ALKEM LABORATORIES LTD.



Regd. Office: ALKEM HOUSE, Senapati Bapat Marg, Lower Parel (West), Mumbai - 400 013, Maharashtra, India.

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Press Release

Alkem reports Q4FY23 and FY23 results

Mumbai, May 19, 2023: Alkem Laboratories Ltd. (Alkem) today announced its standalone and consolidated financial results for the fourth quarter and twelve months ended March 31, 2023. These results were taken on record by the Board of Directors at its meeting held in Mumbai today.

Key highlights of Q4FY23 financial performance

- Total Revenue from Operations was ₹ 29,026 million, year-on-year growth of 16.9%
 - o India sales were ₹ 20,113 million, year-on-year growth of 17.0%
 - o International sales were ₹ 8,570 million, year-on-year growth of 15.6%
- Earnings before Interest, Tax, Depreciation and Amortization (EBITDA) was ₹ 3,533 million, resulting in EBITDA margin of 12.2% vs. 13.6% in Q4FY22. EBITDA grew by 4.8% YoY
- R&D expenses for the quarter was ₹ 1,472 million, or 5.1% of total revenue from operations compared to ₹ 1,635 million in Q4FY22 at 6.6% of total revenue from operations
- Profit before tax (PBT) was ₹ 2,117 million, a decline of 12.8% compared to Q4FY22
 - Exceptional Item of ₹ 1,030 million debit was on account of impairment of fixed assets
- Net Profit (after Minority Interest) was ₹ 710 million, year-on-year decline of 34.0%

Key highlights of FY23 financial performance

- Total Revenue from Operations was ₹ 115,993 million, year-on-year growth of 9.1%
 - o India sales were ₹ 80,011 million, year-on-year growth of 8.1%
 - o International sales were ₹ 34,393 million, year-on-year growth of 10.7%
- Earnings before Interest, Tax, Depreciation and Amortization (EBITDA) was ₹ 16,095 million, resulting in EBITDA margin of 13.9% vs. 19.3% in FY22. EBITDA declined by 21.6% YoY
- R&D expenses for FY23 was ₹ 5,394 million, or 4.7% of total revenue from operations compared to ₹ 5,674 million in FY22 at 5.3% of total revenue from operations
- Profit before tax (PBT) was ₹ 13,048 million, a decline of 29.3% compared to FY22
 - Exceptional Item of ₹ 1,030 million debit was on account of impairment of fixed assets.
- Net Profit (after Minority Interest) was ₹ 9,842 million, year-on-year decline of 40.2%

Commenting on the results, Sandeep Singh, Managing Director, Alkem said, "In FY23, India business outperformed the market with exceptional performance surpassing industry benchmarks and achieved good growth on a large base while our US performance was impacted due to significant pricing pressure. Our biotech franchise, Enzene raised funds from Eight Roads Ventures and F-Prime Capital during the year. Enzene also received approval for launch of 3 more mAbs in Indian market and made significant strides in conducting global trials for launch of select biosimilars in regulated markets. While we are very confident about growth, our primary focus going forward is to drive profitability and

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operational efficiency through cost optimization, process improvements, and streamlining operations thereby maximizing value for our stakeholders."

Operational Highlights

Domestic Business

In Q4FY23, the Company's India sales grew by 17.0% YoY, recording sales of ₹ 20,113 million as compared to ₹ 17,187 million in Q4FY22. For FY23, the Company's India sales was ₹ 80,011 million compared to ₹ 74,045 million in FY22 – growth of 8.1% YoY.

As per secondary sales data by IQVIA, for the quarter ended March 31, 2023, the Company grew ahead of Indian Pharmaceutical Market (IPM) with growth of 22.5% YoY compared to IPM growth of 14.9% YoY. Even for the full year FY23, the Company outperformed the IPM with growth of 12.8% YoY compared to IPM growth of 7.9% YoY. The contribution of new introductions to our growth was 3.1% significantly surpassing IPM at 2.3%, underscoring our exceptional ability to introduce and successfully commercialize new products. Acute therapies like Anti-infectives, gastro intestinal, and pain management outperformed the market both in Q4 and FY23 thereby increasing the market share and maintaining its leadership position. The Company also significantly outperformed the IPM in the chronic therapy areas of neuro / CNS, anti-diabetes and derma. Company gained 2 ranks each in both anti-diabetic segment and Neuro / CNS segment in FY23. Company's trade generic business delivered steady incremental growth in FY23 despite large base of last year.

The performance highlights of the key therapeutic segments in Q4FY23 and FY23 are as shown in the table below:

	Q4FY23				FY23			
Key Therapy segment	Alkem Rank	YoY change in Rank*	YoY growth (Alkem)	YoY growth (IPM)	Alkem Rank	YoY change in Rank*	YoY growth (Alkem)	YoY growth (IPM)
Anti-infectives	1	Unchanged	29.7%	28.2%	1	Unchanged	8.6%	6.2%
Gastro Intestinal	3	Unchanged	14.6%	14.5%	3	Unchanged	17.5%	12.3%
Pain / Analgesics	3	Unchanged	23.4%	15.3%	3	Unchanged	18.4%	12.4%
VMN**	2	Unchanged	2.2%	8.7%	2	Unchanged	2.5%	3.5%
Neuro / CNS	7	+2	35.7%	12.8%	7	+2	19.8%	11.5%
Derma	19	+1	34.2%	9.3%	19	Unchanged	16.0%	6.2%
Cardiac	28	-1	8.4%	13.1%	28	-1	1.3%	8.7%
Anti-Diabetic	15	+4	37.2%	9.3%	16	+2	29.4%	6.8%
Respiratory	18	-1	27.0%	25.2%	17	Unchanged	14.8%	7.0%
Total	5	Unchanged	22.5%	14.9%	5	Unchanged	12.8%	7.9%

^{*}Positive change in rank reflects improvement over same period previous year

Source: IQVIA Data

^{**}VMN – Vitamins / Minerals / Nutrients

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International Business

In Q4FY23, the Company's International sales grew by 15.6% YoY, recording sales of ₹ 8,570 million as compared to ₹ 7,411 million in Q4FY22. For FY23, the Company's International sales grew by 10.7% to ₹ 34,393 million compared to ₹ 31,075 million in FY22.

- US sales for the quarter was ₹ 5,916 million compared to ₹ 5,419 million in Q4FY22, recording a year-on-year growth of 9.2 %. For FY23, US sales was ₹ 25,134 million, compared to ₹ 23,291 million in FY22 a year-on-year growth of 7.9% YoY.
- Other International Markets sales for the quarter was ₹ 2,654 million compared to ₹ 1,991 million in Q4FY22, recording a year-on-year growth of 33.3%. For FY23, Other International Markets sales was ₹ 9,259 million compared to ₹ 7,785 million in FY22 a year-on-year growth of 18.9% YoY.

R&D Investments

During the quarter, the Company filed 4 abbreviated new drug applications (ANDAs) with the US FDA and received 3 tentative approvals. For FY23, the Company filed 12 ANDAs with the US FDA and received 14 approvals (including 7 tentative approvals).

As on March 31, 2023, the Company has filed a total of 173 ANDAs and 2 new drug applications (NDA) with the US FDA. Of these, it has received approvals for 132 ANDAs (including 17 tentative approvals) and 2 NDAs.

Update on US FDA Inspections

Facility	Capability	Last inspection	Status post last inspection		
Ankleshwar (India)	API	April 2023	Successfully closed without any observations.		
St. Louis (US)	Formulations	November 2022	EIR# received in December 2022, thereby successfully closing the inspection.		
Taloja (India)	Bioequivalence Centre	October 2022	Successfully closed without any observations.		
Indore (India)	Formulations	July 2022	EIR# received in February 2023, thereby successfully closing the inspection.		
Baddi (India)	Formulations	February 2020	EIR# received in March 2020, thereby successfully closing the inspection.		
Daman (India)	Formulations	August 2019	EIR# received in October 2019, thereby successfully closing the inspection.		
California (US)	API	August 2018	Successfully closed without any observations. EIR received in October 2018.		

EIR – Establishment Inspection Report

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Q4FY23 and FY23 Conference Call at 4:00pm IST, May 19, 2023

Alkem will organize a conference call for investors and analysts on Friday, May 19, 2023 from 4:00 pm to 5:00 pm IST to discuss its Q4FY23 and FY23 financial results.

Alkem will be represented on the call by Mr. Sandeep Singh, Managing Director and the senior management team.

Motilal Oswal Securities Ltd. will host the call.

Details of the conference call are as under:

Time: 4:00 pm IST (GMT + 5:30) on Friday, May 19, 2023

Dial in Details:

India : +91 22 6280 1149 / +91 22 7115 8050

International Toll Free

USA : 1 866 746 2133 UK : 0 808 101 1573 Singapore : 800 101 2045 Hong Kong : 800 964 448

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You are requested to dial in 10 mins ahead of the scheduled start time. A transcript of this conference call will also be available on our website www.alkemlabs.com

About Alkem Laboratories Ltd.

Established in 1973 and headquartered in Mumbai, Alkem (NSE: ALKEM, BSE: 539523, Bloomberg: ALKEM.IN, Reuters: ALKE.NS) is a leading Indian pharmaceutical company with global operations, engaged in the development, manufacture and sale of pharmaceutical and nutraceutical products. The Company produces branded generics, generic drugs, active pharmaceutical ingredients (APIs) and nutraceuticals, which it markets in India and International markets. With a portfolio of more than 800 brands in India, Alkem is ranked the fifth largest pharmaceutical company in India in terms of domestic sales (Source: IQVIA March 2022). The Company also has presence in more than 40 international markets, with the United States being its key focus market. For more information on Alkem Laboratories Ltd., please visit www.alkemlabs.com

For further information or queries, please contact

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