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

August 8, 2024

SOUTH SAN FRANCISCO, Calif., Aug. 08, 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 second quarter ended June 30, 2024, and provided a corporate update.

“Our team continues to make significant progress in the advancement of our evorpacept development pipeline across multiple oncology indications,” said Jason Lettmann, Chief Executive Officer of ALX Oncology. “Data readouts across our Phase 1 and 2 clinical trials highlight the potential of evorpacept as a disruptive therapy in combination with anti-cancer antibodies and ADCs. In particular, the recent ASPEN-06 Phase 2 clinical trial readout in patients with previously treated HER2-positive advanced gastric cancer is a significant growth milestone for the Company. We are well positioned to build on our second quarter achievements and continue to advance toward our anticipated milestones in the months ahead.”

Second Quarter 2024 Highlights and Recent Developments

Evorpacept Clinical Development Program

- On July 31, ALX Oncology reported topline data from the multi-center, international ASPEN-06 Phase 2 clinical trial evaluating evorpacept in combination with 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 (NCT05002127).
  - Results demonstrated that 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.
  - The primary endpoint was confirmed overall response rate (“ORR”) with key secondary endpoints being safety, median duration of response (“mDOR”), progression-free survival (“PFS”) and overall survival (“OS”). Primary study objectives were to compare confirmed ORR of Evo-TRP to an assumed ORR of 30% for CYRAMZA (ramucirumab) and paclitaxel (“RP”) with one-sided alpha error of 0.025, and to identify a clinically meaningful contribution of Evo to TRP in ORR (delta $\geq$10%).
  - Evo-TRP achieved a confirmed ORR of 40.3% compared to 26.6% for the TRP control arm and demonstrated a mDOR 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% (p=0.095). When a comparison of Evo-TRP to the observed TRP control arm ORR of 26.6% was explored using a similar testing procedure, a p-value of p=0.027 was observed. 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 this population, Evo-TRP compared to an assumed RP control ORR of 30% yielded a p-value of p=0.030 . When Evo-TRP compared to the observed TRP ORR of 23.1% was explored using a similar testing procedure, a p-value of p=0.0038 was observed, suggesting HER2-expression strongly correlates with evorpacept efficacy and validating its mechanism of action.
- In June, ALX Oncology presented the first evorpacept combination data with an antibody-drug conjugate (“ADC”) from the Phase 1 ASPEN-07 clinical trial in patients with advanced urothelial cancer at the 2024 American Society of Cancer Oncology (“ASCO”) Annual Meeting.
  - This open-label, single-arm, clinical trial of evorpacept in combination with an approved ADC, PADCEV® (enfortumab vedotin), demonstrated promising activity and was generally well tolerated in patients with locally advanced or metastatic urothelial cancer (NCT05524545).
- In April, ALX Oncology reported positive data from the ongoing Phase 1/2 investigator-sponsored clinical trial of evorpacept in combination with standard-of-care in patients with relapsed or refractory B-cell non-Hodgkin lymphoma (NCT05025800).
  - The combination achieved promising initial activity with a best ORR of 94% and a complete response rate ("CRR") of 83% in patients with indolent R/R B-NHL (compared to rituximab and lenalidomide historical CRR benchmark of 34%).
- In April, ALX Oncology announced the initiation of a Phase 2 investigator-sponsored trial 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 (NCT05787639).

Conference Presentations

- At the 2024 ASCO Annual Meeting, ALX Oncology presented the first evorpacept combination data with an ADC from the Phase 1 ASPEN-07 clinical trial in patients with locally advanced or metastatic urothelial cancer.
    - In the open-label, single-arm, clinical trial of evorpacept in combination with an approved ADC, PADCEV® (enfortumab vedotin), demonstrated promising activity and was generally well tolerated in patients.
    - The Company also presented results of an investigator-sponsored, Phase 2 study of evorpacept, cetuximab and pembrolizumab in patients with refractory microsatellite stable metastatic colorectal cancer.
- At the 2024 American Association of Cancer Research Annual Meeting, ALX Oncology presented two evorpacept clinical abstracts including:
    - Phase 1 investigator-initiated trial of evorpacept, lenalidomide and rituximab for patients with relapsed or refractory B-cell non-Hodgkin lymphoma.
    - Phase 1 study of azacitidine in combination with evorpacept for higher-risk myelodysplastic syndrome (MDS)

Board and Executive Appointments

- ALX Oncology strengthened the Company's board and leadership team with the appointment of Alan Sandler, M.D., to its Board of Directors, and the addition of Allison Dillon, Ph.D., to its executive leadership team as Chief Business Officer.

Upcoming Clinical Milestones for Evorpacept's Development Pipeline

- ALX Oncology is well-positioned to achieve numerous milestones across multiple oncology indications in its evorpacept clinical development program:
    - Head and Neck Squamous Cell Carcinoma – Topline results from a Phase 2 randomized clinical trial of ASPEN-03 with KEYTRUDA (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)
    - Gastric/GEJ Cancer – Updated results of ASPEN-06 Phase 2 clinical trial (1H 2025)
    - Urothelial Cancer – Updated results from a Phase 1 clinical trial of ASPEN-07 in combination with PADCEV (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)

Second Quarter 2024 Financial Results:

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of June 30, 2024, were $186.2 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 June 30, 2024, were $34.7 million, compared to $29.5 million for the prior-year period. R&D expenses increased by $5.2 million during the three months ended June 30, 2024, compared to the three months ended June 30, 2023. The increase was primarily attributable to an increase of $1.7 million in preclinical costs for development of new targets, an increase of $1.2 million in personnel and related costs primarily driven by headcount growth, an increase of $1.8 million in stock-based compensation expense and an increase of $0.7 million in other research costs primarily due to absence of VAT refunds in the current quarter compared to prior year quarter.
- **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 June 30, 2024, were $6.9 million, compared to $7.3 million for the prior year period. G&A expenses decreased by $0.4 million during the three months ended June 30, 2024, compared to the three months ended June 30, 2023. The decrease was primarily attributable to a decrease of $0.8 million in stock-based compensation expense primarily due to a change in classification from the comparative periods of stock-based compensation from G&A to R&D as described above under R&D expenses, offset by an increase of $0.3 million in other G&A costs from accounting consulting and personnel costs driven by headcount growth.
- **Net loss:** GAAP net loss was $39.4 million for the three months ended June 30, 2024, or ($0.76) per basic and diluted share, as compared to a GAAP net loss of $34.2 million for the three months ended June 30, 2023, or ($0.84) per basic and diluted share. Non-GAAP net loss was $32.1 million for the three months ended June 30, 2024, as compared to a non-GAAP net loss of $27.9 million for the three months ended June 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 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 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 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.

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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 34,653	$ 29,482	$ 66,370	$ 54,245
General and administrative	6,872	7,295	12,917	14,735
Total operating expenses	41,525	36,777	79,287	68,980
Loss from operations	(41,525)	(36,777)	(79,287)	(68,980)
Interest income	2,563	2,666	5,185	4,977
Interest expense	(429)	(372)	(856)	(759)
Other (expense) income, net	(8)	324	(22)	419
Net loss	$ (39,399)	$ (34,159)	$ (74,980)	$ (64,343)
Net loss per share, basic and diluted	$ (0.76)	$ (0.84)	$ (1.47)	$ (1.57)
Weighted-average shares of common stock used to compute net loss per shares, basic and diluted	51,831,157	40,875,457	50,969,089	40,869,021

Condensed Consolidated Balance Sheet Data
(in thousands)

	June 30, 2024	December 31, 2023
Cash, cash equivalents and investments	$ 186,198	$ 218,147
Total assets	$ 214,618	$ 242,553
Total liabilities	$ 55,301	$ 52,841
Accumulated deficit	$ (561,252)	$ (486,272)
Total stockholders' equity	$ 159,317	$ 189,712

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
GAAP net loss, as reported	$ (39,399)	$ (34,159)	$ (74,980)	$ (64,343)
Adjustments:				
Stock-based compensation expense	7,252	6,237	14,283	12,588
Accretion of term loan discount and issuance costs	66	62	130	123

Total adjustments	7,318	6,299	14,413	12,711
Non-GAAP net loss	$ (32,081)	$ (27,860)	$ (60,567)	$ (51,632)

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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