 145 crore) and the balance for servicing the debt repayment obligations (including unsecured loans) and operational creditors. ICRA notes that the company has received Rs 395 crore from Syngene which is deposited in an escrow account as of now.The same is expected to be accessible to Stelis post satisfaction of conditions precedent. The timelines for receipt of entire sale consideration and subsequent deleveraging remain a key monitorable.

Investments in development of limited-competition biosimilars support long-term prospects – Stelis has made sizeable investments in developing biosimilars in the therapeutic areas of osteoporosis, osteoarthritis, and diabetes. As understood from the company, the market potential of the former two is estimated at ~$2 billion each and the number of competitors is limited, providing strong market opportunity and healthy revenue visibility to the company for the long term. However, the same is contingent upon the company successfully securing approval for its products, launching the same and gaining market share for the same in the regulated markets of Europe and the US. While the revenues are yet to be recognised, the company has received licensing income/cash flow of ~Rs. 18 crore for the said product till Q1 FY2024. Further, the company is expected to commence commercial supplies of biosimilar osteoporosis from Q4 FY2024, which remains to be seen.

Credit challenges

CDMO operations continue to generate losses – Stelis commenced its CDMO operations in FY2021. However, the segment is yet to witness sustained breakeven at the operating profit level, with the company deriving ~Rs. 41 crore of revenues with an operating loss of Rs. 225 crore in FY2023 (against Rs. 132 crore of revenues with operating loss of Rs. 95 crore in FY2022). While CDMO operations achieved breakeven at the OPBDITA level in Q3 FY2022, high unabsorbed costs for the greenfield facility (which commenced in December 2021) and deferral of certain CDMO orders for undertaking regulatory audits and delays in signing contracts, increased the operating losses during FY2023. While the company also gradually reduced its fixed operating costs from September 2022 on the vaccine/Unit-3 facility, lower-than-expected revenues in CDMO operations led to increase in operating losses in FY2023. While the company has undertaken billings of ~Rs 52 crore during Q1 FY2024, the revenues recognised were to the extent of ~Rs. 9 crore in its CDMO operations. This is mainly on account of deferment of recognition of revenues to subsequent months based on order execution stage[2]. Further, ICRA notes that the same has reduced

[2] *as per accounting standards*

sequentially from ~Rs. 22 crore in Q4 FY2023. . This, coupled with fixed costs for the manufacturing facilities, has led to operating and net loss of ~Rs. 43 crore and ~Rs. 107 crore in Q1 FY2024. Till date, the revenues of the company pertain to the income from the manufacturing service agreement, which is expected to witness ramp-up with commencement of manufacturing based on commercial service agreement. This is expected to support improvement in profitability over the near term. ICRA notes that the company has a confirmed order book, which is expected to generate revenue of ~Rs. 150 crore during FY2024; however, timely execution of the same remains a key monitorable.

Financial profile characterised by elevated debt levels – The company's financial profile is characterised by an elevated debt position, owing to the significant investment in developing its products and for the construction of its greenfield facilities. As on March 31, 2023, the company's total debt had increased to Rs. 864.2 crore from Rs. 396.7 crore as on March 31, 2021, primarily owing to incremental debt of ~Rs. 750.0 crore, availed for funding the capex for its new manufacturing facility and working capital requirements of the vaccine operations. Further, the company has availed high-cost incremental loans in the form of unsecured non-convertible debentures to fund the debt obligations in FY2024. This resulted in debt increasing to Rs. 928.6 crore as of August 31, 2023. The company has sizeable repayment obligations of ~Rs. 249 crore (including outstanding working capital debt of Rs. 96.5 crore as on August 31, 2023) during September 2023 – March 2024 and ~Rs. 319 crore in FY2025. The company expects to meet the repayment obligations over the next two years through the cash flows from sale of the Unit-3 facility. However, continuing losses due to a longer-than-expected delay in recognition of revenues under the CDMO segment could further increase the debt levels of the company.

Various market and regulatory risks associated with products developed by the company – The pharmaceutical industry is regulated as per the guidelines of the USFDA and various pharmaceutical regulatory authorities of the target markets. Typically, biosimilar development demands high compliance, which exposes the company's operations to regulatory risks in the form of stricter regulations and scrutiny, along with changes in the regulatory landscape, which could affect its operations. Further, Stelis is exposed to the market risks associated with the industry due to the anticipated competition in various therapeutic areas. The delay in receiving necessary approvals or a larger impact on demand in the end-user industries will be a key rating monitorable. However, ICRA notes the recent regulatory approvals (EU GMP and USFDA) received for its CDMO facility in Bengaluru.

Liquidity position

For the rated entity (Stelis): Stretched

Stelis' liquidity position is stretched, characterised by negative retained cash flows due to the continued operating and net losses. The company has substantial repayment obligations of ~Rs. 300 crore (net of additions and including outstanding working capital loan of Rs. 96.5 crore and vaccine term loan of Rs. 137 crore) and ~Rs. 319 crore during September 2023 - March 2024 and FY2025, respectively, for its existing debt (excluding inter-group debt). The company is also expected to incur maintenance capex of ~Rs. 20 crore per annum. While ICRA notes that the receipt of ~Rs. 725 crore by sale of the Unit-3 facility in FY2024 will support the cash flows of the company, timelines and quantum of deleveraging will continue to be key monitorables. Further, timely ramp-up in CDMO operations is critical to improve the retained cash flows of the company.

For the support provider (Strides): Adequate

The company's liquidity position is adequate, supported by consolidated free cash and liquid investments of ~Rs. 350 crore and undrawn working capital lines of ~$13 million as on June 30, 2023. The average utilisation of the working capital limits (on standalone basis) was 94% during the last 12-month period ending July 31, 2023. The company has repayment obligations of ~Rs. 304 crore in FY2024 and ~Rs. 271 crore in FY2025 on the existing term debt. In addition, the company is expected to spend ~$10-12 million per annum on maintenance capex and upgradation, going forward. ICRA expects Strides to meet its near-term commitments through internal accruals, existing cash reserves, and divestments, if any.

Rating sensitivities

Positive factors: The outlook could be revised to Stable, in case of any material improvement in earnings, liquidity position and debt coverage metrics. The rating assigned would remain sensitive to any movement in the credit profile of the guarantor, Strides.

Negative factors: Pressure on the rating could arise in case of further continued cash losses in the CDMO business, or in case there are delays in deleveraging post receipt of Unit 3 sale proceeds. The ratings would remain sensitive to any movement in the credit profile of the guarantor, Strides.

Analytical approach

Analytical Approach	Comments
Applicable Rating Methodologies	Corporate Credit Rating Methodology Rating Methodology for Pharmaceutical Industry
Parent/Group Support	Strides Pharma Sciences Limited (rated [ICRA]A- (Negative)/[ICRA]A2+)
Consolidation/Standalone	For arriving at the rating, ICRA has considered the consolidated financials of Stelis. As on March 31, 2023, the company had three subsidiaries, which are all enlisted in Annexure-2.

About the company

Stelis is a vertically-integrated biopharmaceutical company that offers CDMO services across all phases of pre-clinical and clinical development and commercial supply of biologics. Its operations include R&D, process development, scale-up and manufacturing capabilities from drug substance through drug product in all formats and packaging. Stelis has also invested in in developing biosimilars in the therapeutic areas of osteoporosis, osteoarthritis, and diabetes and expects to commerce commercial supplies of one of the products by Q4 FY2024. Stelis forayed into contract manufacturing Covid-19 vaccines (Sputnik V) and invested in a facility that can produce multiple vaccine types, which is currently proposed to be sold. Stelis' R&D facility and 2,00,000 sq. ft., fully-integrated manufacturing facility are located in Bengaluru, India.

About the guarantor

Strides Pharma Science Limited, incorporated in 1990, is a medium-sized pharmaceutical company that develops, manufactures, and exports a wide range of pharmaceutical products. The company has followed both organic and inorganic growth strategies over the years that has led to its foray into new markets and the addition of new businesses, therapy segments and manufacturing infrastructure. The company's product range covers most dosage forms including soft gel capsules, tablets, capsules and semi-solids. It has also acquired a basket of ANDAs (abbreviated new drug application) and a facility at Chestnut Ridge (USA) from Endo in October 2021 for a consideration of $24 million. At present, its business is broadly classified into regulated market formulations (mainly comprising the US, the UK, Europe and Australia) and emerging markets (primarily Africa and institutional segments). As on June 30, 2023, 29.29% of the company's fully-diluted shareholding was held by the promoter Group, with the rest held by various institutions and the public.

For the last, detailed rationale of the guarantor: Click here

Key financial indicators

Stelis consolidated	FY2022	FY2023
Operating income (Rs. crore)	132.2	41.1
PAT (Rs. crore)	-236.0	-799.8
OPBDIT/OI (%)	-72.1%	-547.8%
PAT/OI (%)	-178.5%	-1947.3%
Total outside liabilities/Tangible net worth (times)	1.4	1.6
Total debt/OPBDIT (times)	-12.4	- 3.8
Interest coverage (times)	- 1.4	- 1.9

Source: Company and ICRA Research; PAT: Profit after Tax; OPBDIT: Operating Profit before Depreciation, Interest, Taxes and Amortisation; All ratios are 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 Aug 31, 2023 (Rs. crore)	Date & Rating in FY2024		Date & Rating in FY2023			Date & Rating in FY2022		Date & Rating in FY2021
					Sep 21, 2023	Jul 12, 2023	Jan 05, 2023	Oct 20, 2022	Oct 06, 2022	Mar 24, 2022	Jun 14, 2021	-
1	Term loans	Long-term	258.80	258.80	[ICRA]BBB(CE)(Negative)	[ICRA]A-(CE)(Negative)	[ICRA]A-(CE)(Negative)	[ICRA]A-(CE)(Negative)	[ICRA]A-(CE)(Negative)	[ICRA]A(CE)(Negative)	[ICRA]A+(CE)(Stable)	-
2	Term loans	Long-term	183.70	183.70	[ICRA]BB-(Negative)	[ICRA]BB+(Negative)	[ICRA]BB+(Negative)	[ICRA]BB+(Negative)	[ICRA]BB+(Negative)	[ICRA]BBB-(Negative)	-	-
3	Working capital facilities	Long-term	96.50	--	[ICRA]BB-(Negative)	[ICRA]BB+(Negative)	[ICRA]BB+(Negative)	[ICRA]BB+(Negative)	[ICRA]BB+(Negative)	[ICRA]BBB-(Negative)	-	-
4	Unallocated limits	Long-term	--	--	-	[ICRA]BB+(Negative)	[ICRA]BB+(Negative)	-	-	-	-	-

Amount in Rs. crore

Complexity level of the rated instruments

Instrument	Complexity Indicator
Long term - fund based – Term loan	Simple
Long term - fund based – Term loan	Simple
Working capital facilities	Simple

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 No	Instrument Name	Date of Issuance	Coupon Rate	Maturity Date	Amount Rated (Rs. crore)	Current Rating and Outlook
NA	Term Loan-I	Dec 2015	LIBOR+3.65%	FY2026	58.60	[ICRA]BBB(CE) (Negative)
NA	Term Loan-II	Dec 2015	9.65%	FY2026	25.20	[ICRA]BBB(CE) (Negative)
NA	Term Loan-III	May 2019	9.55%	FY2027	120.00	[ICRA]BBB(CE) (Negative)
NA	Term Loan-IV	Aug 2021	9.50%	FY2026	55.00	[ICRA]BBB(CE) (Negative)
NA	Term loan- V	Sep 2021	7.31%	FY2025	137.00	[ICRA]BB- (Negative)
NA	Term loan- VII	Nov 2021	8.25%	FY2027	24.40	[ICRA]BB- (Negative)
NA	Term loan- VIII	Nov 2021	8.35%	FY2027	22.30	[ICRA]BB- (Negative)
NA	Working capital facilities	Sep 2021	NA	NA	96.50	[ICRA]BB- (Negative)

Source: Company; Note: Amounts in Rs. crore

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

Annexure II: List of entities considered for consolidated analysis

Company Name	Ownership	Consolidation Approach
Biolexis Pte Ltd, Singapore	100.00%	Full Consolidation
Biolexis Private Limited	100.00%	Full Consolidation
Stelis Biopharma UK Private Limited	100.00%	Full Consolidation

Source: Company's annual report FY2022

Corrigendum

Document dated September 21, 2023 has been correction with revisions as below:

The section 'Adequacy of credit enhancement for ratings of the Rs. 258.80-crore term loan facilities' has been updated.

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