



ALKEM LABORATORIES LTD.

Regd. Office : ALKEM HOUSE, Senapati Bapat Marg,

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• CIN: L00305MH1973PLC174201

Press Release

Alkem reports Q2FY23 and H1FY23 results

Mumbai, November 11, 2022: Alkem Laboratories Ltd. (Alkem) today announced its standalone and consolidated financial results for the second quarter and six months ended September 30, 2022. These results were taken on record by the Board of Directors at its meeting held in Mumbai today.

Key highlights of Q2FY23 financial performance

- Total Revenue from Operations was ₹ 30,793 million, year-on-year growth of 10.0%
 - India sales were ₹ 22,161 million, year-on-year growth of 13.0%
 - International sales were ₹ 8,291 million, year-on-year growth of 3.0%
- Earnings before Interest, Tax, Depreciation and Amortization (EBITDA) was ₹ 4,539 million, resulting in EBITDA margin of 14.7% vs. 22.3% in Q2FY22. EBITDA declined by 27.3% YoY
- R&D expenses for the quarter was ₹ 1,305 million, or 4.2% of total revenue from operations compared to ₹ 1,407 million in Q2FY22 at 5.0% of total revenue from operations
- Profit before tax (PBT) was ₹ 4,023 million, a decline of 30.8% compared to Q2FY22
- Net Profit (after Minority Interest) was ₹ 3,308 million, year-on-year decline of 39.2%

Key highlights of H1FY23 financial performance

- Total Revenue from Operations was ₹ 56,558 million, year-on-year growth of 2.2%
 - India sales were ₹ 39,976 million, year-on-year growth of 3.3%
 - International sales were ₹ 15,895 million, year-on-year decline of 0.4%
- Earnings before Interest, Tax, Depreciation and Amortization (EBITDA) was ₹ 6,572 million, resulting in EBITDA margin of 11.6% vs. 22.0% in H1FY23. EBITDA declined by 46.0% YoY
- R&D expenses for H1FY23 was ₹ 2,625 million, or 4.6% of total revenue from operations compared to ₹ 2,590 million in H1FY22 at 4.7% of total revenue from operations
- Profit before tax (PBT) was ₹ 5,542 million, a decline of 51.3% compared to H1FY22
- Net Profit (after Minority Interest) was ₹ 4,585 million, year-on-year decline of 54.7%

Commenting on the results, Sandeep Singh, Managing Director, Alkem said, *“After a market beating performance in Q1, our domestic franchise has significantly outperformed IPM even in Q2. We increased market share across all acute therapies, anti-diabetic and urology during this quarter. While our US business continues to face significant pricing pressure, our other international business is growing at a healthy pace. Various cost optimization initiatives are underway which should help in building sustainable and profitable business and also drive margin expansion. We are receiving encouraging response for our biosimilar and CDMO franchise.”*



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Operational Highlights

Domestic Business

In Q2FY23, the Company's India sales grew by 13.0% YoY, recording sales of ₹ 22,161 million as compared to ₹ 19,605 million in Q2FY22. For H1FY23, the Company's India sales was ₹ 39,976 million compared to ₹ 38,702 million in H1FY22 – growth of 3.3% YoY.

As per secondary sales data by IQVIA for the quarter ended September 30, 2022, the Company sales grew ahead of Indian Pharmaceutical Market (IPM) with growth of 13.2% YoY compared to IPM growth of 8.2% YoY. Even for H1FY23, the Company outperformed the IPM with growth of 6.9% YoY compared to IPM growth of 3.3% YoY. This outperformance was driven by all round strong outperformance across acute therapies like anti-infective, gastrointestinal, vitamins/minerals/nutrients and pain management. The company demonstrated leadership across all acute therapies gaining market share in all of them. Company's chronic therapies like anti-diabetes is growing at more than 3X the segment growth rate on the back of new launches and strong execution, thereby gaining market share and improving market ranking. The Company continues to feature amongst the top five companies in the Indian pharmaceutical market. The Company has 19 brands which features among top 300 brands in IPM and have 18 brands with annual sales of over ₹ 1 bn.

The performance highlights of the key therapeutic segments in Q2FY23 and H1FY23 are as shown in the table below:

Key Therapy segment	Q2FY23				H1FY23			
	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	7.8%	7.2%	1	Unchanged	-1.9%	-4.9%
Gastro Intestinal	3	Unchanged	22.7%	12.5%	3	Unchanged	21.0%	12.9%
Pain / Analgesics	3	Unchanged	19.2%	11.6%	3	+1	14.9%	11.0%
VMN**	2	Unchanged	11.5%	6.4%	2	Unchanged	-0.5%	-0.9%
Neuro / CNS	8	Unchanged	5.4%	9.8%	8	Unchanged	8.1%	11.1%
Derma	17	-3	0.1%	4.5%	18	+1	6.1%	3.9%
Cardiac	28	-1	-1.4%	10.4%	28	-1	-4.8%	5.1%
Anti-Diabetic	17	+2	29.5%	7.8%	16	+4	24.5%	5.9%
Total	4	Unchanged	13.2%	8.2%	5	Unchanged	6.9%	3.3%

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

**VMN – Vitamins / Minerals / Nutrients

Source: IQVIA Data



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International Business

In Q2FY23, the Company's International sales grew by 3.0% YoY, recording sales of ₹ 8,291 million as compared to ₹ 8,052 million in Q2FY22. For H1FY23, the Company's International sales declined by 0.4% to ₹ 15,895 million compared to ₹ 15,955 million in H1FY22.

- **US sales** for the quarter was ₹ 6,040 million, recording a year-on-year decline of 0.9%. For H1FY23, US sales was ₹ 11,605 million, compared to ₹ 12,140 million in H1FY22 - a decline of 4.4% YoY.
- **Other International Markets sales** for the quarter was ₹ 2,251 million, recording a year-on-year growth of 15.2%. For H1FY23, Other International Markets sales was ₹ 4,290 million compared to ₹ 3,815 million in H1FY22 - a growth of 12.5% YoY.

R&D Investments

During the quarter, the Company filed 3 abbreviated new drug applications (ANDAs) with the US FDA and received 4 approvals (including 2 tentative approvals). For H1FY23, the Company filed 6 abbreviated new drug applications (ANDAs) with the US FDA and received 8 approvals (including 3 tentative approvals).

As on September 30, 2022, the Company filed a total of 167 ANDAs and 2 new drug applications (NDA) with the USFDA. Of these, it has received approvals for 128 ANDAs (including 15 tentative approvals) and 2 NDAs.

Update on US FDA Inspections

Facility	Capability	Last inspection	Status post last inspection
Indore (India)	Formulations	July 2022	Received 1 observation. The Company has already submitted a detailed response to the US FDA on the corrective and preventive actions it is taking to address them.
St. Louis (US)	Formulations	November 2022	Received 3 new observations. The Company is preparing the response for USFDA.
Taloja (India)	Bioequivalence Centre	April 2022	Successfully closed without any observations.
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)	APIs	August 2018	Successfully closed without any observations. EIR received in October 2018.
Ankleshwar (India)	APIs	December 2016	EIR# received in March 2017, thereby successfully closing the inspection.
Mandva (India)	APIs	September 2015	EIR# received in March 2016, thereby successfully closing the inspection.

EIR – Establishment Inspection Report



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Q2FY23 and H1FY23 Conference Call at 5:00pm IST, November 11, 2022

Alkem will organize a conference call for investors and analysts on Friday, November 11, 2022 from 5:00 pm to 6:00 pm IST to discuss its Q2FY23 and H1FY23 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: 5:00 pm IST (GMT + 5:30) on Friday, November 11, 2022

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 2021). 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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