PEL Pharma Inc

December 29, 2023

Facilities/Instruments	Amount (₹ crore)	Rating[1]	Rating Action
Long-term bank facilities	224.87 (Reduced from 269.82)	CARE A+; Stable	Reaffirmed

Details of instruments/facilities in Annexure-1.
USD 27.08 million converted at an exchange rate of ₹83.04 per USD.

Rationale and key rating drivers

The reaffirmation of the rating of the bank facility of PEL Pharma Inc. continues to derive strength from the strong business profile of the ultmiate parent company, Piramal Pharma Limited (PPL) backed by diversified business segments, the presence in various niche therapeutic segments, and well-spread geographical footprints. The rating also factors in the unconditional and irrevocable corporate guarantee (CG) extended by PPL. As per the sanction terms, the present and future cash flows of seven companies (list mentioned as restricted group below) will be utilised for the repayment of foreign currency term loan (FCTL). The rating also derives strength from the experienced promoters and management team, long track record of PPL in the pharmaceutical industry, accredited manufacturing facilities with well-equipped R&D facilities and a well-established marketing network. That said, the aforementioned rating strengths are partially offset by the relatively moderate capital structure and increased debt levels as on September 30, 2023. Moreover, the competition in the CDMO segment as well as macro-economic factors may impact the operating profitability. PPL also has a significant presence in regulated markets, especially the USA and the UK, and hence is exposed to the regulatory risk that is inherent in the pharmaceutical industry.
However, CARE Ratings Limited (CARE Ratings) notes that PPL has a track record of zero official action indicated (OAI) from U.S. Food & Drug Association (USFDA) audits. The ability of the parent company, i.e, PPL to successfully turn around the business and achieve the cash accruals envisaged remains a key monitorable in the near term.

Rating sensitivities: Factors likely to lead to rating actions

Positive factors

- Combined cash flows of restricted group companies to become sufficient to meet debt payment obligations.

Negative factors

- Any weakening of linkages with the parent, or lack of adequate support or deterioration in the credit profile of the parent.

Analytical approach: Combined

Combined approach for the restricted group while factoring linkages with the parent company, PPL. As per the sanction terms, the present and future cash flows of the following mentioned restricted group entities will be utilised for repayment of FCTL.

List of companies combined (Restricted group)

S.No	Name of the company	% shareholding by the parent; PPL
1	Piramal Dutch Holdings NV (Overseas holding co)	100%
2	PEL Pharma Inc	100%
3	Piramal Critical Care Limited UK	100%
4	Piramal Healthcare UK Limited	100%
5	Piramal Healthcare (Canada) Limited	100%
6	Ash Stevens LLC	100%
7	Piramal Pharma Solutions Inc	100%

Outlook: Stable

CARE Ratings believes the restricted group will continue to benefit from its strong promoter group and has got financial flexibility from its parent, PPL, which has extended unconditional and irrevocable CG for FCTL taken by the restricted group.

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

Detailed description of the key rating drivers:

Key strengths

Strong parentage providing financial flexibility

The restricted group companies are subsidiaries/step-down subsidiaries of PPL and PPL has extended unconditional and irrevocable corporate guarantee to the facility being rated. The promoters of Piramal Enterprises Ltd (PEL) are also the promoters of PPL. PEL is the flagship company of the Piramal group spearheaded by Ajay Piramal (Chairman). The group is a diversified Indian business house with interests in financial services businesses and pharmaceuticals (CDMO, Critical Care, OTC).

Nandini Piramal (Chairman; daughter of Ajay Piramal) along with Peter DeYoung (CEO; son-in-law of Ajay Piramal) are responsible for steering strategy and driving profitable growth of PPL. Nandini Piramal is a part of the promoter group of the holding company i.e., PEL. Peter DeYoung has spearheaded several leadership mandates at the Piramal group, including CEO and President. Previously, he has worked in various investing and consulting roles in healthcare in the USA, Europe and India. PPL's board comprises eminent personalities with professional experience in the pharma domain.

Diverse product mix of subsidiaries and accredited manufacturing facilities with wide-spread geographical presence

Restricted group companies are engaged in multiple products like manufacturing of hormone drugs (Morpeth), antibody drug conjugates (Grangemouth), active pharmaceutical ingredients (API) (Aurora & Riverview), potent sterile injectables (Lexington). The company offers diverse products in both generic and critical care segments across globe.

The manufacturing facilities in the restricted group and their capabilities are as follows:

Country	Location	Capability	Company	Approving regulatory authorities
UK	Morpeth	API and Formulations	Piramal Healthcare UK Ltd	USFDA, MHRA, PMDA, HC
UK	Grangemouth	Antibody Drug Conjugate (ADC)	Piramal Healthcare UK Ltd	USFDA, MHRA, PMDA
Canada	Aurora	API Development and Manufacturing	Piramal Healthcare (Canada) Limited	USFDA, PMDA, HC
US	Lexington	Sterile Development and Manufacturing	Piramal Pharma Solutions Inc.	USFDA, PMDA
US	Riverview	High Potent API Development and Manufacturing	Ash Stevens LLC	USFDA, PMDA, HC

All the facilities in the restricted group have necessary regulatory approvals and the products manufactured by subsidiaries of Piramal Dutch Holdings NV Netherlands (PDHNV) are sold across globe. The manufacturing bases of PDHNV's subsidiaries are spread in various geographies which has strengthened the Piramal group's presence in the global pharma business.

Key weaknesses

Moderate financial risk profile of restricted group albeit strong support from parent company

The combined net worth of the restricted group companies stood at around ₹1,838 crore as on December 31, 2022. The total operating income (TOI) of the restricted group improved from ₹1,898 crore in the calendar year (CY), CY21 to ₹2,102 crore in CY22 and is estimated to improve to about ₹2,150 crore in CY23. The profit before interest, lease rentals, depreciation and taxation (PBILDT) margins moderated from 7.54% in CY21 to 1.55% in CY22. The PBILDT margin moderated in CY22 primarily due to increase in raw material cost, increased employee costs. CDMO revenue for the group has remained subdued due to continued tight funding in the biotech segment and soft demand in generic API and certain vitamins portfolio. However, the company is seeing requests for proposals inflows and increasing number of customer visits and audits. During CY22, the inhalation anaesthetic products have shown a significant recovery mainly due to hospitals getting back to elective surgeries for clearing the backlog that had built up due to COVID-19.

Presently, the debt profile of the restricted group consists of loans availed from related parties, i.e., group companies which do not have fixed repayments and FCTL amounting USD 225 million from State bank of India (SBI) (USD 152.35 million outstanding as on September 30, 2023) which is guaranteed by PPL and would be serviced from combined cash flows of restricted group. PPL being a corporate guarantee provider to the term loan is expected to support the debt repayment in case of shortfall from cashflows from the restricted group.

Regulatory risk

The restricted group has its presence in multiple countries across the world and it has five production units. Considering the nature of the product usage and application, and consequent impacts, the restricted group companies are required to comply with various laws, rules and regulations and operate under strict regulatory environment. Thus, infringement in any of the law, and any significant adverse change in the import/export policy or environmental/regulatory policies in the area of operations of the company, can have an impact on the operations of the company. Nevertheless, the company is continuously taking adequate steps to address the regulatory risks. Furthermore, all the manufacturing sites continue to successfully clear regulatory audits, conducted by various leading global regulatory agencies.

Exposure to raw material price volatility and macro-economic factors
For the Piramal Restricted Group companies, majority of key raw materials are procured from India and China which exposes the company to raw material price volatility. However, the restricted group acquires raw material from client-approved vendors for certain segment, wherein the raw material price is charged as per the contract. Hence, price volatility risk is taken care to an extent. The impact of pricing of raw material have dented the operating margins of the group during recent past. The rise in prices of inputs and solvents as well as energy prices due to the Russia – Ukraine war and other supply chain disruptions have impacted the overall cost and therefore profitability of the group.

Liquidity: Adequate
The debt profile of the restricted group consists of loans availed from related parties (for which there are no scheduled repayment terms) and FCTL amounting ₹1,265 crore as on September 30, 2023 (USD 152.35 million outstanding out of total loan of USD 225 million) that was availed from SBI in June 2020 for repayment of intercompany debt. The said loan is backed by unconditional and irrevocable guarantee from PPL and the companies in the restricted group who are also jointly and severally liable. As per the sanction terms, the present and future cash flows of the restricted group will be utilised for repayment of the SBI loan. The gross cash accruals (GCA) from the seven entities are expected be lower as compared to the term debt repayment obligation of around ₹345 crore in CY24. As per discussion with the management and on the basis of the corporate guarantee, CARE Ratings expects that the shortfall, if any, will be met by PPL. Also, debt service reserve account (DSRA) for the ensuing three months' principal and interest payment (USD 12.05 million around ₹100 crore) has been created and maintained.

Assumptions/Covenants: Not applicable

Environment, social, and governance (ESG) risks: Not applicable

Applicable criteria

Policy on default recognition
Rating Methodology - Consolidation and Combined Approach
Factoring Linkages Parent Sub JV Group
Financial Ratios – Non financial Sector
Liquidity Analysis of Non-financial sector entities
Rating Outlook and Credit Watch
Pharmaceutical

About the company and industry

Industry classification

Macro-economic Indicator	Sector	Industry	Basic Industry
Financial services	Financial services	Finance	Holding company

PEL Pharma Inc., incorporated on August 26, 2015, in the State of Delaware, is an international holding company and a wholly-owned subsidiary of PDHNV (owning 90% of the common stock) and PPL (owning 10% of the common stock). PEL Pharma Inc. owns Piramal Pharma Solutions Inc. and Ash Stevens LLC as its wholly-owned subsidiaries. Through its subsidiaries, it has three manufacturing facilities in USA. Ash Stevens LLC offers diverse products in large pharma generics and biotech segment across North America. Piramal Pharma Solutions Inc. is a global CDMO player with niche product profile. It also has presence in nutrition solutions (vitamins + premixes).

Brief Financials of restricted group (₹ crore)	December 31, 2021 (A)	December 31, 2022 (A)
Total operating income	1897.99	2101.54

PBILDT	143.12	32.56
PAT	-81.35	-310.68
Overall gearing (times)	1.45	2.16
Interest coverage (times)	0.97	0.17

A: Audited ; Note: 'the above results are latest financial results available'
2021 conversion rate – ₹74.34 per USD
2022 conversion rate – ₹82.73 per USD

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
Fund-based - LT-Term loan	-	-	-	30-06-2025	224.87	CARE A+; Stable

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	Fund-based - LT-Term loan	LT	224.87	CARE A+; Stable	-	1)CARE A+; Stable (13-Mar-23) 2)CARE AA (CE); Stable (14-Jul-22) 3)CARE AA (CE) (CW with Developing Implications) (04-Apr-22)	1)CARE AA (CE) (CW with Developing Implications) (18-Oct-21)	1)CARE AA (CE) (CW with Developing Implications) (18-Feb-21) 2)CARE AA (CE); Stable (14-Dec-20)

2	Unsupported rating-Unsupported rating (Long term)	LT	-	-	-	1)Withdrawn (13-Mar-23) 2)CARE A (14-Jul-22) 3)CARE A (04-Apr-22)	1)CARE A (18-Oct-21)	1)CARE A (18-Feb-21) 2)CARE A (14-Dec-20)

LT – Long 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	Fund-based - LT-Term loan	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.

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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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