# ALX Oncology Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Corporate Update

March 7, 2024

SOUTH SAN FRANCISCO, Calif., March 07, 2024 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc., ("ALX Oncology" or "the Company") (Nasdaq: ALXO), an immuno-oncology company developing therapies that block the CD47 immune checkpoint pathway, today reported financial results for the fourth quarter and full year ended December 31, 2023, and provided a corporate update.

"This past year proved to be a profound growth period for ALX Oncology highlighted by evorpacept's positive results in the prespecified randomized interim analysis of the ASPEN-06 Phase 2 clinical trial in advanced HER2-positive gastric/GEJ cancer," said Jason Lettmann, Chief Executive Officer ("CEO") of ALX Oncology. "Notably, this outcome is particularly important as it represents the first promising activity in a randomized trial in solid tumors in the CD47 space and further underscores evorpacept's differentiation. Over the next 12-18 months, we expect to report multiple value inflection datapoints, with the goal of advancing evorpacept's potential beyond anti-cancer antibodies through ongoing combination studies with ADCs and checkpoint inhibitors. With nine ongoing trials, our goal is to expand evorpacept's value to other tumor types including breast, NHL, multiple myeloma and urothelial cancers as well as accelerate our efforts to identify new indications around this highly differentiated asset."

**Fourth Quarter 2023 Highlights**

- Appointed long-standing board member, Jason Lettmann to CEO, while co-founder and previous CEO, Jaume Pons, Ph.D., transitioned to Chief Scientific Officer in September.
- Reported positive results from a prespecified interim analysis of the Phase 2 randomized multi-center international clinical trial of ASPEN-06 for the treatment of advanced HER2-positive gastric/gastroesophageal junction ("GEJ") cancer in October.
    - Key findings from the 54 randomized subjects, which included those previously treated with ENHERTU® (fam-trastuzumab deruxtecan-nxki) and/or immune checkpoint inhibitors, reported a confirmed overall response rate ("ORR") of 52 percent in the evorpacept combination treatment arm compared to 22 percent for the control group of trastuzumab + CYRAMZA® (ramucirumab) + paclitaxel ("TRP").
    - Median duration of response ("mDOR") was not reached for the evorpacept TRP combination treatment arm compared to 7.4 months for the control group of TRP.
    - The safety profile of evorpacept was consistent with the Company's previous clinical trials and remained well-tolerated in this reported treatment combination.
    - The interim results compared favorably to the efficacy results reported for CYRAMZA + paclitaxel in the RAINBOW study (ORR of 28 percent and mDOR of 4.4 months), which currently serves as the regulatory benchmark and global standard-of-care for second-line gastric/GEJ cancer.
- Executed an oversubscribed underwritten public offering that generated gross proceeds of approximately $63.2 million during October, which helps to extend the Company's expected cash runway into early 2026. The follow-on offering closely followed the report of the positive interim analysis of the Phase 2 ASPEN-06 clinical trial in advanced HER2-positive gastric/GEJ cancer.
    - ALX Oncology sold 8,663,793 shares of common stock, which included 1,293,103 shares of common stock pursuant to the full exercise of the underwriters' option to purchase additional shares and, in lieu of common stock to certain investors, pre-funded warrants to purchase 1,250,000 shares of common stock in the offering. The shares of common stock were sold at a public offering price of $6.38 per share (the closing price on October 4, 2023), and the pre-funded warrants were sold at a public offering price of $6.379 per pre-funded warrant.

**Anticipated 2024 Clinical Milestones for Evorpacept's Maturing Pipeline Development**

- Non-Hodgkin Lymphoma – Data from a Phase 1b IST with rituximab + lenalidomide will be presented in an oral presentation in a Clinical Trials Minisymposium session at the AACR Annual Meeting 2024 on Tuesday, April 9, 2024, from 2:30 pm – 4:30 pm PT.

- Urothelial Carcinoma – Data from a Phase 1b ASPEN-07 clinical trial with PADCEV® (enfortumab vedotin-ejfv) (Q2 2024)
- Gastric/GEJ Cancer – Top line results from all 122 subjects in a Phase 2 randomized clinical trial of ASPEN-06 (June-July 2024)
- Breast Cancer – Top line results from a Phase 1b I-SPY TRIAL with ENHERTU (Q4 2024)
- Head and Neck Squamous Cell Carcinoma – Top line results from a Phase 2 randomized clinical trial of ASPEN-03 with KEYTRUDA® (pembrolizumab) (Q4 2024/Q1 2025)
- Head and Neck Squamous Cell Carcinoma – Top line results from a Phase 2 randomized clinical trial of ASPEN-04 with KEYTRUDA and chemotherapy (Q4 2024/Q1 2025)
- Gastric/GEJ Cancer – Initiation of Phase 3 registrational randomized clinical trial for evorpacept (Q4 2024)

**2023 Full Year and Fourth Quarter Financial Results:**

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of December 31, 2023, were $218.1 million. The Company believes its cash, cash equivalents, and investments along with the ability to draw down an additional $40 million of its term loan are sufficient to fund planned operations into early 2026.
- **Research and Development ("R&D") Expenses:** R&D expenses consist primarily of pre-clinical, clinical and manufacturing expenses related to the development of the Company's current lead product candidate, evorpacept, and R&D employee-related expenses. These expenses for the three months ended December 31, 2023, were $41.8 million, compared to $25.2 million for the prior-year period. The increase was primarily attributable to an increase of $13.6 million in clinical costs from an increase in the number of active trials and patient enrollment as well as manufacturing of clinical trial materials to support a higher number of active clinical trials and future expected patient enrollment related to the advancement of evorpacept. R&D expenses for the year ended December 31, 2023 were $141.8 million, compared to $98.4 million for the prior-year period.
- **General and Administrative ("G&A") Expenses:** G&A expenses consist primarily of administrative employee-related expenses, legal and other professional fees, patent filing and maintenance fees, and insurance. These expenses for the three months ended December 31, 2023, were $6.2 million, compared to $7.0 million for the prior year period. G&A expenses for the year ended December 31, 2023 were $28.5 million, compared to $29.0 million for the prior-year period.
- **Net loss:** GAAP net loss was $45.5 million for the fourth quarter ended December 31, 2023, or ($0.93) per basic and diluted share, as compared to a GAAP net loss of $30.7 million for the fourth quarter ended December 31, 2022, or ($0.75) per basic and diluted share. GAAP net loss was $160.8 million for the year ended December 31, 2023, or ($3.74) per basic and diluted share, as compared to a GAAP net loss of $123.5 million for the year ended December 31, 2022, or ($3.03) per basic and diluted share. Non-GAAP net loss was $38.7 million for the fourth quarter ended December 31, 2023, as compared to a non-GAAP net loss of $24.4 million for the fourth quarter ended December 31, 2022. Non-GAAP net loss was $134.3 million for the year ended December 31, 2023, as compared to a non-GAAP net loss of $99.6 million for the year ended December 31, 2022. A reconciliation of GAAP to non-GAAP financial results can be found at the end of this news release.

**About ALX Oncology**

ALX Oncology is a publicly traded, clinical-stage immuno-oncology company focused on helping patients fight cancer by developing therapies that block the CD47 immune checkpoint inhibitor and bridge the innate and adaptive immune system. ALX Oncology's lead product candidate, evorpacept, is a next generation CD47 blocking therapeutic that combines a high-affinity CD47 binding domain with an inactivated, proprietary Fc domain. To date, evorpacept has been dosed in over 500 subjects and has demonstrated promising activity and a favorable tolerability profile across a range of hematologic and solid malignancies in combination with various leading anti-cancer antibodies. ALX Oncology is currently focusing on combining evorpacept with anti-cancer antibodies, ADCs, and PD-1/PD-L1 immune checkpoint inhibitors.

**Evorpacept's Unique Profile: Anchored by a Rational Design and Dual Development Pillars**

Rationally engineered with an inactive Fc effector function, evorpacept's clinical data to date has demonstrated a substantially improved safety profile over other anti-CD47 molecules in the clinic with an active Fc (i.e., binding the Fc gamma receptor on macrophages). This best-in-class safety profile allows for higher dosage with minimal overlapping toxicity in the combination treatment setting. CD47 expressed on cancer cells binds to its receptor SIRP alpha, which is predominantly expressed on two cell types: macrophages and dendritic cells. The Company's pipeline of therapeutic candidates with standard-of-care agents include:

- **Anti-cancer antibodies (the "*don't eat me*" signal):** evorpacept enables Fc-mediated antibody-dependent phagocytosis by macrophages in combination with anti-cancer antibodies (e.g., Herceptin®) with an active Fc domain, which is otherwise impaired by CD47 expression on cancer cells binding to SIRP alpha on macrophages. This same mechanism of action applies to ADCs.
- **PD-1/PD-L1 immune checkpoint inhibitors (the "*don't activate T-cells*" signal)**: evorpacept enables T-cell activation by dendritic cells that are constitutively inhibited by CD47 expression on cancer cells binding to SIRP alpha on dendritic cells. Activated dendritic cells present neoantigens to T-cells that once activated will kill cancer cells when the PD-1/PD-L1

inhibitory interaction is blocked by T-cell checkpoint inhibitors.

**Cautionary Note Regarding Forward-Looking Statements**

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements regarding future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, plans and objects of management for future operations, as well as statements regarding industry trends. Such forward-looking statements are based on ALX Oncology's beliefs and assumptions and on information currently available to it on the date of this press release. Forward-looking statements may involve known and unknown risks, uncertainties and other factors that may cause ALX Oncology's actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. These and other risks are described more fully in ALX Oncology's filings with the Securities and Exchange Commission ("SEC"), including ALX Oncology's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other documents ALX Oncology files with the SEC from time to time. Except to the extent required by law, ALX Oncology undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

**ALX ONCOLOGY HOLDINGS INC.**
**Consolidated Statements of Operations**
(unaudited for the three months ended December 31, 2023 and 2022)
(in thousands, except share and per share amounts)

| | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Operating expenses: | | | | |
| Research and development | $ 41,784 | $ 25,197 | $ 141,795 | $ 98,400 |
| General and administrative | 6,239 | 7,022 | 28,483 | 29,036 |
| Total operating expenses | 48,023 | 32,219 | 170,278 | 127,436 |
| Loss from operations | (48,023) | (32,219) | (170,278) | (127,436) |
| Interest income | 2,995 | 1,807 | 10,649 | 4,278 |
| Interest expense | (415) | (231) | (1,565) | (238) |
| Other income (expense), net | (29) | (2) | 389 | (22) |
| Loss before income taxes | (45,472) | (30,645) | (160,805) | (123,418) |
| Income tax (provision) benefit | — | (64) | — | (64) |
| Net loss | $ (45,472) | $ (30,709) | $ (160,805) | $ (123,482) |
| Net loss per share, basic and diluted | $ (0.93) | $ (0.75) | $ (3.74) | $ (3.03) |
| Weighted-average shares of common stock used to compute net loss per shares, basic and diluted | 48,995,998 | 40,755,520 | 42,987,767 | 40,699,612 |

**Consolidated Balance Sheet Data**
(in thousands)

| | December 31, 2023 | December 31, 2022 |
|---|---|---|
| Cash, cash equivalents and investments | $ 218,147 | $ 282,906 |
| Total assets | $ 242,553 | $ 306,489 |
| Total liabilities | $ 52,841 | $ 43,025 |
| Accumulated deficit | $ (486,272) | $ (325,467) |
| Total stockholders' equity | $ 189,712 | $ 263,464 |

**GAAP to Non-GAAP Reconciliation**
(unaudited)
(in thousands)

| | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| GAAP net loss, as reported | $ (45,472) | $ (30,709) | $ (160,805) | $ (123,482) |

| | | | | |
|---|---|---|---|---|
| Adjustments: | | | | |
| Stock-based compensation expense | 6,721 | 6,295 | 26,273 | 23,839 |
| Accretion of term loan discount and issuance costs | 64 | 44 | 250 | 44 |
| Total adjustments | 6,785 | 6,339 | 26,523 | 23,883 |
| Non-GAAP net loss | $ (38,687) | $ (24,370) | $ (134,282) | $ (99,599) |

**Use of Non-GAAP Financial Measures**

We supplement our consolidated financial statements presented on a GAAP basis by providing additional measures which may be considered “non-GAAP” financial measures under applicable SEC rules. We believe that the disclosure of these non-GAAP financial measures provides our investors with additional information that reflects the amounts and financial basis upon which our management assesses and operates our business. These non-GAAP financial measures are not in accordance with generally accepted accounting principles and should not be viewed in isolation or as a substitute for reported, or GAAP, net loss, and are not a substitute for, or superior to, measures of financial performance performed in conformity with GAAP.

“Non-GAAP net loss” is not based on any standardized methodology prescribed by GAAP and represents GAAP net loss adjusted to exclude stock-based compensation expense and accretion of term loan discount and issuance costs. Non-GAAP financial measures used by ALX Oncology may be calculated differently from, and therefore may not be comparable to, non-GAAP measures used by other companies.

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