

Alkem Laboratories Limited

January 08, 2025

Facilities/Instruments	Amount (₹ crore)	Rating ¹	Rating Action
Long-term / Short-term bank facilities	300.00	CARE AA+; Stable / CARE A1+	Reaffirmed

Details of instruments/facilities in Annexure-1.

Rationale and key rating drivers

Ratings assigned to bank facilities of Alkem Laboratories Limited (Alkem) continue to derive strength from its experienced promoters and management team, and long track record of the company in the pharmaceutical industry with its accredited manufacturing facilities. Ratings are further underpinned by its dominant position in the domestic formulation market with strong product portfolio across multiple therapeutic segments, an established and wide marketing network, gradual expansion in regulated markets, and its well-equipped research and development (R&D) facilities, leading to strong business profile. Ratings also derive strength from Alkem's robust financial risk profile marked by growing scale of operations with healthy profitability and return indicators, its low leverage, comfortable debt coverage indicators, and strong liquidity. CARE Ratings Limited (CARE Ratings) also take note of the recovery in Alkem's profit before interest, lease rentals, depreciation and taxation (PBILDT) margin in FY24 (FY refers to April 01 to March 31) which improved further in H1FY25. Ratings also factor in diversification of Alkem in the biosimilar segment via its subsidiary, Enzene Bioscience Limited (EBL) and its plans to enter orthopaedic implant business. However, ratings strengths are partially off-set by Alkem's higher dependence on acute therapeutic segment where the company is exposed to price control with ~25%-30% of its products under National List of Essential Medicines (NLEM). Ratings further continue to be constrained considering its exposure to inherent regulatory risk associated with the pharmaceutical industry, competitive industry scenario, and foreign exchange fluctuation risk.

Rating sensitivities: Factors likely to lead to rating actions Positive factors

- Geographical and product portfolio diversification with greater share of chronic therapeutic segment in its revenue profile and significant growth in its revenue and improvement in its PBILDT margin.
- Efficient working capital management with net operating cycle remaining ~60 days on a consistent basis.

Negative factors

- PBILDT margin remaining below 15% on a sustained basis.
- Large-size debt-funded organic or inorganic expansion leading to net debt to PBILDT higher than unity on a sustained basis.

Analytical approach: Consolidated

CARE Ratings has considered Alkem's credit assessment on a consolidated basis since Alkem has considerable overseas operations and there exists financial and operational inter-linkages with its subsidiaries/JV/Associates. The list of entities consolidated is given in **Annexure-6**.

Outlook: Stable

CARE Ratings expects Alkem's operational and financial risk profile to remain strong led by strong position in the domestic pharmaceuticals market and its low reliance on external debt.

Detailed description of key rating drivers:

Key strengths

Long track record of operations in the pharmaceutical industry and extensive experience of its promoters

Incorporated in 1973, Alkem has a track record of over five decades in the pharmaceutical industry. Alkem was founded by the late Samprada Singh, and his brother, Basudeo Singh, who is currently the company's executive chairman with an experience of over four decades in the industry. The company's day-to-day operations are managed by a team of qualified and experienced management spearheaded by Sandeep Singh (grandson of Samprada Singh), who is currently the managing director of Alkem. Sandeep Singh has over 19 years of experience in the pharmaceutical business. Over the years, the promoters have been able to significantly grow the company's scale of operations. Alkem has been gradually increasing its presence in the overseas markets.

Accredited manufacturing facilities supported with well-equipped R&D facilities

Alkem has 19 manufacturing facilities (of which 18 are in India and one is in the United States) as on March 31, 2024. In FY24, as part of the company's operational strategy, Alkem sold the operations at the St. Louis manufacturing facility situated in the USA owned by S&B Pharma LLC, a step-down subsidiary of the company.

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



Within India, the manufacturing facilities are in Gujarat, Pune, Daman, Baddi, Indore and Sikkim. The manufacturing facilities possess the requisite regulatory approvals from drug regulatory agencies such as the United States Food and Drug Administration (USFDA); the Medicine and Healthcare products Regulatory Agency (MHRA - UK); the South Africa Health Products Regulatory Authority (SAHPRA); the Therapeutic Goods Administration (TGA), Australia; The National Health Surveillance Agency (ANVISA), Brazil; the World Health Organization (WHO), Geneva; the Therapeutic Products Directorate (TPD), Canada; the Pharmacy and Poisons Board (PPB), Kenya; the National Drug Authority (NDA), Uganda; the Ministry of Health (MOH), Sudan; the Colombia National Food and Drug Surveillance Institutes (INVIMA); and the Tanzania Food and Drug Authority (TFDA), among others. They are routinely audited to ensure compliance with current good manufacturing practices (cGMP). Alkem spends an average of ~4-5% of its revenue on R&D for the development of branded generics, non-branded generics, biosimilars, active pharmaceutical ingredients (APIs), and nutraceutical products. As articulated by the management, the R&D cost of the company is envisaged to remain in similar range in the medium term. Alkem's R&D team comprises over 500 scientists for developing new products at its four R&D centres across India and the US. Due to Alkem's continuous efforts on R&D, the company has been able to regularly develop and launch new products, which is crucial in the competitive pharmaceutical Industry. Alkem has filed three abbreviated new drug applications (ANDAs) with the USFDA and received 13 approvals in FY24. It received five ANDA approvals in H1FY25. With this, the company has cumulatively filed 178 ANDAs, including two new drug applications (NDA) with the USFDA. Of these, it has received approvals for 152 ANDAs and two NDAs as on September 30, 2024.

Dominant market position in domestic formulation market with a diversified product portfolio

Alkem is the fifth-largest player in domestic formulation market with market share of 4.02% as on March 31, 2024 (PY: 4.08%) (Source: Company). Over the years, Alkem has established its position as one of the leading companies in the domestic market for acute therapeutic segments with a strong market position in anti-infective, gastrointestinal, pain-management and, vitamins and nutrients therapy segments. Alkem has comprehensive product portfolio of over 800 brands with over 1,500 SKUs, spanning major therapy areas in acute and chronic segments. In FY24, Alkem earned ~80% domestic revenue from top five therapeutic segments which includes anti-infective (36%), gastro-intestinal (19%), vitamins/minerals/nutrients (11%), pain/analgesics (11%) and anti-diabetic (5%). Alkem earned ~38% domestic revenue from top 10 brands in FY24 (PY: 38%), demonstrating a diversified portfolio. In the domestic market, Alkem is the largest player in the anti-infective therapy segment consistently for the last 15 years. It is also a dominant player in gastro-intestinal, pain-management and vitamin/minerals/nutrients therapy segments. Alkem's six brands are among top 100 domestic formulation brands and 18 brands are among the top 300 domestic formulation brands indicating its dominant position in the domestic formulation market (Source: Company). Alkem has been expanding its presence in chronic therapy areas, such as neuro/central nervous system (CNS), cardiac, anti-diabetes, and dermatology.

Wide and established marketing network with geographically diversified revenue stream

Over the years, the company has developed large field force of over 12,000 medical representatives (MRs) and PAN India supply chain and distribution network of over 8,000 stockists, over 70 depots and carrying and forwarding agents (CFAs) which ensures assured demand off-take for existing and new products. The company has expanded its presence in the export market organically and through certain strategic acquisitions with primary focus on the US market. Currently, Alkem has a wide geographical presence with sales to regulated and semi-regulated markets such as India, US, Australia, Philippines, Chile, Kazakhstan, Europe, Middle East and East Africa, among others. It has presence in over 40 countries across the globe. In FY24, Alkem earned 68% revenue from domestic market (PY: 70%), 22% from the US market (PY: 22%) and remaining 10% from the rest of world markets (ROW) (PY: 8%). Alkem registered sales growth of 10% in the US market in FY24 year-over-year (y-o-y). However, US sales de-grew by 15% in H1FY25 y-o-y considering price erosion and supply chain related issues. Alkem is expected to launch few new products in H2FY25 in the US market including one with the 180 days exclusivity. With the company rationalising its existing product portfolio and investment in new product approvals, sales growth in US market may remain subdued in the near-to-medium term. This is expected to negate the impact of price erosion to certain extent. Alkem's ROW sales grew by 33% and 7% y-o-y in FY24 and H1FY25 respectively. CARE Ratings notes the company is consistently focusing on markets such as Australia, Chile, Philippines, Europe, Middles East, and East Africa among others to grow its scale of operation.

Diversifying into biosimilars and orthopaedic implant segments which entails higher growth opportunities

Alkem through its subsidiary, EBL, has ventured in development and distribution of biosimilar products. EBL focuses on development and production of biosimilars, novel biologics, synthetic peptides and phytopharmaceuticals. It also offers a range of biologics contract development and manufacturing operation ([CDMO] and contact manufacturing operation [CMO]) services with capabilities from clone development up to c-GMP manufacturing supported by bio-reactor capacities ranging from 20 litres to 2,000 litres. EBL generated robust growth in revenue from product sale and CDMO. EBL's revenue grew from ₹151 crore in FY23 to ₹262 crore in FY24. The company is among the first movers globally to have set up an end-to-end continuous manufacturing platform for biologics. Presently, EBL has set-up an R&D and manufacturing centre in US which shall replicate these capabilities, helping EBL to expand its footprint globally. Its US manufacturing facility is expected to commence commercial operations from Q1FY26 onwards. Till H1FY25, Alkem has commercialised seven biosimilar products in the domestic market and



five biosimilar products in the US markets. Alkem entered a partnership with Exactech Inc (USA), where Alkem has licenced design and technology of Exactech's USFDA approved orthopaedic implants for the purpose of manufacturing and marketing in the domestic market. Alkem plans to get orthopaedic implants contract manufactured in India and will sell the same under its own brand name in the domestic market. This partnership allows Alkem to leverage its existing marketing and distribution network for rapidly scaling the business line and also diversifies its existing revenue profile.

Growing scale of operations with healthy profitability margins and return indicators

Alkem's total operating income (TOI) grew by 9% in FY24 on y-o-y basis driven by healthy growth across geographies. Domestic formulation sales grew by \sim 6% while its US sales and ROW sales grew by \sim 10% and \sim 33%, respectively. Higher sales growth in some chronic therapies offset lower sales growth in acute segment from where Alkem derives over 80% of its sales. Alkem's TOI grew by \sim 1% in H1FY25 y-o-y as \sim 6% and \sim 7% growth in domestic formulation sales and ROW sales respectively was offset by \sim 15% de-growth in US sales considering price erosion of the products and supply chain related issue. The domestic sales growth is expected to remain stable while the company expects strong sales growth in ROW market. With few product launches planned for the US market in H2FY25, the US sales growth is also expected to remain healthy in H2FY25. Alkem's TOI is expected to grow \sim 5% to \sim 8% per annum in the near-to-medium term.

Alkem's PBILDT margin improved by \sim 375 bps in FY24 y-o-y considering normalisation of raw material, freight and other input cost, better product mix and cost control measures undertaken by the company during the year. The PBILDT margin improved by \sim 520 bps in in H1FY25 on y-o-y as the raw material prices continued to remain benign and better product mix. The company has rationalised its existing product portfolio to drive more profitable growth. Alkem's PBILDT margin is expected to remain \sim 19-20% in the near-to-medium term. The company's return indictors remained healthy marked by average operating return on capital employed (ROCE) of 20% in FY20-FY24 and likely to remain \sim 22% in FY25-FY27.

Comfortable leverage and debt coverage indicators

Alkem's capital structure continued to remain comfortable marked by overall gearing of 0.14x and total outside liabilities to tangible net worth (TOL/TNW) of 0.47x as on March 31, 2024. The company has strong net worth base of ₹10,250 crore as on March 31, 2024. The company's total debt largely includes the working capital borrowings. The company has unencumbered cash and liquid investments of over ₹4,000 crore as on March 31, 2024. Going forward, CARE Ratings expects the company's overall gearing to remain below 0.15x over FY25-FY27 in absence of large debt-funded capex plan over the same period. The company's debt coverage indicators also continued to remain comfortable marked by total debt to gross cash accruals (TD/GCA) of 0.75x and PBILDT interest coverage of above 17x in FY24 supported by healthy profitability and cash accruals. CARE Ratings expects the debt coverage indicators to remain strong in the medium term with the expectation of steady cash flow from operations and continued lower reliance on external debt.

Stable growth prospects of Indian pharmaceuticals Industry

The size of the Indian pharmaceutical market (IPM) was ~USD 54 billion in FY24. Growth in the domestic pharma market is expected to be driven by increase in the penetration of health insurance, improving access to healthcare facilities, rising prevalence of chronic diseases and rising per capita income. However, recent regulations of price controls under the DPCO and ban on fixed does combinations (FDCs), can affect the industry growth and profitability to an extent. The export growth is expected to be led by increasing generic penetration in the regulated markets on the back of enhanced focus on the niche and complex product segments, patent expiries, medicine patent pool announcing licensing agreement with pharmaceutical companies and growing demand from semi-regulated pharma markets.

CARE Ratings expects the industry to grow at 7% to 8% in FY25-FY27 supported by 6% to 7% growth in exports and 8% to 9% growth in the domestic market in the same period. With the stabilisation of raw material prices, freight rates, and easing of pricing pressure in US generics market and a focus on complex and specialty products, CARE Ratings expects the operating margin of industry players to remain stable over FY25-FY26 compared to FY24.

Liquidity: Strong

Alkem's liquidity remained strong marked by strong cash accruals, and low average utilisation of fund-based working capital limits of \sim 46% in the last 12 months ended June 2024. The cash flow from operations also remained healthy at \sim ₹1,527 crore in FY24. The company's GCA is expected to remain sufficient for its modest term-debt repayment obligation, capex requirement and incremental working capital requirement over medium term. The company plans to incur capex of \sim ₹1,200 crore over FY25 and FY26 which is being funded through the term debt of \sim ₹450 crore and balance through the internal accruals and available liquidity. The company has unencumbered cash and liquid investments of \sim ₹4,390 crore as on March 31, 2024, which also provides cushion to its liquidity.



Key weaknesses

High dependence on the acute therapeutic segment in the domestic market

Alkem earned ~80-85% revenue from the acute therapeutic segment, which is a relatively slow-growing and less margin-accretive segment. ~25-30% products fall under the DPCO, which restricts the pricing power and restricts profitability. In recent years, Alkem is consciously increasing its focus on the chronic and sub-chronic segment products, including neuro and CNS, cardiac, anti-diabetic, and dermatology. Alkem also entered ophthalmic therapeutic segment in FY24. Alkem has created a separate division with a dedicated field force to focus on increasing its market share in the chronic segment over the medium-to-long term. A well-balanced portfolio of acute and chronic will enable the further strengthening of its business risk profile. CARE Ratings expects the acute segment to continue to remain Alkem's significant revenue contributor over the medium term.

Inherent regulatory risk associated with pharmaceutical industry apart from competitive intensity

Alkem has its presence in multiple countries across the world. It has 19 manufacturing units including one in the USA. Considering the product usage and application, and consequent impacts, Alkem is required to comply with laws, rules and regulations and operate under strict regulatory environment. Thus, infringement in of the law, and significant adverse change in the import/export policy or environmental/regulatory policies in the company's operations, can have an impact. The company is continuously taking adequate steps to address regulatory risks. Manufacturing sites continue to successfully clear regulatory audits, conducted by leading global regulatory agencies. Alkem has Establishment Inspection Report (EIR) in place for all its USFDA approved manufacturing facilities. Alkem faces competition and pricing pressure in the global and domestic markets. Globally, the generic players are facing severe price erosions, significant government pressures to reduce prices and intense increasing competition, increasing regulation and increased sensitivity towards product performance. Alkem's strong focus on R&D enables it to develop differentiated products that are difficult for the competitors to replicate.

Environment, social	, and governance (ESG) risks
Risk	Mitigating Factors
Environment	 Alkem focuses on conserving natural resources and reducing emissions and waste. To curb greenhouse gas emissions, the company ensures to upgrade its equipment's to use less fuel and electricity. The company has taken steps to reduce the energy consumption by using power saving electrical fittings & LED fixtures. Alkem uses treated water to reduce its freshwater intake as much as possible. Furthermore, the company seeks to minimise the waste generated at source and recycle the rest. The company's operations and processing activities have the potential to emit particular matter, sulphur dioxide and nitrogen oxides among others. The company minimises this through facility design, closed operations and the use of emission control devices including scrubbers, dust collectors and filters. Emission parameters are recorded to ensure compliance with norms set by the government.
Social	 Alkem has Environment, Health and Safety (EHS) risk management practices in place. It has also availed ISO 14001 and ISO 45001 certifications which validate the health and safety practices. Employee trainings & regular EHS committees are being conducted to make the employee aware & trained. In partnership with Tata Memorable Centre, Alkem has set up three small cancer centres at Buxar, Jehanabad and Bhagalpur in Bihar, while the main centre – an advanced radiotherapy facility is upcoming at Muzaffarpur, Bihar.
Governance	 Alkem's board has mix of executive directors with one-woman executive directors and non-executive directors with two women independent directors having rich experience and expertise. The present strengths of board of directors (BoD) of Alkem is 11 which includes six executive directors and five independent directors. Being a listed entity with over five decades of operational track record, the company has required approvals in place and statue required committees are formed.

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

Incorporated in 1973, Alkem has ~50 years of experience in the pharmaceutical industry. The company was founded by the late Samprada Singh, and his brother, Basudeo Singh. Alkem is engaged in development, manufacturing, and marketing pharmaceuticals with operational footprints across 50+ countries. The company offers a wide range of products spanning across multiple therapeutic areas such as anti-infective, gastroenterology, pain relief and analgesic, anti-diabetic, cardiology, oncology, dermatology, osteoporosis, gynaecology, neurology, CNS, and vitamins, minerals and nutrients. Alkem has 19 manufacturing facilities (of which 18 are in India and one is in the US) and four R&D centres as on March 31, 2024. All the manufacturing facilities possess necessary regulatory approvals.

Brief Financials (Consolidated) (₹ crore)	March 31, 2023 (A)	March 31, 2024 (A)	H1FY25 (UA)
Total operating income	11,599	12,668	6,446
PBILDT	1,624	2,249	1,361
PAT	1,007	1,811	1,252
Overall gearing (times)	0.16	0.14	NA
Interest coverage (times)	15.13	20.00	23.79

A: Audited UA: Unaudited; 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
LT/ST Fund-based/non-fund-based-CC/WCDL/OD/LC/BG	-	-	-	-	300.00	CARE AA+; Stable/ CARE A1+

Annexure-2: Rating history for last three years

		Current Ratings			Rating History			
Sr. No.	Name of the Instrument/ Bank Facilities	Туре	Amount Outstandin g (₹ 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	LT/ST Fund- based/Non-fund- based- CC/WCDL/OD/LC/BG	LT/ ST	300.00	CARE AA+; Stable/ CARE A1+	1	1)CARE AA+; Stable / CARE A1+ (02-Jan-24)	1)CARE AA+; Stable / CARE A1+ (27-Dec-22)	1)CARE AA+; Stable / CARE A1+ (14-Dec-21)

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

Sı	r. 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 lender-wise details of bank facilities please click here

Annexure-6: List of entities consolidated as on September 30, 2024

Sr No	Name of the entity	Extent of consolidation	Rationale for consolidation
1	Ascend Laboratories (Pty) Ltd		Consonaution
2	Ascend Gmbh		
3	Alkem Laboratories Corporation		
4	S & B Holdings BV		
5	Pharmacor Pty Ltd		
6	Pharmacor Limited (wholly owned subsidiary of Pharmacor Pty Ltd.)		
7	The Pharma Network, LLC (wholly owned subsidiary of S & B Holdings BV)		
8	Ascends Laboratories SpA		
9	Ascends Laboratories SDN BHD		
10	Enzene Biosciences Ltd		
11	Enzene Inc.		
12	Alkem Laboratories Korea Inc		
13	Pharmacor Ltd		
14	The PharmaNetwork, LLP		Cultarialia multaria
15	Ascend Laboratories, LLC (wholly owned subsidiary of The Pharma	1	Subsidiary/ step- down subsidiary; material operational and financial linkages
15	Network, LLC)	Full	
16	Ascend Laboratories SAS	i un	
17	Ascend Laboratories (UK) Ltd		
18	Cachet Pharmaceuticals Pvt Ltd		
19	Indchemie Health Specialities Pvt Ltd		
20	Ascend Laboratories Ltd		
21	Pharma Network SpA (wholly owned subsidiary of Ascend Laboratories SAS)		
22	Ascend Laboratories S.A. DE C.V (wholly owned subsidiary of Ascend Laboratories SAS)		
23	Alkem Foundation		
24	Connect two Clinic Pvt Ltd.		
25	S&B Pharma LLC (wholly owned subsidiary of The Pharma Network, LLC;		1
25	on April 08, 2020)		
26	Alkem Medtech Private Limited, India		
27	Alixer Nextgen Therapeutics Limited		
28	Alkem Wellness Limited		

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.



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About us:

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