Steriscience Specialties Private Limited (Revised)

December 20, 2023

Facilities/Instruments	Amount (₹ crore)	Rating[1]	Rating Action
Long Term / Short Term Bank Facilities	50.00	CARE BB+ / CARE A4 (RWD)	Assigned

Details of instruments/facilities in Annexure-1.

Rationale and key rating drivers

The ratings assigned to the bank facilities of Steriscience Specialties Private Limited (SSPL) takes into account the nascent stage of operations with moderate scale, customer concentration risk and inherent exposure to regulatory risks with the pharmaceutical industry. The company primarily focuses on manufacturing injectables. SSPL's customers are also highly concentrated, though the same is expected to diversify going forward with sales expansion.

The ratings are positively driven by the existence of experienced and resourceful promoters, who extended financial, operational, managerial support to the entity. The promoters have demonstrated track record of turning around business and exiting them profitably. The strong order book combined with the positive outlook for the injectables segment and overall pharma sector provides reasonable visibility regarding the future sales growth.

The reason for placing the ratings on watch with developing implications is owing to the impending restructuring and the possible impact of the same on the credit profile of SSPL. The restructuring involves demerger of CDMO and soft gel business of Strides, identified CDMO business of Steriscience speciality private limited both of which is expected to get merged with Stelis Biopharma limited. Further the name of Stelis Biopharma Limited is proposed to be changed to OneSource Specialty Pharma Limited. CARE Ratings Ltd. will take a view on the ratings once the exact implications of the above event on the credit risk profile of the company are clear.

Rating sensitivities: Factors likely to lead to rating actions

Positive factors

- Ability to successfully scale up operations and achieve sustained Total Operating Income growth of 15% while maintaining PBILDT margins at above 20%
- Reduction of total debt/PBILDT below 4x

Negative factors

- Fall in sales below Rs. 300 crores or fall in PBILDT below 10%
- Any change in support philosophy of parent company or promoter towards SSPL resulting in weakening of operational/financial linkages between the two.

Analytical approach: Standalone

CARE Ratings has adopted a standalone factoring linkages with promoter and other group companies.

Outlook: Not applicable

Detailed description of the key rating drivers:

Key weaknesses

Moderate scale of operations:

The company has commenced its operations during FY22 and has reported TOI of about Rs. 69 crore, with improvement in scale of operations it has reported Rs. 316 crore of TOI during FY23. Intense competition is expected to constrain scalability, with revenue expected at Rs 400-450 crore in FY24, despite growing by more than 50% from Rs 311 crore in FY23. The growth in revenue is expected to stem from launch of new products, long term supply agreements and demand prospects.

At present the global injectables industry is dominated by few large international players occupy significant market share. The domestic contract manufacturing space is highly fragmented with multiple players operating at different scale of operations.

[1]Complete definition of the ratings assigned are available at www.careedge.in and other CARE Ratings Ltd.'s publications

SSPL targets products where there is a shortage with a potential addressable market size of USD 200 million. The ability of the company to successfully scale up operations will remain a key monitorable in the near term.

High customer concentration risk:
Since the intellectual property is held by another group company called Steriscience pte, in Singapore, the sales are routed through that company, which inturn has multiple customers. The ultimate consumers are located in US, Brazil, Australia and Canada.
Around 50-60% of the sales in FY23 was from CMO segment for which Mylan laboratories is the primary customer. Given that Mylan has acquired Agila's injectable business and the rapport shared by the promoter, it is expected that SSPL will continue to derive revenue from sale of its products to Mylan. This in addition to the long-term sales agreement provides additional comfort and reduces the customer concentration risk to some extent.
Also, currently majority of the products are exposed to one therapeutic area which is anti-infectives. Going forward, high demand therapeutic areas like anaesthetics amongst others will be focused by the company for diversification.

Exposure to regulatory risk
SSPL is exposed to regulatory risk with its operations centered majorly into manufacturing pharmaceutical formulations and injectables. Besides, the pharmaceutical industry is highly regulated in many other countries and requires various approvals, licenses, registrations and permissions for business activities. The approval process for a new product registration is complex, lengthy and expensive. The time taken to obtain approval varies by country but generally takes from six months to several years from the date of application. Any delay or failure in getting approval for new product launch could adversely affect the business prospect of the company. Given, India's significant share in the USA's generic market, the USFDA has increased its scrutiny of manufacturing facilities and other regulatory compliance of the Indian pharma companies supplying generics drugs to the USA. Non-compliance may result in regulatory ban on products/facilities (as in the recent cases of import alerts issued by the USFDA to top pharma companies) and may impact a company's future approvals from USFDA. Hence, ongoing regulatory compliance has become critical for Indian pharma companies including SSPL they seek to strengthen its position in the regulated markets like USA, UK etc. till date there have been no major audit observations for the company.

Key strengths

Extensive industry experience and proven turn around track record of promoters

The primary promoter of SSPL is Mr. Arun Kumar, who also founded Strides in 1990. The main business model of the promoter and holding companies is to acquire distress companies, turnaround its operations and monetize them profitably. The profits made out of such divestment is used for reinvestment into existing businesses, acquisition of other distress businesses or is distributed to promoters or other shareholders. Mr. Arun Kumar has demonstrated track record of turning around business and exiting them profitably. Under his leadership, Strides Pharma has sold Agila Specialities to Mylan Laboratories at USD 1.6 billion in FY13 and exited the injectables segment.

Leveraging established relationships and brand name of promoters to attract PE investments:

Promoters have been able to infuse funds from own sources as well as attract PE investors for infusion of funds to support the operations of its businesses in its development phase. The investments from PE players acts as a testament to the industry's confidence in the promoters' ability and the SSPL's sales growth visibility.

Accredited manufacturing facilities & well qualified R&D team:

Though the company was incorporated in FY21, in order to enable quick scalability, acquired 3 integrated US FDA and 1 EU GMP approved facility (In FY23, all facilities have been approved by US FDA). On a combined basis, these units have a capacity to produce 121 million of liquid vitals, 40 million of dry powder vitals, 28 million pre-filled syringes, 36 million autoinjectors, 20 million Lyophilized Vials (removing the water) and 54 million of Ampoules (capsule containing injectables). The availability of highly experienced quality and regulatory personnel to meet the highest global quality standards, ensures compliance and the company also guides its clients through the regulatory approval process.
The other strength of SSPL is that it is fully integrated with a strong R&D team. The R&D team is lead by Dr. Vijaykanth who has over 20 years of extensive research and development experience in sterile pharmaceutical parenteral, including complex injectables and novel drug delivery systems for USA, Europe, and emerging markets. Prior to joining Steriscience, Dr. Vijay worked in leading pharmaceutical companies like Astron Research Ltd., Mylan (where he was the Director, R&D). Having an experienced R&D team in house enables fast-track development of products and ensures quick facility inspections & approvals. The ability of the company maintains accredited manufacturing facilities reduces the regulatory risk to some extent.

Reasonable sales growth visibility in the near term, albeit limited past track record

SSPL has locked in long term supply agreement with established players like Mylan. SSPL has completed Phase 1 R&D development for 31 projects including critical ready-to-use Pre filled syringes program. In May 2022, the company had its first launch in the US market. The company has 18 approved ANDAs of which 13 were acquired and 5 was developed in house. In FY24, the company has filed 4 and in the past 1.5 years the company has done about 20-23 filings out of which 5 has been approved. CARE Ratings expects the company to achieve sales of Rs. 400-500 crores in FY24. In addition, the company plans to do another 10 filings in the next 6 months.

Liquidity: Stretched

Given that SSPL is in its growth phase and in the absence of an established long track record on a standalone basis, the cash accruals are yet to turn positive in FY23. With more than 50% YoY growth expected, the gross cash accruals are expected to turn positive in the FY24. The debt repayments mainly include the HDFC term loan instalments of Rs. 13.70 crores in FY24, of which the company has already paid ~Rs. 10 crores till date. The existence of DSRA also provides comfort. There are no major capex plans except maintenance capex of Rs. 5-10 crores. The existence of long-term supply agreements (3 years) with established players, strong H1FY24 sales performance along with strong order book provides revenue visibility. SSPL enjoys considerable financial flexibility and technical support from its promoter group. Its management has a track record of incubating and developing pharmaceutical businesses globally. The company utilizes 100% of its fund based and non-fund based working capital limits and cash balance is negligible. As per the discussions with the management and the past track record of promoters supporting the entity, it is understood that the parent company will continue infusing funds on a need basis to SSPL.

Assumptions/Covenants- Not applicable

Environment, social, and governance (ESG) risks – Not given as company is unlisted

Applicable criteria

Policy on default recognition
Financial Ratios – Non financial Sector
Liquidity Analysis of Non-financial sector entities
Factoring Linkages Parent Sub JV Group
Rating Outlook and Credit Watch
Short Term Instruments
Manufacturing Companies
Pharmaceutical
Policy on Withdrawal of Ratings

About the company and industry

Industry classification

Macro Economic Indicator	Sector	Industry	Basic Industry
Healthcare	Healthcare	Pharmaceuticals & Biotechnology	Pharmaceuticals

SSPL was incorporated in the year 2020 and is involved in the development and manufacture of a range of products primarily in the sterile injectables segment namely – Ampoules, liquid Vials, Dry powder Vials, Lyophilized Vials, Autoinjectors and Pre-filled Syringes. Steriscience's origination started with Agila Specialties, which was part of Strides Group up to 2012-13, after which it was acquired through strategic transaction by Mylan laboratories limited. The promoter Mr. Arun Kumar had signed a noncompete agreement in FY2014 for a span of six years during the sale of the injectables unit of Agila Specialities to Mylan. Post this, Steriscience was formed to continue and build on the legacy of Agila. The manufacturing facility was purchased from Mylan and majority of the team is also retained. Steriscience India includes two plants in Bangalore.

Brief Financials Standalone (₹ crore)	March 31, 2022 (A)	March 31, 2023 (A)	H1FY24 (UA)
Total operating income	67.42	311.20	205.93
PBILDT	-27.71	11.68	24.81
PAT	-38.50	-40.68	-19.03
Overall gearing (times)	7.87	NM	NA
Interest coverage (times)	-10.11	0.46	0.87

A: Audited UA: Unaudited NA: Not available NM: Not meaningful; Note: 'the above results are latest financial results available'

Status of non-cooperation with previous CRA: not applicable

Any other information: not applicable

Rating history for last three years: Please refer Annexure-2

Covenants of rated instrument / facility: Detailed explanation of covenants of the rated instruments/facilities is given in Annexure-3

Complexity level of various instruments rated: Annexure-4

Lender details: Annexure-5

Annexure-1: Details of instruments/facilities

Name of the Instrument	ISIN	Date of Issuance (DD-MM-YYYY)	Coupon Rate (%)	Maturity Date (DD-MM-YYYY)	Size of the Issue (₹ crore)	Rating Assigned along with Rating Outlook
LT/ST Fund-based/Non-fund-based-CC/WCDL/OD/LC/BG	-	-	-	-	50.00	CARE BB+ / CARE A4 (RWD)

Annexure-2: Rating history for the last three years

Sr. No.	Name of the Instrument/Bank Facilities	Current Ratings			Rating History			
		Type	Amount Outstanding (₹ crore)	Rating	Date(s) and Rating(s) assigned in 2023-2024	Date(s) and Rating(s) assigned in 2022-2023	Date(s) and Rating(s) assigned in 2021-2022	Date(s) and Rating(s) assigned in 2020-2021
1	LT/ST Fund-based/Non-fund-based-CC/WCDL/OD/LC/BG	LT/ST*	50.00	CARE BB+ / CARE A4 (RWD)				

*Long term/Short term.

Annexure-3: Detailed explanation of covenants of the rated instruments/facilities – not applicable

Annexure-4: Complexity level of the various instruments rated

Sr. No.	Name of the Instrument	Complexity Level
1	LT/ST Fund-based/Non-fund-based-CC/WCDL/OD/LC/BG	Simple

Annexure-5: Lender details

To view the lender wise details of bank facilities please click here

Note on the complexity levels of the rated instruments: CARE Ratings has classified instruments rated by it on the basis of complexity. Investors/market intermediaries/regulators or others are welcome to write to care@careedge.in for any clarifications.

Contact us

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About us:

Established in 1993, CARE Ratings is one of the leading credit rating agencies in India. Registered under the Securities and Exchange Board of India, it has been acknowledged as an External Credit Assessment Institution by the RBI. With an equitable position in the Indian capital market, CARE Ratings provides a wide array of credit rating services that help corporates raise capital and enable investors to make informed decisions. With an established track record of rating companies over almost three decades, CARE Ratings follows a robust and transparent rating process that leverages its domain and analytical expertise, backed by the methodologies congruent with the international best practices. CARE Ratings has played a pivotal role in developing bank debt and capital market instruments, including commercial papers, corporate bonds and debentures, and structured credit.

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