January 30, 2024

Stelis Biopharma Limited: Ratings reaffirmed

Summary of rating action

Instrument*	Previous Rated Amount (Rs. crore)	Current Rated Amount (Rs. crore)	Rating Action
Long-term, Fund-based – Term loan	258.80	160.00	[ICRA]BBB(CE)(Negative); Reaffirmed
Long-term, Fund-based – Term loan	183.70	22.00	[ICRA]BB-(Negative); Reaffirmed
Long term, Fund-based/ non-fund based – Working capital facilities	96.50	0.00	-
Total	**539.00**	**182.00**	

**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/SBL) 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 reaffirmation considers the significant reduction in the debt levels of the company from the proceeds of Unit-III sale along with the expected improvement in the operational profile of the company. That said, ratings remain constrained by the continuing operating losses being incurred by the company in its contract development and manufacturing (CDMO) segment. While the losses have reduced sequentially in the past few quarters, the losses remain substantial in 9M FY2024. 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 and ~Rs 83 crore in 9M FY2024. 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. The inventory loss is expected to be ~Rs 125 crore in FY2024 which will further impact the total expected loss in the current fiscal. During 9M FY2024, the company reported ~Rs. 55 crore of revenues with sequential increase in revenues each quarter (Rs 9 crore in Q1 FY2024, Rs 13 crore in Q2FY2024 and Rs 33 crore in Q3 FY2024). This, coupled with fixed costs, forex and operational costs for the manufacturing facilities, led to operating loss of ~Rs 83 crore, in 9M 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.

In December 2023, the deal concluded with Stelis receiving Rs 607 crore (Rs 10 crore payment has been withheld by Syngene and will be released later) against gross cash consideration of Rs. 617 crore after setting off Rs 85 crore of amount as Stelis retained 10 bio-reactors. The company utilized 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, Stelis has repaid the balance working capital loan in FY2024 as well, in addition to the scheduled repayments of its term loans, resulting in total outstanding debt of ~Rs 463 crore as on December 31, 2023. As of December 31, 2023, the CDMO related bank loans stood at ~Rs 182 crore and remaining high-cost unsecured loans (partially backed by corporate guarantee of Strides) amounted to ~Rs. 281.5 crore (including loan of ~Rs 125 crore from its shareholders). Going forward, the company plans to pay-off entire unsecured loans and part of bank debt through refinancing of ~Rs 350 crore. While the sale transaction has resulted in reduction of the overall outstanding debt, given the continued losses in the company's CDMO business, refinancing of balance loans to meet its debt repayment commitments on a timely basis remains extremely critical.

The ratings are further constrained by 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.

On September 25, 2023, Strides Pharma Science Limited (Strides or SPCL/the company) announced that it will be demerging its Contract Development and the Manufacturing (CDMO) segment and soft gelatin business into Stelis Biopharma Limited (Stelis or SBL), subject to regulatory and other approvals, which are currently awaited. Further, there will be a demerger of CDMO (whole India operations) from Steriscience Specialties Private Limited (Steriscience or SSPL) to SBL. The above businesses will be moved into Stelis, which is being renamed as Onesource, and will be a speciality pharmaceutical company of the group dealing in CDMO with capabilities in biologics, oral soft-gels, complex injectables, sterile injectables, including other complex drug delivery systems. This apart, the resultant company i.e., Onesource is also proposed to be listed as part of the scheme. The progress of 'Onesource' and developments regarding the same, also remains a rating monitorable.

ICRA maintains its Negative outlook on the long-term rating of Stelis given continued losses being generated from its core operations and considerable debt levels. However, ICRA notes significant reduction in debt in the past quarter. 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. 160.00-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. 90-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.*
- *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. 160.00 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 supported cash flows and resulted in debt reduction– 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 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 resulted in cash inflow of ~Rs. 607 crore during FY2024. The company broadly utilized the same towards repaying bank-debt of ~Rs. 420 crore (including DSRA paid to several banks), ~Rs. 100 crore to Tenshi Life Sciences and remaining towards capex creditors and normal creditors. As on date, the outstanding capex creditors stands at Rs 100 crore, part of which is also expected to be paid off from planned refinancing. The timelines for refinancing, fund raising, and subsequent deleveraging remain a key monitorable.

The company also has access to ~Rs 80 crore of committed equity from Tenshi Life, which has to be utilized before September 2024. The company may utilize it going forward, in case any requirement arises.

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. Further, the company is expected to commence commercial supplies of biosimilar osteoporosis in the near future, 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. 55 crore of revenues with an operating loss of ~Rs. 139 crore in 9M FY2024 (against ~Rs. 41 crore of revenues with an operating loss of Rs. 225 crore in FY2023). While CDMO operations achieved breakeven at the OPBDITA level in Q3 FY2022, high unabsorbed costs for the Unit-3 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 & 9M FY2024. 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 higher billings, the revenues recognised were to the extent of ~Rs. 55 crore in its CDMO operations in 9M FY2024. This is mainly on account of deferment of recognition of revenues to subsequent months based on order execution stage[1]. 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

[1] *as per accounting standards*

profitability over the near term. ICRA notes that the company has a confirmed order book, which is expected to generate revenue of ~Rs. 160 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, which continues to remain elevated despite significant repayment in December 2023. In addition to its existing debt as on March 31, 2023, the company had also 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. Thereafter, from the proceeds of Rs 607 crore, the company repaid ~Rs. 420 crore of bank-debt and Rs 100 crore of unsecured loans. While remaining amount has been utilized towards paying capex and normal creditors. Subsequently, as on December 31, 2023, the company's total debt has reduced to ~Rs. 463 crore from Rs. 928.6 crore in August 31, 2023, primarily owing to proceeds received from the sale of Unit-III. Going forward, the company expects to meet the repayment obligations from its ongoing operations and refinancing exercise resulting in overall elevated debt levels going forward. Timely turnaround of the company's CDMO operations and consequent deleveraging will be a key monitorable going forward.

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 repayment obligations of ~Rs. 59 crore (after payment of major bank loans pertaining to CDMO operations, through proceeds from Syngene transaction) and ~Rs. 56 crore during FY2025, respectively, for its remaining bank debt. The company is also expected to incur maintenance capex of ~Rs. 20 crore per annum. While ICRA notes the receipt of ~Rs. 607 crore by sale of the Unit-3 facility in FY2024 which has supported the cash flows of the company utilized towards paring down the debt, ramp-up in CDMO operations is critical to improve the retained cash flows of the company. Company may also be required to raise additional debt to meet its short-term obligations given the gradual ramp up of its core operations.

For the support provider (Strides): Adequate

The company's liquidity position is adequate, supported by consolidated free cash and liquid investments of ~Rs. 320 crore and undrawn working capital lines of Rs 316 crore as on September 30, 2023. The company has healthy repayment obligations in FY2024 and FY2025 on the existing term debt. Proceeds from the receipt of from divestment of Singapore unit has been utilised towards debt prepayment or reduction in working capital utilisation in the near term. ICRA expects Strides to be able to meet its near-term commitments through internal accruals, existing cash reserves, incremental equity, deferred consideration and divestments, if any.

Rating sensitivities

Positive factors – The rating can be upgraded, in case of any material improvement in earnings, liquidity position and debt coverage metrics. The rating would remain sensitive to any movement in the credit profile of the guarantor, Strides.

Negative factors – The rating may be downgraded in case of further continued cash losses in the CDMO business or with any further material increase in the debt levels. 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 has now been sold off and the transaction stands concluded. 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. At present, its business is broadly classified into regulated market formulations (mainly comprising the US, the UK, Europe and Australia), emerging markets (primarily Africa) and institutional segments (tender-driven business mainly in developing markets). As on September 30, 2023, 27.78% of the company's 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 (audited/provisional)

Strides consolidated	FY2022	FY2023	H1 FY2024*
Operating income	132.2	41.1	42.6
PAT	-236.0	-799.8	-220.3
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, ICRA Research; * Provisional numbers; 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

Instrument		Current rating (FY2024)			Chronology of rating history for the past 3 years								
		Type	Amount rated (Rs. crore)	Amount outstanding as on March 31, 2023 (Rs. crore)	Date & rating in FY2024			Date & rating in FY2023			Date & Rating in FY2022		Date & Rating in FY2021
					Jan 30, 2024	Oct 05, 2023	Sep 21, 2023	Jan 05, 2023	Oct 20, 2022	Oct 06, 2022	Mar 24, 2022	Jun 14, 2021	-
1	Term loans	Long term	160.00	160.00	[ICRA]BBB (CE) (Negative)	[ICRA]BBB (CE) (Negative)	[ICRA]BBB (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	22.00	22.00	[ICRA]BB- (Negative)	[ICRA]BB- (Negative)	[ICRA]BB- (Negative)	[ICRA]BB+ (Negative)	[ICRA]BB+ (Negative)	[ICRA]BB+ (Negative)	[ICRA]BBB- (Negative)	-	-
3	Working capital facilities	Long-term	-	--	-	[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)	-	-	-	-	-

Complexity level of the rated instruments

Instrument	Complexity Indicator
Long-term Fund Based - Term Loans	Simple
Long-term Fund-based Facilities	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	Instrument Name	Date of Issuance	Coupon Rate	Maturity	Amount Rated (Rs. crore)	Current Rating and Outlook
NA	Term Loan-I	Dec 2015	9.65%	FY2026	22.00	[ICRA]BBB(CE) (Negative)
NA	Term Loan-II	May 2019	9.55%	FY2027	90.00	[ICRA]BBB(CE) (Negative)
NA	Term Loan-III	Aug 2021	9.50%	FY2026	48.00	[ICRA]BBB(CE) (Negative)
NA	Term loan- VII	Nov 2021	8.25%	FY2027	22.00	[ICRA]BB- (Negative)

Source: Company

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 Consolidaton

Source: Company's annual report FY2023

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About ICRA Limited:

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