Orchid Pharma Limited

March 10, 2025

Facilities/Instruments	Amount (₹ crore)	Rating[1]	Rating Action
Long-term bank facilities	207.50 (Enhanced from 135.00)	CARE A- (RWD)	Continues to be on Rating Watch with Developing Implications
Long-term / Short-term bank facilities	75.00	CARE A- / CARE A2 (RWD)	Continues to be on Rating Watch with Developing Implications
Short-term bank facilities	84.00	CARE A2 (RWD)	Continues to be on Rating Watch with Developing Implications

Details of instruments/facilities in Annexure-1.

Rationale and key rating drivers

The ratings assigned to bank facilities of Orchid Pharma Limited (OPL) continue to be on "Rating watch with developing implications" following the company's announcement of the approval of board of directors for a proposed scheme of amalgamation and arrangement between Dhanuka Laboratories Limited (DLL), and OPL. DLL is the parent company of OPL and holds 69.84% shares in OPL as on 31 December 2024. CARE Ratings notes the aforementioned scheme is pending for the requisite approvals. CARE Ratings will continue to monitor the progress of these developments in this regard.

Ratings continue to draw comfort from the promoter's experience in the pharmaceutical industry and internationally accredited manufacturing facilities, steady improvement in the operational performance and the company's comfortable capital structure. However, ratings are constrained by the concentration of product portfolio with application in limited number of therapeutic segments, moderate proportion of sales from regulated markets and exposure to the regulatory risk and dependence on imports for the raw materials.

CARE Ratings notes the company, as part of the backward integration, is setting up a unit for production of key starting material (KSM) in one of its subsidiaries. This capex is expected to be relatively large-sized debt-funded project. Project is being set up under the production-linked incentive (PLI) scheme of the government of India (GOI) and is also entitled to interest subvention and tax concession benefits. While there has been delay in the project progress due to delay in land acquisition, construction has started. Timely completion of this project within cost estimates would be key to the company's prospects.

This apart company is also undertaking investments in other projects including setting up Vial Lyophilization facility for manufacturing Cefiderocol Injection under the manufacturing sub-license agreement with Global Antibiotic Research & Development Partnership (GARDP), and construction of a downstream plant at its existing facility in Alathur. The successful completion of the same and scaling up of the same would be important credit monitorable.

Rating sensitivities: Factors likely to lead to rating actions

Positive factors

- Timely completion of the capex at subsidiary and deriving benefits from the same at a consolidated level.
- Improvement in scale of operations above ₹1000 crore with margins above 20% deriving benefits from expansion in regulated markets, receipt of royalty payments from new chemical entity (NCE).

Negative factors

- Any Negative regulatory observations resulting in disruption of operations.
- Any Large debt funded capital expenditure resulting in deterioration of overall gearing above 1x.

Analytical approach: Consolidated

CARE Ratings has adopted consolidated approach for analysis as OPL and its subsidiaries are in similar business with exposure to subsidiaries and likelihood of financial support for subsidiaries in the future. Details of subsidiaries are mentioned in Annexure-6.

Detailed description of key rating drivers:

Key strengths

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

State-of-the-art manufacturing facility with approvals from regulated markets

OPL has its manufacturing plant at Alathur, Chennai, which is its active pharmaceutical ingredients (API) manufacturing unit. This plant is certified by USFDA, MHRA –UK, EDQM, and GMP for manufacturing Cephalosporin-based APIs. The company is also one among the three global players to have a USFDA approvals for Cephalosporin-based Sterile APIs. In the generic formulation's domain, as on March 2024, OPL holds 06 ANDAs in the generic formulation domain and in the API domain, OPL's cumulative filings of US DMF stand at 48. EU GMP audit for the facility was completed in October 2024 and the company has received certificate of compliance. The company underwent a USFDA inspection in February 2025, which concluded without major critical observations.

Over three decades of experience of promoters in the pharmaceutical industry

The promoters, the Dhanuka group, have presence in the agrochemical and pharmaceutical industries. Their experience in the pharmaceutical business comes from two companies, including Dhanuka Laboratories Limited (DLL) and Synmedic Laboratories. DLL operates in the API space with major presence in Cephalosporin API business. DLL primarily operates in the non-regulated/semi-regulated markets. Synmedic Laboratories, a partnership firm, operates in the formulation segment, and exports finished pharmaceutical formulations to the non-regulated markets. DLL holds a small stake in Otsuka Chemical India Private Limited and is engaged in manufacturing of 7-Phenylacetamido-3-Chloromethyl Cephalosporanaic Acid Para-Methoxy Benzylester (GCLE), a key raw material, for manufacturing Cephalosporin and is a major supplier for OPL.
Manish Dhanuka, OPL's managing director, is a chemical engineer from IIT Delhi, completing his master's in chemical engineering from University of Akron, USA. After completing his education, he worked with Ranbaxy Labs Limited, before starting with DLL. He has over 26 years of experience in the pharmaceutical industry.

Stable operational performance

The company has improved the production level and capacity utilisation in the recent past. With the capacity utilisation in sterile reaching over 100%, the company has further expanded the capacity from 140 MT to ~165 MT in FY24 and further increased to 200 MT in H1FY25. With the increasing demand for anti-biotics and improvement in the production levels, the company has achieved 14% growth in TOI in FY24 and maintained similar growth rate for 9MFY25 compared to the same period of previous year.
In terms of margins, due to lower-than-envisaged expansion to regulated markets, the margins have been remained lower than 15%. However, with continuous process efficiency measures, PBILDT margins are sustained at 11-13% over the last three years. With improved scale and cost rationalisation, the company has shown a slight improvement in operating margin to 14.28% in FY24 (PY: 13.36%). Increasing exposure to regulated markets and scaling up operations through new initiatives while improving margins remains key to the company's prospects.

Comfortable capital structure; albeit expected to deteriorate

The capital structure is comfortable with overall gearing of 0.19x as of FY24 (PY: 0.65x) at a consolidated level. Of total debt of ₹203 crore as on March 2024, ₹188.77 crore pertains to OCDs issued by the company which are held by the holding company, DLL. Total external debt stands at ₹14 crore of working capital borrowings. The improvement in gearing from the March 2023 levels is primarily due to the QIP fundraise of ~₹400 crore by the company in June 2023 and repayment of external debts worth ₹141 crore from the issue proceeds. However, overall gearing is expected to increase in the coming years due to the planned capex projects that the company is undertaking which are partly funded through external debt, which has already been tied up.

Commercialisation of NCE and new products in pipeline

The company has successfully developed its own molecule, Enmetazobactum, which has cleared phase 3 clinical trials, becoming the first such molecule from India to achieve this milestone. Enmetazobactum was out-licensed to Allecra Therapeutics in 2013, and following the completion of phase 3 trials in 2020, the molecule was further out-licensed to Advanz Pharma in Europe and Shanghai Haini in China. This product has been commercialised in EU and the company has started receiving royalty income from the partners. Marketing rights of this molecule for India is with the company and they partnered with Cipla for marketing this product. The company also started selling this product under their own brand 'ORBLICEF' directly to hospitals. While the contribution from the new product in the form of royalty or sales is marginal at this juncture, this expected to increase in the coming years with more market penetration. The royalty income would be a direct accretion to the company's profits, improving the company's margins going forward.
OPL has entered a manufacturing sublicense agreement with GARDP to manufacture Cefiderocol, which is still under the patent of Shionogi. OPL has exclusive agreement for manufacturing this product and would manufacture the end-product not just the API.

Key weaknesses

Concentrated product portfolio

The major products of OPL and DLL remain Cephalosporin based APIs which are mainly used in anti-bacterial, anti-biotic and anti-inflammatory formulations. While the company has a wide range of product portfolio within this, the revenue is concentrated on the top two products - Cefixime and Cefuroxime Axetil, which accounts for ~71% revenue in FY24. These key products are among the essential bulk drugs listed by the Government of India to reduce dependence on Chinese imports.

Exposure to regulatory risk

The pharmaceutical industry is highly regulated and requires approvals, licenses, registrations and permissions for conducting business activities. The approval process for a new product registration is complex, lengthy and expensive. The time taken to obtain approval varies across countries and authorities, usually taking a minimum of six months to several years from the date of application. Delay or failure in obtaining approvals for new product launch could adversely affect the company's business prospects.

Debt-funded capital expenditure plans

OPL has set up a subsidiary called Orchid Bio Pharma Limited for undertaking PLI-based capital expenditure project in Jammu. OPL has received 1,000 metric tonne per annum (MTPA) approval from GoI in its wholly owned subsidiary (WoS). The estimated cost of the project is ₹596 crore, of which ₹90 crore is expected to be funded of QIP proceeds, ₹59 crore from internal accruals and remaining ~₹447 crore by debt. The debt at subsidiary is expected to be guaranteed by OPL. The project is expected to have benefit of interest subvention and tax concessions under government schemes. ~75% off-take is expected to be from OPL, and the rest would be to third parties directly from the subsidiary. There have been delays in the project due to land acquisition issues in Jammu. However, these have been resolved and construction has started, and debt has also been tied up. As on February 2025, the company has incurred a capex of ₹80 crore for this project, primarily towards land acquisition, and advances against orders for plant machinery. The management expects the project to be completed by end of FY26, with commercial operations starting from FY27. Parallelly, OPL is also envisaging a capex for the processing of the 7ACA from the subsidiary at an estimated cost of ~₹100 crore, to be entirely funded from the QIP funds. OPL is also setting up Vial Lyophilization facility for manufacturing Cefiderocol Injection under the manufacturing sub-license agreement with GARDP. Total project cost is estimated to be ₹190 crore, of which ₹142.50 crore is expected to be debt funded. As on January 2025, the company has already spent ~₹20 crore in capex for this project, primarily towards capital advances for plant and machinery. The project completion is expected by FY27 with commercial production starting from FY28. Timely completion of these projects within cost estimates would be a key monitorable.

Liquidity: Adequate

Liquidity profile is adequate marked by sufficient cash accruals against nil term loan as of September 30, 2024. In FY24, OPL with the QIP proceeds, had repaid ₹40 crore term loan and ₹101 crore working capital borrowings. However, there are sizeable capex plans that are expected to be funded by a mix of QIP proceeds, internal accruals and debt funding. Repayment for the proposed term loans is envisaged to commence from FY27. The operations are working capital intensive with the company availing ~60-90 days of credit period from suppliers and 2-3 months credit period given to customers. The average working capital utilisation for the 12 months ended September 2024 stands low at 14.71%. OPL has an unencumbered cash and bank balance of ₹30.22 crore as of September 30, 2024, and unutilised QIP proceeds of ₹204.30 crore is also parked in FD.

Environmental, Social and Governance Risk assessment:

Environmental	OPL has employed a state-of-the-art technology, zero liquid discharge (ZLD) treatment plant and world class treatment facilities for its liquid and gaseous pollutants generated from the production processes. Hazardous wastes are collected and stored in protected storage shed and disposed per hazardous waste authorisation. Bio sludge generated from the biological process of effluent treatment are converted into useful compost. The Company has taken several ongoing measures to reduce consumption of water and energy. World Environment Day was celebrated on June 05, 2023, by planting trees within factory premises to create awareness on environment among employees.

Social	The company prioritises the well-being of its employees by providing training on health, safety measures, and skill upgrades. The company has health and safety standards in place and has given over 850 trainings on health and safety and skill upgradations. In FY24, training programs covering Chemical safety-SDS, Work Permit System, Fire prevention and mitigation, Emergency preparedness, first aid and Process Safety Management was provided to employees.
Governance	In Compliance with Regulation 34(3) read with Schedule V of the Listing Regulations. The company has eight directors out of which four are independent directors. Composition of different boards and committees per the regulations.

Applicable criteria

Consolidation
Definition of Default
Liquidity Analysis of Non-financial sector entities
Rating Outlook and Rating Watch
Manufacturing Companies
Pharmaceuticals
Financial Ratios – Non financial Sector
Short Term Instruments

About the company and industry

Industry classification

Macroeconomic indicator	Sector	Industry	Basic industry
Healthcare	Healthcare	Pharmaceuticals and biotechnology	Pharmaceuticals

OPL, established in 1992, is an integrated pharmaceutical company with presence in bulk drug manufacturing and formulations. The company was acquired by Dhanuka Laboratories Limited (DLL) under Corporate Insolvency Resolution Process (CIRP) by The National Company Law Tribunal (NCLT) and the resolution plan has been implemented on March 31, 2020. OPL, at present, has three manufacturing facilities in Chennai. The API unit at Alathur is USFDA certified, while the two formulations units in Alathur cater exports to non-regulated markets and the domestic market.

Brief Financials (₹ crore)	2023 (A)	2024 (A)	9M FY25 (UA)
Total operating income	671.10	826.10	684.45
PBILDT	89.66	117.98	89.20
PAT	53.09	92.17	77.36
Overall gearing (times)	0.65	0.19	NA
Interest coverage (times)	2.72	7.05	8.39

A: Audited; UA: Unaudited; NA: Not available; Note: these are latest available financial results

Status of non-cooperation with previous CRA: Not applicable

Any other information: Not applicable

Rating history for last three years: Annexure-2

Detailed explanation of covenants of rated instrument / facility: Annexure-3

Complexity level of 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 and Rating Outlook
Fund-based - LT-Cash Credit		-	-	-	65.00	CARE A- (RWD)
Fund-based - LT-Term Loan		-	-	Proposed	142.50	CARE A- (RWD)
LT/ST Fund-based/Non-fund-based-CC/WCDL/OD/LC/BG		-	-	-	75.00	CARE A- / CARE A2 (RWD)
Non-fund-based - ST-BG/LC		-	-	-	84.00	CARE A2 (RWD)

Annexure-2: Rating history for 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 2024-2025	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
1	Fund-based - LT-Term Loan	LT	-	-	-	1)Withdrawn (30-Nov-23)	1)CARE BBB; Stable (10-Feb-23) 2)CARE BBB- (RWD) (27-Dec-22)	1)CARE BBB- (CW with Developing Implications) (27-Dec-21) 2)CARE BBB-; Stable (29-Sep-21)
2	Non-fund-based - ST-BG/LC	ST	84.00	CARE A2 (RWD)	-	1)CARE A2 (RWD) (15-Dec-23) 2)CARE A2 (30-Nov-23)	1)CARE A3+ (10-Feb-23) 2)CARE A3 (RWD) (27-Dec-22)	1)CARE A3 (CW with Developing Implications) (27-Dec-21) 2)CARE A3 (29-Sep-21)
3	Fund-based - LT-Cash Credit	LT	65.00	CARE A- (RWD)	-	1)CARE A- (RWD) (15-Dec-23) 2)CARE A-; Stable (30-Nov-23)	1)CARE BBB; Stable (10-Feb-23) 2)CARE BBB- (RWD) (27-Dec-22)	1)CARE BBB- (CW with Developing Implications) (27-Dec-21) 2)CARE BBB-; Stable (29-Sep-21)
4	LT/ST Fund-based/Non-fund-based-CC/WCDL/OD/LC/BG	LT/ST	75.00	CARE A- / CARE A2 (RWD)	-	1)CARE A- / CARE A2 (RWD) (15-Dec-23) 2)CARE A-; Stable / CARE A2 (30-Nov-23)	1)CARE BBB; Stable / CARE A3+ (10-Feb-23)	-
5	Fund-based - LT-Term Loan	LT	142.50	CARE A- (RWD)	-	1)CARE A- (RWD) (15-Dec-23) 2)CARE A-; Stable (30-Nov-23)	-	-

LT: Long term; ST: Short term; LT/ST: Long term/Short term

Annexure-3: Detailed explanation of covenants of rated instruments/facilities: Not applicable

Annexure-4: Complexity level of instruments rated

Sr. No.	Name of the Instrument	Complexity Level
1	Fund-based - LT-Cash Credit	Simple
2	Fund-based - LT-Term Loan	Simple
3	LT/ST Fund-based/Non-fund-based-CC/WCDL/OD/LC/BG	Simple
4	Non-fund-based - ST-BG/LC	Simple

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

Annexure-5: Lender details

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

Annexure-6: List of entities consolidated

Sr No	Name of the entity	Extent of consolidation	Rationale for consolidation
1	Orchid Pharmaceuticals Inc.	Full	Wholly owned subsidiary
2	Orgenus Pharma Inc.	Full	Wholly owned subsidiary
3	Orchid Pharma Inc. / Karalex Pharma LLC	Full	Wholly owned subsidiary
4	Bexel Pharmaceuticals Inc.	Full	Wholly owned subsidiary
5	Diakron Pharmaceuticals Inc.	Full	Subsidiary
6	Orchid Bio-Pharma Limited (OBPL)	Full	Wholly owned subsidiary

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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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