# Alkem Laboratories Limited

December 27, 2022

## Rating

| Facilities/Instruments | Amount (₹ crore) | Rating[1] | Rating Action |
|---|---|---|---|
| Long-term/short-term bank facilities | 300.00 | CARE AA+; Stable/CARE A1+ (Double A Plus; Outlook: Stable/ A One Plus) | Reaffirmed |
| **Total bank facilities** | **300.00 (₹ Three hundred crore only)** | | |

Details of instruments/facilities in Annexure-1.

## Detailed rationale and key rating drivers

The ratings assigned to the bank facilities of Alkem Laboratories Limited (Alkem) continues to derive strength from its experienced promoters and management team along with a long track record of the company in the pharmaceutical industry with its accredited manufacturing facilities. The rating is further underpinned by its strong business profile, backed by a dominant position in the domestic formulation market with a strong product portfolio across multiple therapeutic segments and an established marketing network, apart from the gradual expansion in regulated markets and its well-equipped research and development (R&D) facilities. The rating also derives strength from the healthy financial risk profile of Alkem, marked by its growing scale of operations, healthy profitability, low leverage, comfortable debt coverage indicators, and strong liquidity.

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

CARE Ratings Limited (CARE Ratings) takes cognisance of the moderation in the operating profitability margin of Alkem during H1FY23 (FY; refers to the period from April 1 to March 31) due to higher raw material cost, sharp price erosion in its product portfolio in the US market, elevated freight cost, and some one-off expenses incurred during the period. However, the profitability margin is expected to recover in H2FY23, with a price hike taken across the product portfolio and the normalisation of freight cost.

## Rating sensitivities

**Positive factors – Factors that could lead to positive rating action/upgrade:**

- Geographical and product portfolio diversification with a greater share of the chronic therapeutic segment in its revenue profile along with significant growth in its revenue and improvement in its profit before interest, lease rentals, depreciation and taxation (PBILDT) margin above 30% on a sustained basis.
- Efficient working capital management with a net operating cycle remaining around 60 days on a consistent basis

**Negative factors – Factors that could lead to negative rating action/downgrade:**

- PBILDT margin remaining below 15% on a sustained basis.
- Any large-size debt-funded organic or inorganic expansion, leading to an overall gearing ratio higher than 0.5x (on a gross debt basis) and net debt to PBILDT higher than unity on a sustained basis.

## Detailed description of the key rating drivers

**<u>Key rating strengths</u>**

**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 nearly 50 years 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 18 years of experience in the pharmaceutical business.

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

**Accredited manufacturing facilities supported with well-equipped R&D facilities**: Alkem had 19 manufacturing facilities (of which 17 are in India and two are in the US) as on March 31, 2022. Within India, its manufacturing facilities are mainly located in 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).
Moreover, 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 range of 5-6% in medium term. 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 11 and 6 abbreviated new drug applications (ANDAs) with the USFDA and received 13 and 8 approvals respectively during FY22 and H1FY23. With this, the company has cumulatively filed 169 ANDAs, including 2 new drug applications (NDA) with the USFDA. Of these, it has received approvals 128 ANDAs (including 15 tentative approvals) and 2 NDAs. Alkem has a healthy pipeline of over 160 ANDAs filed with the USFDA.

**Dominant market position in the domestic formulation market with a diversified product portfolio:** Alkem is the fifth largest player in the domestic formulation market with a market share of 3.9% as on March 31, 2022 (Source: company). Alkem has established its position as one of the leading companies in India for acute therapy, with a strong market position in anti-infective, gastrointestinal, pain-management, and vitamins, minerals and nutrients therapy segments. Alkem is the largest player in the anti-infective therapy segment and among the top four in gastrointestinal, pain-management, and vitamins, minerals and nutrients therapy segments in the domestic market. During FY22, Alkem earned 82% of its domestic revenue from the top five therapeutic segments, which include anti-infective (39%), gastrointestinal (18%), vitamins, minerals and nutrients (11%), pain and analgesics (10%), and neuro and central nervous system (4%). Furthermore, Alkem earned around 37% of its domestic revenue from the top ten brands during FY22 (PY: 38%), thereby demonstrating a fairly diversified product portfolio. Each of its top 10 brands (from acute therapy) held the top two positions in their respective molecular categories, indicating its strong brand recall. Furthermore, Alkem's six brands are among the top 100 domestic formulation brands as on March 31, 2022 (Source: Company), indicating its dominant position in the domestic formulation market.

**Wide and established marketing network with geographically diversified revenue stream:** Over the years, the company has developed a pan-India supply chain and distribution network of over 7,000 stockiest, which ensures assured demand offtake for existing and new products. Alkem has also gradually expanded its presence in the overseas market through both, organic as well as through certain strategic acquisitions with a primary focus on the US market. Alkem has a presence in regulated markets like the US, Europe and Australia, apart from a presence in semi-regulated markets like the Philippines, Chile, Kazakhstan, West Asia, East Africa, etc.
During FY22, Alkem earned 71% of its revenue from the domestic market (PY: 66%), 22% from the US market (PY: 28%) and the remaining 7% from the rest of the world (RWO) markets (PY: 7%). Alkem had witnessed healthy revenue growth in the US market over the last five years ended FY21, however, its revenue from the US market de-grew by 6% and 4% on a y-o-y basis, respectively, during FY22 and H1FY23, owning to a sharp price erosion in its product portfolio. Going forward, Alkem's revenue from the US market is expected to improve gradually, supported by an easing in price erosion coupled with new product launches in the US market. 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.

**Growing scale of operations with healthy profitability and return indicators**: Alkem's total operating income (TOI) grew healthy by 20% on a y-o-y basis during FY22, backed by healthy sales growth of 29% from the domestic market, which was partly offset by the lower sales growth of 2% from the export market. The healthy growth in the domestic market was mainly driven by strong volume growth, partially supported by the COVID-19 tailwind in acute therapies like anti-infective, vitamins, minerals and nutrients (VMN), pain management, and gastrointestinal. The lower sales growth in the export market was due to the subdued performance in the US market, which was partially offset by the healthy growth in the ROW markets. The US business of the company de-grew by 6% on a y-o-y basis owing to a double-digit price erosion in the US market, which negated the impact of new launches. Furthermore, the company witnessed healthy sales growth of 35% on a y-o-y basis, albeit

on the lower base in the ROW market, supported by healthy business performance in the Australia and Chile markets. The TOI of the company grew merely by 2% on a y-o-y basis and stood at ₹5,785 crore during H1FY23 due to lower sales growth of 3% in the domestic market (albeit on higher base of the past years) and muted revenue growth in the export market.
Alkem's PBILDT margin declined by nearly 300 bps, albeit stood healthy at 19.33% during FY22. The decline in the PBIDLT margin was attributed to the normalisation of travelling and marketing costs post-COVID-19 along with higher freight costs. The PBILDT margin of the company further declined to 13.19% during H1FY23, primarily due to higher raw material prices, price erosion in the US market, continued elevated freight cost, and some one-off expenses incurred during the period. The normalisation of raw materials, freight and other input costs, coupled with the easing of pricing pressure in the US market is expected to improve the operating profitability going ahead.
Recently, India's drug pricing authority has allowed a price hike of around 10.7% on Drug Price Control Order (DPCO) products owing to the increasing cost of raw materials, which is expected to help the company to maintain its gross margin to some extent. Alkem's PBILDT margin is expected to remain in the range of 15-16% during FY23. As articulated by the management, the company is also planning to take cost optimisation steps to reduce its overhead cost by ₹200-250 crore in the next 12 months, which is expected to further improve its PBILDT margin. The return indicators of the company, marked by an operating return on capital employed (ROCE) continued to remain healthy at 23.79% in FY22 (PY: 26.43%) and is expected to remain around 20% in the medium term.

**Comfortable leverage and debt coverage indicators**: The capital structure of the company continued to remain comfortable, marked by an overall gearing of 0.32x (on a gross debt basis) (PY: 0.25x) and total outside liabilities (TOL)/ tangible net worth (TNW) of 0.62x as on March 31, 2022 (PY: 0.55x). The company had a strong net worth base of ₹8,443 crore as on March 31, 2022, as against an outstanding debt of ₹2,688 crore, which largely includes working capital borrowings of ₹2,571 crore as on even date. Moreover, the company had unencumbered cash and liquid investments of ₹1,854 crore (excluding line-marked fixed deposits [FDs] and real estate funds). Going forward, the overall gearing of the company is expected to remain below 0.25x over FY23-FY25 in the absence of any debt-funded capex plans and continued accretion of profits to net worth. Furthermore, the debt coverage indicators of the company also remained comfortable, marked by total debt (TD)/PBILDT of 1.30x, TD/gross cash accruals (GCA) of 1.49x (gross debt basis) and PBILDT interest coverage of 39.25x in FY22. The debt coverage indicators are expected to remain strong in the medium term with the expectation of steady cash flow from operations and continued lower reliance on external debt.

**Stable demand prospects for the Indian pharmaceutical industry (IPI):** The outlook for IPI is envisaged to remain stable in the medium to long term, backed by growth opportunities in terms of capitalising on major blockbuster drugs coming off-patent, paving the way for entry of generics, especially in the US market, and geographical diversification into emerging markets. In the domestic market, the growth in the formulations segment is expected to be led by a rise in chronic diseases, increasing per capita income, government initiatives like new national health protection schemes, the Ayushman Bharat programme, and improvement in the access to healthcare facilities along with growing penetration of health insurance.

**Liquidity:** Strong

Alkem's liquidity remained strong, marked by strong cash accruals and cash flow from operations, a healthy current ratio of 1.46x as on March 31, 2022, and around 50% average utilisation of the fund-based working capital limits during the trailing 12 months ended June 30, 2022. The cash flow from operations stood at around ₹1,059 crore during FY22. Furthermore, the company's GCA is expected to remain sufficient for its capex requirements (mainly maintenance capex) and incremental working capital requirements over the medium term. Furthermore, the liquidity of the company is also supported by unencumbered cash and liquid investments of ₹1,854 crore (excluding line-marked FDs and real estate funds) as on March 31, 2022.

**Key rating weaknesses**

**High dependence on the competitive acute therapeutic segment:** 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 central nervous system (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. However, the acute segment is expected to continue to remain its 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 19 production units. Considering the nature of the product usage and application, and its consequent impact, Alkem is required to comply with various laws, rules and regulations. It operates under strict regulatory environments. Thus, the infringement of any law or any significant adverse changes in the import or export policy or environmental or regulatory policies in the area of operations of the company can have an impact on its operations. 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. However, the USFDA had conducted a pre-approval inspection of its formulation facilities at Indore and issued an observation in July 2022. Furthermore, Alkem's St Louis facility (the US) was inspected by the USFDA and three observations were received in November 2022. Alkem's management has articulated that they have already replied to the USFDA with the corrective and preventive action plan to resolve these observations for its Indore facilities, whereas for the St Louis facility, the company is preparing a response for the observations issued by the USFDA. Early resolution of the aforementioned issues may lead to faster-than-anticipated growth in its US sales given the planned product filing and launches.
Alkem also faces competition and pricing pressure in global as well as domestic markets. Globally, the generic players are facing severe price erosion, significant government pressures to reduce prices, along with intense competition, increasing regulation, and heightened sensitivity towards product performance.

**Foreign exchange fluctuation risk**: The company derives about 29-30% of its overall revenues from exports; thus, it is exposed to foreign currency fluctuation risk. In FY22, Alkem reported forex earnings of ₹1,992 crore (PY: ₹1,955 crore) and a forex outgo of ₹391 crore (PY: ₹247 crore). The currencies in which these transactions are primarily denominated are US Dollar, Euro, Australian Dollar, Chilean Peso, and Kazakhstani Tenge. On a standalone basis, the company has reported net forex (transaction and translation) gains amounting to ₹33.72 crore in FY22 (PY: ₹30.52 crore), whereas on a consolidated basis, it reported a net forex loss of ₹1.65 crore in FY22 (as compared to a forex gain of ₹45.83 crore in FY21). 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) assessment

| Parameter | Compliance and action by the company |
|---|---|
| **Environment** | • Alkem focuses on conserving natural resources and reducing emissions and waste. To curb greenhouse gas emissions, the company ensures to upgrade its equipment to use less fuel and electricity. Alkem uses treated water to reduce its freshwater intake as much as possible. Furthermore, the company ensures to minimise the waste generation at source. |
| **Social** | • Alkem gives utmost importance to the safety of its employees and arranges regulator training to increase awareness towards the same.<br>• 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 a mix of executive directors and non-executive directors having rich experience and expertise. The present strength of the board of directors (BoD) of Alkem is 12, which includes six executive directors (including one-woman executive director) and six independent directors (including two women independent directors). |

## Analytical approach: Consolidated

CARE Ratings has considered Alkem's credit assessment on a consolidated basis since it has considerable overseas operations and operational inter-linkages with its subsidiaries (the list of subsidiaries is given in **Annexure-3**).

## Applicable criteria

CARE's Policy on Default Recognition
Policy on Withdrawal of Ratings
Rating Methodology – Consolidation
Financial Ratios – Non-financial Sector
Liquidity Analysis of Non-financial sector entities
Criteria on assigning 'Outlook' and 'Credit Watch' to Credit Ratings
Criteria for Short Term Instruments
Rating Methodology – Manufacturing Companies
Rating Methodology – Pharmaceutical Sector

## About the company

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, gynecology, neurology, central nervous system, and vitamins, minerals and nutrients. Alkem has 19 manufacturing facilities (of which 17 are in India and two are in the US) and six R&D centres as on March 31, 2022. All the manufacturing facilities possess necessary regulatory approvals.

| Brief Consolidated Financials (₹ crore) | FY21 (A) | FY22 (A) | H1FY23 (UA) |
|---|---|---|---|
| TOI | 8,909 | 10,634 | 5,758 |
| PBILDT | 1,989 | 2,055 | 759 |
| PAT | 1,618 | 1,680 | 479 |
| Overall gearing (times) | 0.25 | 0.32 | NA |
| PBILDT Interest coverage (times) | 33.76 | 39.25 | 14.79 |

A: Audited; UA: Un-audited; NA: Not applicable; Financials are reclassified as per CARE Ratings' standards.

**Status of non-cooperation with previous CRA:** Not applicable

**Any other information:** Not applicable

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

**Covenants of the rated instruments/facilities:** Not applicable

**Complexity level of the various instruments rated for this company**: Annexure-4

### 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

| Sr. No. | Name of the Instrument/ Bank Facilities | Current Ratings | | | Rating History | | | |
|---|---|---|---|---|---|---|---|---|
| | | Type | Amount Outstanding (₹ crore) | Rating | 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 | Date(s) and Rating(s) assigned in 2019-2020 |
| 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+ (14-Dec-21) | 1)CARE AA+; Stable / CARE A1+ (05-Jan-21) | - |

*Long term/short term.

### Annexure-3: List of subsidiaries of Alkem

| Names of Entities Consolidated | % Shareholding as on March 31, 2022 | Extent of Consolidation |
|---|---|---|
| Ascend Laboratories (Pty) Ltd [formerly known as Alkem Laboratories (Pty) Ltd] | 100.00 | Fully consolidated |
| Ascend Gmbh (formerly, Alkem Pharma Gmbh) | 100.00 | Fully consolidated |
| Alkem Laboratories Corporation | 100.00 | Fully consolidated |
| S & B Holdings BV | 100.00 | Fully consolidated |
| Pharmacor Pty Ltd | 100.00 | Fully consolidated |
| ThePharmaNetwork, LLC (wholly owned subsidiary of S & B Holdings BV) | 100.00 | Fully consolidated |
| Ascends Laboratories SDN BHD | 100.00 | Fully consolidated |
| Ascend Laboratories SpA | 100.00 | Fully consolidated |
| Enzene Biosciences Ltd | 99.72 | Fully consolidated |
| Alkem Laboratories Korea Inc | 100.00 | Fully consolidated |
| Pharmacor Ltd | 100.00 | Fully consolidated |
| The PharmaNetwork, LLP | 100.00 | Fully consolidated |
| Ascend Laboratories, LLC (wholly owned subsidiary of The PharmaNetwork, LLC) | 100.00 | Fully consolidated |
| Ascend Laboratories SAS | 100.00 | Fully consolidated |
| Ascend Laboratories (UK) Ltd | 100.00 | Fully consolidated |
| Cachet Pharmaceuticals Pvt Ltd | 66.63 | Fully consolidated |
| Indchemie Health Specialities Pvt Ltd | 51.00 | Fully consolidated |
| Ascend Laboratories Ltd | 100.00 | Fully consolidated |
| Pharma Network SpA (wholly-owned subsidiary of Ascend Laboratories SAS) | 100.00 | Fully consolidated |
| Alkem Foundation | 100.00 | Fully consolidated |
| Connect 2 Clinic Pvt Ltd. | 100.00 | Fully consolidated |
| S&B Pharma LLC (wholly owned subsidiary of The PharmaNetwork, LLC) | 100.00 | Fully consolidated |
| Ascend Laboratories S.A DE. CV (wholly owned subsidiary of Ascend PharmaNetowrk, LLC; w.e.f. Sep 02, 2021) | 100.00 | Fully consolidated |

### Annexure-4: Complexity level of the various instruments rated for this company

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

### Annexure-5: Bank lender details for this company

To view the lender-wise details of the 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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