



ALX Oncology Reports First Quarter 2025 Financial Results and Provides Corporate Update

May 8, 2025

- **Following announcement of prioritized development strategy for evorpcept in combination with anti-cancer antibodies at R&D Day in March, Company is on track to initiate Phase 2 ASPEN-Breast and Phase 1 ASPEN-CRC studies in mid-2025**
- **IND clearance received from U.S. FDA for novel EGFR-targeted antibody-drug conjugate (ADC), ALX2004, paving way for mid-year clinical program initiation; Company to host webcast focused on ALX2004 research program on May 20**
- **Company will not pursue U.S. registrational path in gastric cancer following receipt of FDA feedback that accelerated approval pathway is not feasible based on ASPEN-06 due to standard-of-care evolving to ENHERTU®**
- **Data milestones expected across Company's three clinical programs in 2026**
- **Cash runway has been extended into Q4 2026**

SOUTH SAN FRANCISCO, Calif., May 08, 2025 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc., ("ALX Oncology" or "the Company") (Nasdaq: ALXO), a clinical-stage biotechnology company advancing a pipeline of novel therapies designed to treat cancer and extend patients' lives, today reported financial results for the first quarter ended March 31, 2025, and provided a corporate update.

"In the first quarter of the year, we focused our development strategy for evorpcept on the anti-cancer antibody combinations, as we now have proof-of-concept for this mechanism in gastric cancer, breast cancer and NHL," said Jason Lettmann, Chief Executive Officer of ALX Oncology. "In addition to the evorpcept program, we diversified our pipeline by moving our in-house ADC candidate, ALX2004, through IND clearance and look forward to beginning clinical trial enrollment by mid-year for this potentially first- and best-in-class EGFR ADC. We also made the difficult but critical decision to streamline the company and, by doing so, extended cash runway into Q4 2026. We are now hyper-focused on pursuing the validated mechanism of action for evorpcept in combination with anti-cancer antibodies and delivering data in breast cancer in combination with HERCEPTIN®, in colorectal cancer in combination with ERBITUX®, as well as from ALX2004, in 2026."

ALX Oncology Q1 2025 Highlights and Recent Developments

- Received Investigational New Drug (IND) clearance for ALX2004 from the U.S. Food and Drug Administration (FDA). ALX2004 is a potential best- and first-in-class ADC for the treatment of epidermal growth factor receptor (EGFR)-expressing solid tumors that was fully designed and developed in-house by ALX Oncology scientists utilizing the Company's proprietary linker-payload platform. Phase 1 clinical trials of ALX2004 are expected to initiate in mid-2025, with initial safety data available in 1H 2026. ALX Oncology will host a webcast highlighting the research program, clinical progress and novel mechanism of action for ALX2004 on May 20, 2025.
- Continued progress with the Phase 2 ASPEN-Breast and Phase 1 ASPEN-CRC clinical studies evaluating evorpcept in combination with anti-cancer antibodies and chemotherapy in breast and colorectal cancers based on strong supporting data that, when combined with an anti-cancer antibody, evorpcept generates durable responses and a consistent safety profile. First patient dosing for both trials is anticipated mid-year 2025.
 - The randomized Phase 2 ASPEN-Breast clinical trial will evaluate evorpcept with HERCEPTIN® (trastuzumab) and single-agent chemotherapy in patients with HER2-positive metastatic breast cancer after prior treatment with ENHERTU® (fam-trastuzumab deruxtecan-nxki).
 - The Phase 1 ASPEN-CRC clinical trial will evaluate evorpcept with ERBITUX® (cetuximab) and FOLFIRI in patients with second-line metastatic colorectal cancer.
- Announced encouraging final results from the Phase 1 trial evaluating evorpcept with standard-of-care RITUXAN® (rituximab) and lenalidomide (R²) treatment in patients with B-cell non-Hodgkin Lymphoma (B-NHL) presented at the American Association for Cancer Research (AACR) Annual Meeting 2025. The trial was conducted by Paolo Strati, M.D., Associate Professor of Lymphoma-Myeloma at The University of Texas MD Anderson Cancer Center, and colleagues at MD Anderson.
 - As previously published, the combination of evorpcept plus R² was well tolerated and demonstrated promising

anti-tumor activity, generating complete responses (CR) in 83% of patients with indolent relapsed or refractory B-NHL comparing favorably to the 34% historical CR rate with R² alone.

- The Phase 2 portion of the trial in patients with previously untreated indolent NHL is ongoing and has completed enrollment.
- Reported topline results from the ASPEN-03 and ASPEN-04 Phase 2 trials evaluating evorpaccept with a checkpoint inhibitor, which did not meet their primary endpoints. In the trials, efficacy data did not support advancing evorpaccept in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), into a registrational study. The combination of evorpaccept and pembrolizumab with or without chemotherapy in ASPEN-03 and ASPEN-04 demonstrated a manageable safety profile and was consistent with what has been previously reported for pembrolizumab and chemotherapy in this setting.
- Received guidance from the U.S. FDA that the ASPEN-06 Phase 2 trial data evaluating evorpaccept in combination with trastuzumab, ramucirumab and paclitaxel was not eligible for submission for accelerated approval given the availability of ENHERTU®. A Phase 3 versus ENHERTU® trial would be needed to pursue a regulatory approval of evorpaccept in the second-line setting for HER2-positive gastric and gastroesophageal cancers. Given the Company's disciplined focus and the allocation of its resources, ALX Oncology will not pursue a U.S. registrational path with a Phase 3 trial in gastric cancer and will consider exploring development partnerships to advance this program in gastric cancer.
- The Company made the decision to discontinue its evaluation of evorpaccept in combination with PADCEV® (enfortumab vedotin-ejfv) in urothelial cancer based on the final data analysis showing that, in the ASPEN-07 trial, the addition of evorpaccept to treatment with PADCEV® did not meet the bar for improved efficacy. Aligned to these data and consistent with recent guidance, ALX Oncology maintains its focus on continuing to progress its trials of evorpaccept with anti-cancer antibodies, where there is demonstrated proof-of-concept across multiple clinical settings.
- Through previously announced strategic reprioritization efforts, the Company extended its cash runway into Q4 2026. Data milestones that are expected across the three studies evaluating evorpaccept and ALX2004 are included in cash runway.

Upcoming Clinical Milestones

- Breast Cancer: Patient dosing anticipated to initiate for ASPEN-BREAST Phase 2 clinical trial in mid-year 2025. Interim results from this trial are anticipated in 2H 2026.
- Colorectal Cancer: Patient dosing anticipated to initiate for ASPEN-CRC Phase 1b clinical trial in mid-year 2025. Safety and early efficacy data are anticipated in 1H 2026.
- ALX2004: Patient dosing anticipated to initiate in mid-2025, following IND clearance from the FDA in April 2025. Safety data are anticipated in 1H 2026.
- Breast Cancer: Topline results from Phase 1b I-SPY clinical trial of evorpaccept with ENHERTU® are anticipated in 2H 2025.

First Quarter 2025 Financial Results

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of March 31, 2025, were \$107.0 million. The Company believes its cash, cash equivalents and investments are sufficient to fund planned operations into Q4 of 2026.
- **Research and Development ("R&D") Expenses:** R&D expenses consist primarily of preclinical, clinical and development costs related to the development of the Company's current lead product candidate, evorpaccept, and R&D personnel-related expenses including stock-based compensation. R&D expenses for the three months ended March 31, 2025, were \$23.9 million compared to \$31.7 million for the prior-year period or a decrease of \$7.8 million. This decrease was primarily attributable to a decrease of \$7.0 million in clinical and development costs primarily due to less manufacturing of clinical trial materials to support active clinical trials for our lead product candidate, evorpaccept, and a decrease in stock-based compensation expense slightly offset by increased personnel and related costs.
- **General and Administrative ("G&A") Expenses:** G&A expenses consist primarily of administrative personnel-related expenses, including stock-based compensation and other costs such as legal and other professional fees, patent filing and maintenance fees, and insurance. G&A expenses for the three months ended March 31, 2025, were \$7.9 million compared to \$6.0 million for the prior year period or an increase of \$1.9 million. This increase was primarily attributable to an increase in personnel and related costs.
- **Net loss:** GAAP net loss was (\$30.8) million for the three months ended March 31, 2025, or (\$0.58) per basic and diluted share, as compared to a GAAP net loss of (\$35.6) million for the three months ended March 31, 2024, or (\$0.71) per basic and diluted share. The lower net loss is primarily attributed to lower R&D expenses. Non-GAAP net loss was (\$25.5) million for the three months ended March 31, 2025, as compared to a non-GAAP net loss of (\$28.5) million for the three months ended March 31, 2024. A reconciliation of GAAP to non-GAAP financial results can be found at the end of this news release.

About ALX Oncology

ALX Oncology (Nasdaq: ALXO) is a clinical-stage biotechnology company advancing a pipeline of novel therapies designed to treat cancer and extend patients' lives. ALX Oncology's lead therapeutic candidate, evorpaccept, has demonstrated potential to serve as a cornerstone therapy upon which the future of immuno-oncology can be built. Evorpaccept is currently being evaluated across multiple ongoing clinical trials in a wide range of cancer indications. ALX Oncology's second pipeline candidate, ALX2004, is a novel EGFR-targeted antibody-drug conjugate with a differentiated mechanism of action and is anticipated to enter Phase 1 trials mid-2025. More information is available at www.alxoncology.com and on LinkedIn [@ALX Oncology](https://www.linkedin.com/company/alxoncology).

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 objectives 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.
Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended	
	March 31,	
	2025	2024
Operating expenses:		
Research and development	\$ 23,888	\$ 31,717
General and administrative	7,932	6,045
Total operating expenses	31,820	37,762
Loss from operations	(31,820)	(37,762)
Interest income	1,483	2,622
Interest expense	(406)	(427)
Other (expense) income, net	(11)	(14)
Net loss	\$ (30,754)	\$ (35,581)
Net loss per share, basic and diluted	\$ (0.58)	\$ (0.71)
Weighted-average shares of common stock used to compute net loss per shares, basic and diluted	53,359,338	50,120,758

Condensed Consolidated Balance Sheet Data
(unaudited)
(in thousands)

	March 31,	December 31,
	2025	2024
Cash, cash equivalents and investments	\$ 106,992	\$ 131,281
Total assets	\$ 120,900	\$ 147,775
Total liabilities	\$ 32,605	\$ 34,157
Accumulated deficit	\$ (651,876)	\$ (621,122)
Total stockholders' equity	\$ 88,295	\$ 113,618

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

	Three Months Ended	
	March 31,	
	2025	2024
GAAP net loss, as reported	\$ (30,754)	\$ (35,581)
Adjustments:		
Stock-based compensation expense	5,216	7,031
Accretion of term loan discount and issuance costs	67	64
Total adjustments	5,283	7,095
Non-GAAP net loss	\$ (25,471)	\$ (28,486)

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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