June 14, 2021

Stelis Biopharma Pvt. Ltd.: Rating upgraded to [ICRA]A+(CE) (Stable) from [ICRA]A(CE) (Stable); rating without explicit credit enhancement upgraded to [ICRA]BBB from [ICRA]BBB-

Summary of rating action

Instrument*	Previous Rated Amount (Rs. crore)	Current Rated Amount (Rs. crore)	Rating Action
Fund Based – Term Loan	507.55	507.55	[ICRA]A+(CE) (Stable); upgraded from [ICRA]A(CE) (Stable)
Total	**507.55**	**507.55**	

Rating Without Explicit Credit Enhancement	[ICRA]BBB

**Instrument details are provided in Annexure-1*

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 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 for the term loan facilities of Stelis Biopharma Pvt. Ltd. (Stelis) is based on the credit profile of the company as well as its parent, Strides Pharma Science Limited (Strides; rated [ICRA]A+ (Stable)/[ICRA]A1). 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 a key driver of the rating. The rating upgrade is primarily driven by the improvement in the credit profile of Stelis. The Stable outlook on the rating reflects ICRA's outlook on the rating of the guarantor as well as the expectation that Stelis would continue to maintain its standalone credit profile over the medium term aided by the timely commercialisation of its vaccine programme.

Adequacy of credit enhancement

For assigning the above rating, ICRA has assessed the attributes of the corporate guarantee provided by Strides for the rated bank facilities of Stelis. While the guarantee is legally enforceable, irrevocable, unconditional, and covers the entire amount and tenor of the rated instrument, it does not have a well-defined invocation and payment mechanism. Given these attributes, the guarantee provided by Strides is adequately strong to result in the enhancement of the rating of the said instrument to [ICRA]A+(CE) against the rating of [ICRA]BBB without explicit credit enhancement. In case the rating of the guarantor undergoes a change in future, the same would reflect in the rating of the aforesaid instrument. The rating of the instrument may also undergo a change in a scenario whereby, in ICRA's assessment, there is a change in the strength of the business linkages between the guarantor and the rated entity or there is a change in the reputation sensitivity of the guarantor to a default by the rated entity or there is 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 the borrower's stake for raising any loan or for securitising any loans or advances availed/to be availed by them from any bank/financial institution (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 made without prior written approval from the lender in the event of default*

The improvement in Stelis' standalone credit profile is driven by its partnership with RDIF (Russia's sovereign wealth fund) to manufacture and supply 200 million doses of Sputnik V vaccine (against Covid-19 virus). ICRA expects the company to derive revenues of ~USD 800 million from the signed vaccine project, going forward, in turn supporting its cashflow position. The large and immediate demand to vaccinate the global population augurs well for the continued demand for these vaccines. The rating also favourably factors in Stelis' heathy financial flexibility aided by the recent equity raise of USD 155 million from both existing and new investors, which will be available to fund its growth, current needs and future business prospects including the capital required for the vaccine project.

These strengths are, however, partially offset by the nascent stage of operations, sizeable debt-funded capital expenditure (capex) for setting up a brownfield facility for manufacturing vaccines and various regulatory and market risks associated with the products developed by the company. Additionally, any unforeseen delays in the full-fledged commercialisation of the CDMO services (Contract development and manufacturing organisation), the timely commencement of the vaccine project and in ensuring adequate supply of the vaccine, which is expected to generate strong cashflows for the company, will remain key monitorables.

Key rating drivers and their description

Credit strengths

Explicit support in the form of corporate guarantee for bank lines from Strides – The rating derives comfort from the irrevocable and unconditional corporate guarantee extended by the guarantor, Strides.

Stelis' partnership with RDIF provides near-term revenue visibility – Stelis has collaborated with RDIF to manufacture 200 million doses of Sputnik V vaccine with Stelis having the option to increase the quantity to 1 billion doses. Sputnik V is a registered vaccine against the novel coronavirus infection and it is approved for use in over 55 countries. It is a two-dose vaccine, which uses two different human adenoviral vectors. This will be produced from Stelis' new site in Bengaluru, which is expected to commence manufacturing by Q3 FY2022. The company is expected to derive strong revenues (~USD 800 million) from the vaccine project going forward, which will support its cashflow position. ICRA expects that the strong and immediate demand to vaccinate the global population will augur well for the continued demand for the vaccine.

Healthy financial flexibility; Stelis raised USD 155-million funds from existing and external investors – Since inception, Stelis has received regular equity infusions from its promoters {Strides, GMS Pharma Singapore (Pte) Ltd (GMS) and Tenshi Life Sciences Private Limited (Tenshi)} to fund its capex and research and development (R&D) expenses. It recently raised USD 195 million via Series B and C funding, including the partial exit of GMS (USD 40 million), after which USD 155 million would be available to fund its growth, current needs and future business requirements including the capital required for the vaccine project. 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 has already received USD 70 million and expects to receive a total of ~USD 103 million by July 2021 while the balance is likely to be received as and when required. With the fund raise, Stelis is comfortably placed to fund its growth phase going forward.

Investment in development of limited-competition biosimilars provides strong revenue visibility in the long term – Stelis has made sizeable investments in developing biosimilars in the therapeutic areas of osteoporosis, osteoarthritis and diabetes. The market potential of the former two is estimated at ~USD 2 billion each and the number of competitors is limited, providing strong market opportunity and revenue visibility to the company for the long term. However, the same is contingent on Stelis successfully securing approval for its products, launching the same and gaining a respectful market share in the regulated markets of the EU and the US. In addition, Stelis' derived Rs. 21.4-crore revenues from CDMO services. Further, the full-fledged timely commercialisation of the CDMO business is likely to support the company's revenue growth in the near to medium term.

Credit challenges

Nascent stage of operations – Stelis had concluded the civil construction of its maiden greenfield manufacturing facility at Doddaballapura near Bengaluru and it commenced its CDMO operations on a small scale in FY2021. However, it is still in the nascent stage as the company derived only Rs. 21.4 crore of revenues in FY2021. Due to travel restrictions, the company could not organise customer visits and inspections, which, in turn, has led to the delay in the commercialisation of production. Stelis currently has a healthy orderbook position for the CDMO operations and is also expected to commence Sputnik V production in Q3 FY2021 (currently setting up the vaccine block), which is likely to aid its growth prospects.

Financial profile characterised by elevated debt levels; incremental debt to be taken for setting up new vaccine manufacturing facility – 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 maiden greenfield facility at Doddaballapura. As on March 31, 2021, Stelis' o/s debt stood at Rs. 385.9 crore (Rs. 474.2 crore as on March 31, 2020) and its gearing was 0.4 times (1.1 times as on March 31, 2020). Further, the company is expected to draw down the pending balance debt of ~Rs. 75 crore (sanctioned: ~Rs. 200 crore) for its R&D and capex requirements in FY2022. Additionally, Stelis is likely to avail the ~Rs. 550-crore debt to fund the construction of its largescale brownfield facility in Bommasandra, Bengaluru (total cost of ~Rs. 750 crore), which is to be used for manufacturing Sputnik V. Despite the increase in the debt levels, the company's capitalisation indicators are expected to improve FY2023 onwards on the back of the expected incremental growth in revenues from the vaccine project along with the pending equity commitments from existing and external investors.

Various market and regulatory risks associated with the products developed by the company – The pharmaceutical industry is regulated as per the guidelines of the US Food and Drug Administration (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 the therapeutic areas covered by the company. Additionally, it has forayed into manufacturing the Covid-19 vaccine, which demands high compliance. While ICRA expects that Stelis' operations are unlikely to be adversely affected amid the rising Covid-19 cases (second wave) as it is operates under essential services, a delay in receiving necessary approvals or a larger impact on demand in the end-user industries shall be key rating monitorables.

Liquidity position

For the rated entity (Stelis): Adequate

Stelis' liquidity is adequate with a cash balance of Rs. 77.8 crore as on March 31, 2021. It raised USD 155 million in Series B and C rounds, of which it has already received USD 70 million and expects to receive a total of ~USD 103 million by July 2021. The company is expected to receive the balance (~USD 52 million) as and when required, which provides its liquidity profile with a healthy buffer. Stelis is expected to incur capex of Rs. 750 crore in FY2022 towards the setting up of the vaccine block (to be funded by ~Rs. 550-crore debt and ~Rs. 200-crore equity) along with moderate capex towards the Doddaballapura facility. As per the current debt profile, repayments are expected to be Rs. 91.5 crore in FY2022, Rs. 104.0 crore in FY2023 and Rs. 104.0 crore in FY2024. Overall, ICRA expects Stelis to be able to meet its near-term commitments through the recent equity raise and internal accruals going forward.

For the support provider (Strides): Adequate

Strides' liquidity is **adequate** with fund flow from operations remaining positive in FY2020 and H1 FY2021, in line with previous trends. The company had cash and bank balances of ~Rs. 300 crore as on September 30, 2020, supporting its overall liquidity position. It also availed enhancements of USD 65 million in its working capital facilities, providing further liquidity support. Strides has upcoming repayments of Rs. 198.5 crore in FY2022 and Rs. 181.6 crore in FY2023. In addition, it has committed to infuse up to USD 14 million in Stelis by FY2023 and will spend ~Rs. 150 crore on capex each fiscal, going forward. ICRA expects

Strides to be able to meet its near-term commitments comfortably through internal accruals on the basis of its current and expected financial performance.

Rating sensitivities

Positive factors – The rating would remain sensitive to any movement in the rating or outlook of the guarantor, Strides.

Negative factors – The rating would remain sensitive to any movement in the rating or outlook of the guarantor, Strides. Further, pressure on the rating could arise in case of a delay in the commercialisation of the vaccine operations or weakening of Stelis' credit metrics on a sustained basis.

Analytical approach

Analytical Approach	Comments
Applicable Rating Methodologies	Corporate Credit Rating Methodology Rating Methodology for Entities in the Pharmaceutical Industry Approach for rating debt instruments backed by third-party explicit support
Parent/Group Support	The rating is based on the unconditional and irrevocable corporate guarantee extended by Strides
Consolidation/Standalone	For arriving at the rating, ICRA has considered the consolidated financials of Stelis. As on March 31, 2021, the company had two subsidiaries, which are enlisted in Annexure-2.

About the company

Stelis is a vertically integrated biopharmaceutical company. It offers end-to-end CDMO services across all phases of preclinical and clinical development and the commercial supply of biologics. Its operations include R&D, process development, scale-up and end-to end cGMP manufacturing capabilities covering drug substance through drug products in all formats and packaging. Stelis is also developing select follow-on biologic products for global markets in niche and commercially attractive disease categories. It recently forayed into the contract manufacturing of the Covid-19 vaccine (Sputnik V) and is currently investing in a facility, which can produce multiple types of vaccines. Stelis' state-of-the-art R&D facility and 2,00,000 sq. ft. fully-integrated cGMP manufacturing facility are in Bengaluru, India. These facilities cater to the development and cGMP manufacturing of biologics and injectables, conforming to international standards.

About the guarantor

Incorporated in 1990, Strides Pharma Science Limited is a medium-sized pharmaceutical company, which develops, manufactures and exports a wide range of pharmaceutical products. The company has followed an inorganic growth strategy over the years that resulted in its foray into new markets and the addition of new business segments, therapeutic segments and manufacturing infrastructure. Strides' product range covers most dosage forms including soft gel capsules, tablets, capsules and semi-solids. Currently, the company's business is broadly classified into regulated markets formulations (comprising mainly the US, the UK, Europe, Australia,), emerging markets (primarily Africa) and institutional segments (tender-driven business mainly in developing markets). As on December 31, 2020, 29.48% of the company's shares were held by the promoter group while the balance was held by various institutions and public.

Link to detailed last rationale of the guarantor - Here

Key financial indicators

Stelis (consolidated)	FY2020	FY2021*
Operating Income (Rs. crore)	1.5	21.4
PAT (Rs. crore)	-139.8	-120.6
OPBDIT/OI (%)	-4560.6%	-324.9%
PAT/OI (%)	-9065.2%	-563.9%
Total Outside Liabilities/Tangible Net Worth (times)	1.3	0.6
Total Debt/OPBDIT (times)	NM	NM
Interest Coverage (times)	NM	NM

Source: *Company, ICRA research; All calculations are as per ICRA research; NM – Not meaningful, *FY2021 provisional results*

PAT: Profit after Tax; OPBDIT: Operating Profit before Depreciation, Interest, Taxes and Amortisation

Status of non-cooperation with previous CRA: Not applicable

Rating history for past three years

		Current Rating (FY2022)				Chronology of Rating History for the Past 3 Years			
	Instrument	Type	Amount Rated (Rs. crore)	Amount Outstanding as of Mar 31, 2021 (Rs. crore)	Date & Rating in FY2022	Date & Rating in FY2021	Date & Rating in FY2020	Date & Rating in FY2019	
					Jun 14, 2021	-	Dec 30, 2019 Dec 16, 2019	Feb 22, 2019	Jun 22, 2018
1	Term Loan	Long Term	507.55	385.9	[ICRA]A+(CE) (Stable)	-	[ICRA]A(CE) (Stable)	[ICRA]A+ (SO) &	[ICRA]A+(SO) (Negative)

& - Under Watch with Developing Implications

Complexity level of the rated instrument

Instrument	Complexity Indicator
Long-term Fund Based – Term Loan	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: www.icra.in

Annexure-1: Instrument details

ISIN	Instrument Name	Date of Issuance / Sanction	Coupon Rate	Maturity Date	Amount Rated (Rs. crore)	Current Rating and Outlook
NA	Term Loan-I	Dec 2015	LIBOR+3.65%	FY2026	307.55	[ICRA]A+(CE) (Stable)
NA	Term Loan-II	Dec 2015	9.55%	FY2026		[ICRA]A+(CE) (Stable)
NA	Term Loan-III	May 2019	9.55%	FY2027	200.00	[ICRA]A+(CE) (Stable)

Source: *Company*

Annexure-2: List of entities considered for consolidated analysis

Company Name	Ownership	Consolidation Approach
Stelis Pte Ltd, Singapore	100.00%	Full Consolidation
Stelis Biopharma LLC, US	100.00%	Full Consolidation

Source: *Annual report*

Note: *ICRA has taken a consolidated view of the parent (Stelis), its subsidiaries and associates while assigning the rating*

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