

Alkem Laboratories Limited

January 02, 2024

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

The ratings assigned to the bank facilities of Alkem Laboratories Limited (Alkem) continue to derive strength from its experienced promoters and management team along with long track record of the company in the pharmaceutical industry with its accredited manufacturing facilities. The ratings are further underpinned by its strong business profile backed by dominant position in the domestic formulation market with strong product portfolio across multiple therapeutic segments and an established marketing network, apart from gradual expansion in regulated markets along with its well-equipped research and development (R&D) facilities. The ratings also derive strength from strong financial risk profile of Alkem marked by growing scale of operations with healthy profitability and return indicators coupled with its low leverage, comfortable debt coverage indicators, and strong liquidity. The ratings also factor in the growing presence of Alkem in the biosimilar segment via its subsidiary, Enzene Bioscience Limited (EBL). CARE Ratings Limited (CARE Ratings) also take note of the recovery in operating profitability margin during H1FY24 (FY refers to period April 01 to March) after witnessing moderation in FY23. The operating profitability marked by profit before interest, lease rentals, depreciation and taxation (PBILDT) margin is expected to remain at around 16-17% in FY24; better than FY23.

The above rating strengths are, however, partially off-set by Alkem's higher dependence on acute therapeutic segment where the company is exposed to price control with around 25%-30% of its products under National List of Essential Medicines (NLEM). The ratings further continue to be constrained on account of its exposure to inherent regulatory risk associated with the pharmaceutical industry, competitive industry scenario, and foreign exchange fluctuation risk.

There was a survey conducted by the Income tax department in September 2023 at certain offices of Alkem and its subsidiaries. However, there are no adverse findings, and the company has not received any demand notice till date. CARE Ratings will continue to monitor any further developments in this regard.

Rating sensitivities: Factors likely to lead to rating actions

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

Negative factors

- PBILDT margins remaining below 15% on a sustained basis.
- Any 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 & operational inter-linkages with its subsidiaries. The list of the subsidiaries is given in **Annexure-6**

Outlook: Stable; CARE Ratings expects the operational and financial risk profile of Alkem to remain strong led by dominant position in the domestic pharmaceuticals market and its very minimal reliance on external debt.

Detailed description of the key rating drivers:

Key strengths

Long track record of operations of the company in the pharmaceutical industry along with 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, along with his brother, Basudeo Singh, who is currently the Executive Chairman of the company with an experience of over four decades in the industry. The day-to-day operations of the company 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 more than 19 years of experience in the pharmaceutical business. Over the years, the

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



promoters have been able to significantly grow the company's scale of operations, and Alkem ranks fifth in the domestic pharmaceutical market in terms of market share. Also, it has been gradually increasing its presence in the export markets.

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

Alkem has 20 manufacturing facilities (out of which 18 are in India and 2 are in the United States) as on March 31, 2023. Within India, the manufacturing facilities are located 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 around 5-6% 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. The company also spent 14-15% of its total R&D expense towards development of biosimilar products. Alkem's R&D team comprises more than 500 scientists for developing new products at its six R&D centres spread 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 12 and 1 abbreviated new drug applications (ANDAs) with the USFDA and received 14 and 11 approvals, respectively, during FY23 and H1FY24. With this, the company has cumulatively filed 176 ANDAs, including 2 new drug applications (NDA) with the USFDA. Of these, it has received approvals 142 ANDAs (including 15 tentative approvals) and 2 NDAs. Furthermore, the company is planning to file 10 ANDAs annually over the next 2-3 years, which shall support its growth in the US market.

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

Alkem is the fifth-largest player in domestic formulation market with market share of 4.08% as on March 31, 2023 (P.Y.: 3.90%) (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 therapies pain-management, and vitamins, minerals, and nutrients therapy segments. Alkem has comprehensive product portfolio of over 800 brands with more than 1,300 SKUs, spanning all the major therapy areas in both acute and chronic segments. During FY23, Alkem earned more than 80% of its domestic revenue from top five therapeutic segments which includes anti-infective (38%), gastro-intestinal (19%), vitamins/minerals/nutrients (10%), pain/analgesics (11%) and neuro/ central nervous system (4%). Alkem earned around 38% of its domestic revenue from top 10 brands during FY23 (P.Y.:37%), thereby demonstrating a fairly diversified portfolio.

In the domestic market, Alkem is the largest player in the anti-infective therapy segment consistently for the past 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 & distribution network of over 7,000 stockists, over 60 depots and carrying & forwarding agents (CFAs) which ensures assured demand off-take for existing and new products. The company has expanded its presence in the export market through both organically as well as through certain strategic acquisitions with primary focus on the US market. Currently, Alkem has a wide geographical presence with sales to regulated as well as semi-regulated markets like India, US, Australia, Philippines, Chile, Kazakhstan, Europe, Middle East and East Africa, etc.

It has presence in more than 40 countries across the globe. During FY23, Alkem earned 70% of its revenue from domestic market (PY: 71%), 22% from the US market (PY: 22%) and remaining 8% from the rest of world markets (ROW) (PY: 7%). In US market, Alkem registered a growth of 8% and 26% in FY23 and H1FY24, respectively. The growth in US market was driven by new product launches and easing off price erosion in US market. CARE Ratings notes that going forward, Alkem's revenue from the US market is expected to improve gradually supported by its healthy ANDAs pipeline. Furthermore, the US market continues to provide good opportunities for Indian generic players to grow their scale of operations, as a large number of products are going off-patent in the US in the medium term. CARE Ratings also takes note that the company is consistently focusing on other markets like Australia, Chile, Philippines, Europe, Middles East, East Africa and other export market to grow its scale of operation.



Diversifying into high growth and niche segment of biosimilars

Alkem via its subsidiary, EBL, has ventured into 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 improved from ₹90 crore in FY22 to ₹151 crore in FY23, while net loss reduced from ₹70 crore in FY22 to just ₹17 crore in FY23. The company is amongst the first movers globally to have set up an end-to-end continuous manufacturing platform for biologics. Presently, EBL has plans to set-up an R&D and manufacturing center in US which shall replicate these capabilities, helping EBL to expand its footprint globally. EBL has raised ₹161 crore equity from leading healthcare investors, Eight Roads Ventures, and F-Prime Capital. The funds will be used to enhance manufacturing capabilities and drive expansion plans in the US. Alkem has a total investment of ₹914 crore (including investment of ₹250 crore in FY23). Alkem expects the biosimilar segment to generate significant revenue in the future. However, currently, the business is generating gestation losses which is expected to turn around once the company establishes itself in the market with a decent product portfolio. Till H1FY24, EBL has launched seven products in the domestic market.

Growing scale of operations with healthy profitability and return indicators despite some moderation in FY23 which was in-line with envisaged

Alkem's total operating income (TOI) grew healthy by 9% on y-o-y basis on a COVID-19-driven higher base of FY22. The growth was backed by steady growth of 8% from domestic as well as US business. It was further aided by a 19% growth in ROW markets primarily in UK and Chile market. The growth in the domestic market was majorly driven by acute therapies like anti-infective, pain management and gastrointestinal. The US business grew on a reduced base of FY22 owing to rationalisation of price erosion to mid-single digit in the US market apart from new launches.

The TOI of the company grew healthy by 14% on y-o-y basis during H1FY24 due to strong sales growth of 26% in US market and 41% growth in ROW market. Furthermore, the growth was also supported by a decent 6% growth in the domestic market. The company is expected to grow its consolidated revenue at around 15% during FY24 over FY23.

Despite moderation in the PBILDT margin during FY23, it continued to remain healthy at 14%. The decline in PBILDT margin was primarily due to higher raw material prices, price erosion in the US markets, elevated freight cost and forex losses. CARE Ratings notes that the PBILDT margin of the company improved to 17.58% during H1FY24 with normalisation of raw material, freight and other input cost coupled with easing of pricing pressure in the US market. The PBILDT margin of the company is expected to remain in range of 16-17% during FY24-FY26. The return indictors of the company remained healthy marked by average operating return on capital employed (ROCE) of 22% during FY21-FY23 and likely to remain above 25% in FY24-FY25.

Comfortable leverage and debt coverage indicators

The capital structure of the company continued to remain comfortable marked by overall gearing of 0.16x and total outside liabilities (TOL)/tangible net worth (TNW) of 0.48x as on March 31, 2023. The company has strong net worth base of ₹8,955 crore as on March 31, 2023. The total debt of the company largely includes the working capital borrowings. Debt level of the company reduced from ₹2,668 crore as on March 31, 2022 to ₹1,397 crore as on March 31, 2023, owning to strong cash flow from operations. Moreover, the company has unencumbered cash & liquid investments of over ₹3,000 crore as on March 31, 2023. Going forward, CARE Ratings expects the overall gearing of the company to remain below 0.15x over FY24-FY26 in absence of any debt-funded capex plan over the same period.

Furthermore, the debt coverage indicators of the company also continued to remain comfortable marked by total debt to gross cash accruals (TD/GCA) of 1.04x and PBILDT interest coverage of above 15x in FY23 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 companies over a period of next 2-3 years

The size of the Indian pharmaceutical market (IPM) was approximately USD 50 billion in FY23. 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 FY24-FY25 supported by 6% to 7% growth in exports and 8% to 9% growth in the domestic market during the same period. With the stabilisation of raw material prices, freight rates, and easing of



pricing pressure in US generics market along with a focus on complex and specialty products, CARE Ratings expects the operating margin of industry players to improve by 100-150 bps over FY24-FY25 compared with FY23.

Liquidity: Strong

Alkem's liquidity remained strong marked by strong cash accruals, healthy current ratio of 1.87x as on March 31, 2023 and average utilisation of fund-based working capital limits of around 53% during last 12 months ended October 2023. The cash flow from operations also remained healthy at around ₹1,637 crore during FY23. Furthermore, the company's GCA are expected to remain sufficient for its capex requirement (majorly maintenance capex) and incremental working capital requirement over medium term. Furthermore, the company has unencumbered cash and liquid investments of ₹3,454 crore as on March 31, 2023, which also provides cushion to its liquidity.

Key weaknesses

High dependence on the acute therapeutic segment in the domestic market

Alkem earned around 80-85% of its revenue from the acute therapeutic segment, which is a relatively slow-growing and less margin-accretive segment. Furthermore, nearly 25-30% of its products fall under the DPCO, which restricts the pricing power and, in turn, 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 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 the pharmaceutical industry apart from competitive intensity

Alkem has its presence in multiple countries across the world and it has 20 manufacturing units. Considering the nature of the product usage and application, and consequent impacts, Alkem is 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 manufacturing sites continue to successfully clear regulatory audits, conducted by various leading global regulatory agencies. USFDA had conducted pre-approval inspection of its formulation facilities at Indore (set-up in 2020 for catering US and other international market) and issued one observation in July 2022, later EIR was received in February 2023. Further, Alkem's St. Louis facility (in USA) was inspected by USFDA, and three observations were received from USFDA in November 2022 which received EIR in December 2022. Recently, Ankleshwar (API plant) received EIR in July 2023.

Alkem faces competition and pricing pressure in the global as well as domestic markets. Globally, the generic players are facing severe price erosions, significant government pressures to reduce prices along with 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.

Foreign exchange fluctuation risk

The company derived about 30% of its overall revenues from exports, thus it is exposed to foreign currency fluctuation risk. In FY23, Alkem reported forex earnings of ₹1,692 crore (P.Y.: ₹1,992 crore) and a forex outgo of ₹419 crore (P.Y.: ₹391 crore). The currencies in which these transactions are primarily denominated are US Dollars, Euro, Australian dollars, Chilean Peso, and Kazakhstani Tenge. On a standalone basis, the company has reported net forex (transaction & translation) gains amounting to ₹41.24 crore in FY23 (P.Y.: ₹33.72 crore), whereas on a consolidated basis, it reported net forex loss of ₹18.87 crore in FY23 (as compared with forex loss of ₹1.65 crore in FY22). Alkem normally avails foreign currency working capital borrowings against the export receivables to hedge against any adverse movements in foreign currency rates.

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 various 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



Risk	Mitigating Factors
	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 12 which includes 6 executive directors and 6 independent directors. Being a listed entity with over five decades of operational track record, the company has all the required approvals in place along with all the statue required committees are formed.

Applicable criteria

Policy on default recognition

Consolidation

<u>Financial Ratios – Non financial Sector</u>

Liquidity Analysis of Non-financial sector entities

Rating Outlook and Credit Watch

Short Term Instruments

Manufacturing Companies

Pharmaceutical

About the company and industry

Industry classification

Macro-economic Indicator	Sector	Industry	Basic Industry
Healthcare	Healthcare	Pharmaceuticals & biotechnology	Pharmaceuticals

Incorporated in 1973, Alkem has around 50 years of experience in the pharmaceutical industry. The company was founded by the late Samprada Singh, along with his brother, Basudeo Singh. Alkem is engaged in the development, manufacturing, and marketing of 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 20 manufacturing facilities (of which 18 are in India and two are in the US) and five R&D centres as on March 31, 2023. All the manufacturing facilities possess necessary regulatory approvals.

Brief Consolidated Financials (₹ crore)	FY22 (A)	FY23 (A)	H1FY24 (UA)
Total operating income	10,634	11,599	6,537
PBILDT	1,921	1,624	1,149
PAT	1,349	1,007	902
Overall gearing (times) (gross debt basis)	0.32	0.16	NA
Interest coverage (times)	36.68	15.13	19.15

A: Audited UA: Unaudited; NA: Not available; 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	Coupon Rate (%)	Maturity Date	Size of the Issue (₹ crore)	Rating Assigned along with 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 the last three years

		Current Ratings			Rating History			
Sr. No.	Name of the Instrument/Bank Facilities	Туре	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*	300.00	CARE AA+; Stable / CARE A1+	-	1)CARE AA+; Stable / CARE A1+ (27-Dec- 22)	1)CARE AA+; Stable / CARE A1+ (14-Dec- 21)	1)CARE AA+; Stable / CARE A1+ (05-Jan- 21)

^{*}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

Annexure-6: List of subsidiaries

Names of Entities Consolidated	% Shareholding as on March 31, 2023
Ascend Laboratories (Pty) Ltd [formerly known as Alkem Laboratories (Pty) Ltd]	100.00
Ascend Gmbh (formerly, Alkem Pharma Gmbh)	100.00
Alkem Laboratories Corporation	100.00
S & B Holdings BV	100.00
Pharmacor Pty Ltd	100.00
Pharmacor Limited (wholly owned subsidiary of Pharmacor Pty Ltd.)	100.00
The Pharma Network, LLC (wholly owned subsidiary of S & B Holdings BV)	100.00
Ascends Laboratories SDN BHD	100.00
Enzene Biosciences Ltd	99.80
Enzene Inc.	100.00
Alkem Laboratories Korea Inc	100.00
Pharmacor Ltd	100.00
The PharmaNetwork, LLP	100.00
Ascend Laboratories, LLC (wholly owned subsidiary of The PharmaNetwork, LLC)	100.00
Ascend Laboratories SAS	100.00
Ascend Laboratories (UK) Ltd	100.00
Cachet Pharmaceuticals Pvt Ltd	60.60
Indchemie Health Specialities Pvt Ltd	51.00
Ascend Laboratories Ltd	100.00
Pharma Network SpA (wholly owned subsidiary of Ascend Laboratories SAS)	100.00
Ascend Laboratories S.A. DE C.V (wholly owned subsidiary of Ascend Laboratories SAS)	100.00



Names of Entities Consolidated	% Shareholding as on March 31, 2023
Alkem Foundation	100.00
Connect 2 Clinic Pvt Ltd.	100.00
Ascend Laboratories S.A DE. CV (wholly owned subsidiary of Ascend PharmaNetwork, LLC; w.e.f. Sep 02, 2021)	100.00
S&B Pharma LLC (wholly owned subsidiary of The PharmaNetwork, LLC; w.e.f. Apr 08, 2020)	100.00

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:

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Disclaimer:

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