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

November 7, 2025

- *ASPEN-06 data to be presented at SITC demonstrates that evorpacept drove durable clinical benefit across all efficacy measures in HER2+ gastric cancer patients with high CD47 expression*
- *Phase 2 ASPEN-09-Breast Cancer trial remains on track for FPI in Q4 2025 and will evaluate evorpacept efficacy by CD47 expression levels*
- *Phase 1 trial for ALX2004, a novel EGFR-targeted ADC, is currently enrolling patients in the second dose cohort and on track to deliver initial safety data in 1H 2026*
- *Cash runway expected into Q1 2027 to support key milestones, including ALX2004 initial safety data in 1H 2026, interim data for ASPEN-09-Breast Cancer in Q3 2026*
- *Appointed Board Member Barbara Klencke, M.D., as Chief Medical Officer*
- *Company to host webcast including perspective from Breast Cancer Expert Dr. Peter Schmid on Friday, November 7, at 5:30 a.m. PT / 8:30 a.m. ET*

SOUTH SAN FRANCISCO, Calif., Nov. 07, 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 third quarter ended September 30, 2025, and provided a corporate update.

“We are pleased to share data at SITC this weekend from an analysis of our ASPEN-06 trial demonstrating compelling benefit in all outcomes measured for patients with high CD47-expressing HER2-positive gastric cancer treated with evorpacept in combination with trastuzumab, ramucirumab, and paclitaxel,” said Jason Lettmann, Chief Executive Officer at ALX Oncology. “This insight is guiding our targeted clinical development strategy for breast cancer where we will be enrolling patients with HER2-positive tumors that have previously received ENHERTU® and we will evaluate responses by CD47-expression level in our Phase 2 ASPEN-09-Breast Cancer trial. Additionally, we are excited about the progress of our ALX2004 clinical program, where we are currently enrolling the second dose cohort at 2mg/kg after clearing the dose 1 cohort at 1mg/kg, a milestone for this Phase 1 program. We look forward to providing an update with initial safety data from this program in the first half of next year. Given the promising preclinical findings we have seen to date for ALX2004 which demonstrate a favorable toxicity profile and potent anti-tumor activity, we remain very optimistic about the potential success for this approach in treating EGFR+ tumors.”

“The analysis from the evorpacept gastric cancer data is especially interesting for two reasons. First, it is great to see this level of improvement across all efficacy measures among HER2-positive gastric cancer patients with CD47-high expression. Second, I’m eager to evaluate this approach for patients with HER2+ breast cancer in the ASPEN-09 trial since we will be combining evorpacept and chemotherapy with trastuzumab, the same HER2-targeted antibody used in the gastric cancer study,” said Peter Schmid, FRCP, M.D., Ph.D., Professor of Cancer Medicine; Centre Lead, Centre of Experimental Cancer Medicine; Director, Barts Breast Cancer Centre at Queen Mary University of London. “We hope that by using this combination we are able to offer meaningful clinical benefit to patients with HER2-positive breast cancer who have previously received ENHERTU®, and we know this is a patient population in need of new targeted therapies.”

ALX Oncology Q3 2025 Highlights and Recent Developments

- In a pre-planned exploratory analysis of the ASPEN-06 clinical trial in gastric cancer, CD47 overexpression was identified as a key predictive biomarker for response and durable benefit in patients with retained HER2 expression. Retained HER2 expression is defined as patients who are HER2-positive on a tumor biopsy after receiving a HER2-targeted treatment or by HER2 amplification in circulating tumor DNA (ctDNA). Data to be highlighted as part of a poster presentation at the Society for Immunotherapy of Cancer (SITC) Annual Meeting on November 8th.
  - In patients with retained HER2+ and CD47-high gastric cancer (n=43), evorpacept + HERCEPTIN® (trastuzumab), CYRAMZA® (ramucirumab) and paclitaxel (TRP) had a 65.0% objective response rate (ORR) versus 26.1% ORR for TRP, while patients with HER2+ and CD47-low gastric cancer (n=47), evorpacept + TRP had a 37.5% ORR compared to 26.1% ORR for TRP.
  - The duration of response (DOR) was three times longer in the evorpacept + TRP arm relative to TRP in these patients. Evorpacept + TRP had a median DOR of 25.5 months versus 8.4 months median DOR for TRP, while

patients with HER2+ and CD47-low gastric cancer, had a median DOR of 11.2 months for evorpacept + TRP compared to 12 months for TRP. Progression free survival (PFS) and overall survival (OS) data were evaluated in these patients. Treatment with evorpacept + TRP resulted in a PFS of 18.4 months versus 7.0 months for TRP, hazard ratio (HR) of 0.39. Treatment with evorpacept + TRP resulted in an OS of 17 months versus 9.9 months for TRP, HR of 0.63.

- These emerging clinical data demonstrating improved outcomes in patients with CD47-high expression in retained HER2+ gastric cancer from ASPEN-06 support the hypothesis that CD47 expression could be a key predictive biomarker for evorpacept efficacy in other settings. The Phase 2 ASPEN-09-Breast Cancer clinical trial of evorpacept plus trastuzumab and physician's choice chemotherapy in patients with HER2+ breast cancer previously treated with ENHERTU ® (fam-trastuzumab deruxtecan-nxki) is on track to begin enrollment in Q4 2025, with interim data expected in Q3 2026. This trial will evaluate efficacy by CD47 expression levels. A trial-in-progress poster outlining the details of the trial design was recently presented at the European Society for Medical Oncology (ESMO) Annual Meeting.

- Enrollment began in August 2025 in the Phase 1 clinical trial for ALX2004, a novel antibody-drug conjugate (ADC) for the treatment of epidermal growth factor receptor (EGFR)-expressing solid tumors and has cleared the first dose level. Trial-in-progress and preclinical data posters were recently showcased at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics Annual Meeting.
    - ALX2004 demonstrated potent preclinical anti-tumor activity in EGFR-expressing in vivo tumor models across multiple tumor types with differing levels of EGFR expression and varied mutational status across the EGFR signaling pathway. A favorable preclinical safety profile, including no skin toxicity or interstitial lung disease, was observed in NHP toxicology studies at clinically relevant doses.
    - The ongoing Phase 1 dose escalation trial includes patients with relapsed/refractory EGFR-expressing solid tumors and remains on track to share initial safety data in 1H 2026. The Phase 1 trial is currently enrolling the second dose cohort at 2 mg/kg as no dose-limiting toxicities were observed in the first cohort at 1 mg/kg.

- Detailed results from the Phase 2 clinical trials for ASPEN-03 and ASPEN-04, which evaluated evorpacept treatment plus KEYTRUDA® (pembrolizumab), a PD-1 inhibitor, or pembrolizumab in combination with chemotherapy, respectively, for the treatment of recurrent, unresectable or metastatic (R/M) head and neck squamous cell carcinoma (HNSCC) were presented at ESMO in October 2025. As was reported in the topline results announced in May, the trials did not meet their primary endpoints. The Company will not pursue evorpacept in combination with PD-1 inhibitors at this time.

- ALX Oncology is prioritizing evorpacept development in combination with anti-cancer antibodies that directly induce antibody-dependent cellular phagocytosis (ADCP), the primary proposed mechanism of action for evorpacept, based on benefit demonstrated in the ASPEN-06 clinical trial and others in non-Hodgkin lymphoma (NHL), and HER2+ Breast Cancer.

- The Company appointed Board Member Barbara Klencke, M.D., as interim Chief Medical Officer. Dr. Klencke is an accomplished clinical leader with a distinguished track record in oncology drug development. Dr. Klencke has more than 30 years of experience in patient care, academic and scientific research, and clinical drug development in hematology and oncology. She has deep R&D expertise and has made significant contributions to the development, approval and commercialization of numerous oncology products through various executive leadership roles at a range of small, mid-sized and large biotech companies including Sierra Oncology (acquired by GSK), Onyx Pharmaceuticals (acquired by Amgen) and Genentech, a member of the Roche Group. She holds a Bachelor of Science degree from Indiana University and an M.D. from the University of California, Davis. In addition to ALX Oncology, Dr. Klencke is an independent board director of Xencor and TScan Therapeutics.

Upcoming Clinical Milestones

- ASPEN-09-Breast Cancer: Remains on track for FPI in Q4 2025 and interim data readout anticipated in Q3 2026.

- ALX2004: Phase 1 trial enrollment began in August and remains on track to deliver initial safety data in 1H 2026.

Third Quarter 2025 Webcast Information
To access the conference call, please dial +1-877- 407-0752 or +1-201-389-0912 and ask to be joined into the ALX Oncology Third Quarter 2025 Financial Results Conference Call.

Another option for instant telephone access to the event is to use the Call me™ link below:
https://callme.viavid.com/viavid/?callme=true&passcode=13755276&h=true&info=company&r=true&B=6

A live audio webcast of the call, along with accompanying slides, will be available under "Events & Presentations" in the Investor section of the Company's website, www.alxoncology.com. An archived webcast will be available on the Company's website after the event.

Date & Time: Friday, November 7 at 5:30 a.m. PT / 8:30 a.m. ET

Webcast Access: https://viavid.webcasts.com/starthere.jsp?ei=1740362&tp_key=b49359356f

Third Quarter 2025 Financial Results

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of September 30, 2025, were $66.5 million. The Company believes its cash, cash equivalents and investments are sufficient to fund planned operations into Q1 of 2027.
- **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, evorpacept, and R&D personnel-related expenses including stock-based compensation. R&D expenses for the three months ended September 30, 2025, were $17.4 million compared to $26.5 million for the prior-year period or a decrease of $9.0 million. This decrease was primarily attributable to a decrease of $3.5 million in stock-based compensation expense, a $3.2 million in personnel and related costs, $2.6 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, evorpacept, and a decrease of $1.9 million in preclinical costs due to pipeline prioritization strategy. These decreases were partially offset by an increase of $2.5 million due to a development milestone achieved.
- **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 September 30, 2025, were $5.1 million compared to $6.1 million for the prior year period or a decrease of $1.0 million. This decrease was primarily attributable to a decrease in stock-based compensation expense.
- **Net loss:** GAAP net loss was ($22.1) million for the three months ended September 30, 2025, or ($0.41) per basic and diluted share, as compared to a GAAP net loss of ($30.7) million for the three months ended September 30, 2024, or ($0.58) per basic and diluted share. The lower net loss is primarily attributed to lower R&D expenses. Non-GAAP net loss was ($19.6) million for the three months ended September 30, 2025, as compared to a non-GAAP net loss of ($23.7) million for the three months ended September 30, 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, evorpacept, has demonstrated potential to serve as a cornerstone therapy upon which the future of immuno-oncology can be built. Evorpacept 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 entered the clinic in a Phase 1 trial in August 2025. More information is available at www.alxoncology.com and on LinkedIn @ALX Oncology.

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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 17,441	$ 26,471	$ 59,351	$ 92,841
General and administrative	5,091	6,096	18,474	19,013
Impairment charge	—	—	3,175	—
Total operating expenses	22,532	32,567	81,000	111,854

Loss from operations	(22,532)	(32,567)	(81,000)	(111,854)
Interest income	802	2,303	3,391	7,488
Interest expense	(408)	(446)	(1,219)	(1,302)
Other (expense) income, net	(6)	3	(19)	(19)
Net loss	$ (22,144)	$ (30,707)	$ (78,847)	$ (105,687)
Net loss per share, basic and diluted	$ (0.41)	$ (0.58)	$ (1.48)	$ (2.05)
Weighted-average shares of common stock used to compute net loss per shares, basic and diluted	53,577,066	52,693,878	53,452,319	51,544,501

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

	September 30, 2025	December 31, 2024
Cash, cash equivalents and investments	$ 66,464	$ 131,281
Total assets	$ 82,723	$ 147,775
Total liabilities	$ 37,923	$ 34,157
Accumulated deficit	$ (699,969)	$ (621,122)
Total stockholders' equity	$ 44,800	$ 113,618

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
GAAP net loss, as reported	$ (22,144)	$ (30,707)	$ (78,847)	$ (105,687)
Adjustments:				
Stock-based compensation expense	2,521	6,952	9,873	21,235
Accretion of term loan discount and issuance costs	72	66	208	196
Total adjustments	2,593	7,018	10,081	21,431
Non-GAAP net loss	$ (19,551)	$ (23,689)	$ (68,766)	$ (84,256)

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.

Investor Relations Contact:
Elhan Webb, CFA, IR Consultant
ewebb@alxoncology.com

Media Contact:

Audra Friis, Sam Brown Healthcare Communications
audrafriis@sambrown.com
(917) 519-9577