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

May 9, 2024

SOUTH SAN FRANCISCO, Calif., May 09, 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 first quarter ended March 31, 2024, and provided a corporate update.

"We entered the quarter with a great deal of momentum having achieved a key validating development milestone for our platform asset evorpacept in Q4 2023 by reporting positive results in a prespecified randomized interim analysis of ASPEN-06's Phase 2 clinical trial in advanced HER2-positive gastric/GEJ cancer, becoming the first CD47 blocker to demonstrate anti-tumor activity in a global randomized study in solid tumors," said Jason Lettmann, Chief Executive Officer of ALX Oncology. "On the heels of this outstanding accomplishment, our first quarter efforts were focused on ensuring optimal clinical and operational execution as we advance our robust and maturing clinical-stage pipeline of best-in-class oncology programs that are reporting multiple value inflection datapoints in the coming months."

First Quarter 2024 Highlights and Recent Developments

- Reported positive data from an ongoing investigator-sponsored trial ("IST") Phase 1/2 clinical trial of evorpacept in combination with standard-of-care in patients with relapsed or refractory B-cell non-Hodgkin lymphoma ("R/R B-NHL") in an oral presentation at the American Association for Cancer Research Annual Meeting on April 9, 2024, in San Diego.
    - Twenty patients with indolent (n=18) and aggressive (n=2) R/R B-NHL received evorpacept plus standard rituximab and lenalidomide ("R^2").
    - Evorpacept plus R^2 was well tolerated with a safety profile similar to historical R^2.
    - The combination achieved promising initial activity with a best overall response rate ("ORR") of 94% and a complete response rate ("CRR") of 83% in patients with indolent R/R B-NHL (R^2 historical CRR benchmark is 34%).
    - The clinical trial is conducted and sponsored by the University of Texas MD Anderson Cancer Center.
- Received acceptance of two evorpacept abstracts from the 2024 American Society of Cancer Oncology ("ASCO") Annual Meeting taking place in Chicago from May 31-June 4, 2024.
    - **Evorpacept plus enfortumab vedotin in patients with locally advanced or metastatic urothelial carcinoma: Phase 1a dose escalation results**
      Session Type and Title: Poster Presentation – Genitourinary Cancer – Kidney and Bladder
      Session Date and Time: Sunday, June 2, 2024, 9:00 AM – 12:00 PM CDT
      Location: Hall A
      Abstract Number: 4575 (ALX Oncology Sponsored Clinical Trial)
    - **Results of a Phase 2 study of evorpacept (ALX148), cetuximab and pembrolizumab in patients with refractory microsatellite stable metastatic colorectal cancer**
      Session Type and Title: Poster Presentation – Gastrointestinal Cancer – Colorectal and Anal
      Session Date and Time: Saturday, June 1, 2024, 1:30 PM – 4:30 PM CDT
      Location: Hall A
      Abstract Number: 3530 (IST conducted by the University of Colorado Cancer Center and sponsored by the Academic GI Cancer Consortium)
- Announced initiation of a Phase 2 IST of neoadjuvant radiation and evorpacept in combination with KEYTRUDA® (pembrolizumab) in patients with previously untreated and early-stage locally advanced, resectable, human papillomavirus-mediated oropharyngeal cancer.
    - The clinical trial is conducted and sponsored by the Hanna and Mark Gleiberman Head and Neck Cancer Center at the University of California, San Diego.
- Announced appointment of Allison Dillon, Ph.D., as Chief Business Officer.

Upcoming Clinical Milestones for Evorpacept's Development Pipeline

- Urothelial Carcinoma – Data from a Phase 1b ASPEN-07 clinical trial with PADCEV® (enfortumab vedotin-ejfv) (ASCO: Embargo to lift on full abstract May 23, 2024; Poster to be presented on June 2, 2024)
- Gastric/Gastroesophageal Junction ("GEJ") Cancer – Top line results from all 122 subjects in a Phase 2 randomized clinical trial of ASPEN-06 (July 2024)
- Breast Cancer – Top line results from a Phase 1b I-SPY TRIAL with ENHERTU® (fam-trastuzumab deruxtecan-nxki) (Q4 2024)
- Head and Neck Squamous Cell Carcinoma – Top line results from a Phase 2 randomized clinical trial of ASPEN-03 with KEYTRUDA (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)

First Quarter 2024 Financial Results:

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of March 31, 2024, were $184.5 million. Subsequent to March 31, 2024, the Company issued additional shares of common stock under its at-the-market ("ATM") offering for approximately $26.2 million in net proceeds, after deducting commissions. The Company believes its cash, cash equivalents and investments, recent proceeds from sales under its ATM offering, along with the ability to draw down an additional $40 million of its term loan 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 March 31, 2024, were $31.7 million, compared to $24.8 million for the prior-year period. The $6.9 million increase was primarily attributable to increased clinical development costs from an increased 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 evorpacept, an increase of in personnel and related costs primarily driven by headcount growth, an increase in stock-based compensation expense related to a reclassification of stock-based compensation from G&A to R&D because of the change in roles for our former Chief Executive Officer who transitioned to the Chief Scientific Officer in September 2023, and an increase in other research costs primarily due to a development milestone payment related to ScalmiBio.
- **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 March 31, 2024, were $6.0 million, compared to $7.4 million for the prior year period. The $1.4 million decrease was primarily due to lower stock-compensation expense related to a reclassification of stock-based compensation which increased R&D stock-based compensation as detailed under R&D expenses.
- **Net loss:** GAAP net loss was $35.6 million for the three months ended March 31, 2024, or ($0.71) per basic and diluted share, as compared to a GAAP net loss of $30.2 million for the three months ended March 31, 2023, or ($0.74) per basic and diluted share. Non-GAAP net loss was $28.5 million for the three months ended March 31, 2024, as compared to a non-GAAP net loss of $23.8 million for the three months ended March 31, 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 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, antibody-drug conjugates ("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.
Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 31,717	$ 24,763
General and administrative	6,045	7,440
Total operating expenses	37,762	32,203
Loss from operations	(37,762)	(32,203)
Interest income	2,622	2,311
Interest expense	(427)	(387)
Other income (expense), net	(14)	95
Net loss	$ (35,581)	$ (30,184)
Net loss per share, basic and diluted	$ (0.71)	$ (0.74)
Weighted-average shares of common stock used to compute net loss per shares, basic and diluted	50,120,758	40,862,513

Condensed Consolidated Balance Sheet Data
(in thousands)

	March 31, 2024	**December 31, 2023**
Cash, cash equivalents and investments	$ 184,486	$ 218,147
Total assets	$ 212,650	$ 242,553
Total liabilities	$ 48,455	$ 52,841
Accumulated deficit	$ (521,853)	$ (486,272)
Total stockholders' equity	$ 164,195	$ 189,712

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

	Three Months Ended March 31,	
	2024	2023
GAAP net loss, as reported	$ (35,581)	$ (30,184)
Adjustments:		
Stock-based compensation expense	7,031	6,351
Accretion of term loan discount and issuance costs	64	61
Total adjustments	7,095	6,412
Non-GAAP net loss	$ (28,486)	$ (23,772)

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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