ALX Oncology Reports Third Quarter 2024 Financial Results and Provides Corporate Update

November 7, 2024

SOUTH SAN FRANCISCO, Calif., Nov. 07, 2024 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc., ("ALX Oncology" or "the Company") (Nasdaq: ALXO), a clinical-stage biotechnology company advancing therapies that boost the immune system to treat cancer in new ways and extend patients' lives, today reported financial results for the third quarter ended September 30, 2024, and provided a corporate update.

"We made substantial clinical progress during the third quarter, most notably announcing topline data from our ASPEN-06 Phase 2 trial in which our lead candidate evorpacept became the first and only CD47-blocking agent to show a durable clinical benefit and a well-tolerated safety profile in a prospective randomized clinical trial," said Jason Lettmann, Chief Executive Officer of ALX Oncology. "These results provided further validation for evorpacept's novel mechanism of action and our robust evorpacept clinical program. We anticipate achieving several additional clinical milestones in the near-term that could advance evorpacept towards being a best-in-class, combinable therapeutic across a wide range of cancer types."

Third Quarter 2024 Highlights and Recent Developments

- Reported topline data results in July from the multi-center, international ASPEN-06 Phase 2 clinical trial (NCT05002127) evaluating evorpacept in combination with HERCEPTIN® (trastuzumab), CYRAMZA® (ramucirumab) and paclitaxel (Evo-TRP) against trastuzumab, CYRAMZA (ramucirumab) and paclitaxel (TRP) for the treatment of patients with HER2-positive gastric/gastroesophageal junction (GEJ) cancer, where all patients had received an anti-HER2 agent in prior lines of therapy.
    - Evorpacept improved tumor response in patients with HER2-positive gastric/GEJ cancer, becoming the first CD47 blocker to show promising and durable response with a well-tolerated safety profile in a prospective randomized study.
    - Evo-TRP achieved a confirmed overall response rate (ORR) of 40.3% compared to 26.6% for the TRP control arm and demonstrated a median duration of response of 15.7 months compared to 7.6 months in the intent to treat population (ITT) (N=127). The primary analysis of the ITT compared Evo-TRP to an assumed RP control ORR of 30% Secondary endpoints of PFS and OS were immature at the time of analysis.
    - Evo-TRP combination showed the greatest response with an ORR of 54.8% compared to 23.1% in the TRP control arm in a pre-specified population of patients with fresh HER2-positive biopsies (n=48).
- In September, commenced patient dosing to investigate evorpacept plus SARCLISA® (isatuximab-irfc) and dexamethasone in patients with relapsed or refractory multiple myeloma (RRMM) in the Sanofi-partnered arm of the randomized UMBRELLA phase 1/2 clinical study.
    - Sanofi is conducting the two-part multicenter, randomized, open-label, controlled, parallel-group study (NCT04643002) to evaluate the safety, efficacy, pharmacokinetics and biomarker data of evorpacept in combination with SARCLISA and dexamethasone in patients with RRMM.
    - Part 1 is evaluating the dosing of evorpacept in combination with standard doses of SARCLISA and dexamethasone to identify a recommended evorpacept dose.
    - Part 2 is investigating the efficacy and safety of this three-drug combination in an expanded population of patients with RRMM.
- In August, enhanced the leadership team by appointing Alan Sandler, M.D. to Board of Directors, a distinguished leader in oncology and drug development with over 30 years of experience across industry and academia.
    - Dr. Sandler's industry background includes serving as Executive Vice President, Chief Medical Officer at Mirati Therapeutics, prior to its acquisition by Bristol Myers Squibb. Before joining Mirati, he served as President, Global Head of Development in Oncology at Zai Lab, and prior to that, he was the Senior Vice President and Global Head, Product Development of Oncology Solid Tumors at Genentech, a member of the Roche Group.
- Presented at the 2024 Cantor Fitzgerald Global Healthcare Conference in New York City in September.
    - Participated in fireside chat with Analyst, Li Watsek and conducted investor meetings.

Upcoming Clinical Milestones for Evorpacept's Development Pipeline

- Breast Cancer – Results from a Phase 1b/2 combination trial evaluating evorpacept in combination with Jazz Pharmaceuticals' zanidatamab in HER2-positive and HER2-low metastatic breast cancer will be presented at a poster spotlight presentation at the San Antonio Breast Cancer Symposium on December 12, 2024
- Gastric/GEJ Cancer – Updated results of ASPEN-06 Phase 2 clinical trial (1H 2025)
- Head and Neck Squamous Cell Carcinoma – Topline results from a Phase 2 randomized clinical trial of ASPEN-03 with

KEYTRUDA® (pembrolizumab) (1H 2025)
- Head and Neck Squamous Cell Carcinoma – Topline results from a Phase 2 randomized clinical trial of ASPEN-04 with KEYTRUDA and chemotherapy (1H 2025)
- Urothelial Cancer – Updated results from a Phase 1 clinical trial of ASPEN-07 in combination with PADCEV® (enfortumab vedotin) (1H 2025)
- Gastric/GEJ Cancer – Initiation of Phase 3 registrational randomized clinical trial for evorpacept (mid-2025)
- Breast Cancer – Topline results from a Phase 1b I-SPY TRIAL with ENHERTU® (fam-trastuzumab deruxtecan-nxki) (2H 2025)

Third Quarter 2024 Financial Results:

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of September 30, 2024, were $162.6 million. The Company believes its cash, cash equivalents and investments, which includes the proceeds from sales under its at-the-market ("ATM") offering in the first half of 2024 are sufficient to fund planned operations well into Q1 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 September 30, 2024, were $26.5 million, compared to $45.8 million for the prior-year period. R&D expenses decreased by $19.3 million during the three months ended September 30, 2024, compared to the three months ended September 30, 2023. Lower expense was primarily attributable to a decrease of $22.2 million in clinical and development costs primarily due to manufacturing of clinical trial materials to support active clinical trials for our lead product candidate, evorpacept, slightly offset by increased preclinical costs for development of new targets, an increase in personnel and related costs, and an increase in stock-based compensation expense.
- **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 September 30, 2024, were $6.1 million, compared to $7.5 million for the prior year period. G&A expenses decreased by $1.4 million during the three months ended September 30, 2024, compared to the three months ended September 30, 2023. The decrease was primarily attributable to lower stock-based compensation expense and lower accounting consulting costs.
- **Net loss:** GAAP net loss was $30.7 million for the three months ended September 30, 2024, or ($0.58) per basic and diluted share, as compared to a GAAP net loss of $51.0 million for the three months ended September 30, 2023, or ($1.24) per basic and diluted share. Non-GAAP net loss was $23.7 million for the three months ended September 30, 2024, as compared to a non-GAAP net loss of $44.0 million for the three months ended September 30, 2023. 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 therapies that boost the immune system to treat cancer in new ways 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. 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 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.
Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,	Nine Months Ended September 30,

	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 26,471	$ 45,766	$ 92,841	$ 100,011
General and administrative	6,096	7,509	19,013	22,244
Total operating expenses	32,567	53,275	111,854	122,255
Loss from operations	(32,567)	(53,275)	(111,854)	(122,255)
Interest income	2,303	2,677	7,488	7,654
Interest expense	(446)	(391)	(1,302)	(1,150)
Other (expense) income, net	3	(1)	(19)	418
Net loss	$ (30,707)	$ (50,990)	$ (105,687)	$ (115,333)
Net loss per share, basic and diluted	$ (0.58)	$ (1.24)	$ (2.05)	$ (2.82)
Weighted-average shares of common stock used to compute net loss per shares, basic and diluted	52,693,878	41,147,938	51,544,501	40,963,015

Condensed Consolidated Balance Sheet Data
(in thousands)

	September 30, 2024	December 31, 2023
Cash, cash equivalents and investments	$ 162,610	$ 218,147
Total assets	$ 185,715	$ 242,553
Total liabilities	$ 48,908	$ 52,841
Accumulated deficit	$ (591,959)	$ (486,272)
Total stockholders' equity	$ 136,807	$ 189,712

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
GAAP net loss, as reported	$ (30,707)	$ (50,990)	$ (105,687)	$ (115,333)
Adjustments:				
Stock-based compensation expense	6,952	6,964	21,235	19,552
Accretion of term loan discount and issuance costs	66	63	196	186
Total adjustments	7,018	7,027	21,431	19,738
Non-GAAP net loss	$ (23,689)	$ (43,963)	$ (84,256)	$ (95,595)

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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