ALX Oncology Reports Third Quarter 2023 Financial Results and Provides Corporate Update

November 13, 2023

SOUTH SAN FRANCISCO, Calif., Nov. 13, 2023 (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 third quarter ended September 30, 2023, and provided a corporate update.

Third Quarter 2023 Highlights and Recent Developments

- Reported positive interim Phase 2 ASPEN-06 clinical trial results for evorpacept for the treatment of advanced HER2-positive gastric/gastroesophageal junction (“GEJ”) cancer.
- Completed public offering generating gross proceeds of approximately $63.2 million.
- Realigned leadership team to match platform asset evorpacept’s maturing portfolio of programs and refined long-term development strategy.
- Advanced pipeline of nine programs evaluating evorpacept in combination with anti-cancer antibodies, antibody-drug conjugates (“ADCs”), and PD-1/PD-L1 immune checkpoint inhibitors.
- Commenced assessment of indications for future clinical studies where standard of care and market opportunities maximize evorpacept’s potential.

“This past quarter proved to be an important growth milestone for the Company highlighted by the outstanding interim results from the ASPEN-06 phase 2 clinical trial which again demonstrated evorpacept’s best-in-class safety profile and unique mechanism of action,” commented Jason Lettmann, Chief Executive Officer of ALX Oncology. “With this additional clinical validation in gastric cancer and having completed an oversubscribed public offering, we are now accelerating our portfolio of clinical programs combining evorpacept with anti-cancer antibodies as well as with ADCs and PD-1/PD-L1 immune checkpoint inhibitors and are heading into the final months of 2023 with a great deal of momentum.”

Evorpacept Pipeline Update

Throughout the third quarter, the Company continued to advance its pipeline of proprietary and partnered programs addressing multiple hematologic and solid malignancies. In October 2023, the Company reported positive interim Phase 2 data from the ASPEN-06 clinical trial, a randomized multi-center international study evaluating evorpacept in combination with trastuzumab, CYRAMZA® (ramucirumab) and paclitaxel for the treatment of patients with HER2-positive gastric/GEJ cancer, which is the first randomized clinical trial to show activity in the solid tumor setting in the CD47 space. This prespecified interim analysis represented results from 54 randomized patients with second and third line gastric/GEJ cancer, including a meaningful number of patients previously treated with ENHERTU® (trastuzumab deruxtecan) and checkpoint inhibitors. Patients were treated with evorpacept at 30 mg/kg every two weeks, mirroring the treatment cycle of trastuzumab, CYRAMZA and paclitaxel.

To summarize the key findings, a confirmed overall response rate (“ORR”) of 52% was demonstrated for the evorpacept combination treatment arm compared to 22% for the control group of trastuzumab + CYRAMZA + paclitaxel; median duration of response (“mDOR”) was not reached for the evorpacept combination treatment arm compared to 7.4 months for the control group; and the safety profile of evorpacept was consistent with the Company’s previous clinical trials and was well-tolerated. Furthermore, the interim results compare favorably to the efficacy reported for CYRAMZA + paclitaxel in the RAINBOW study (ORR of 28% and mDOR of 4.4 months), which is the regulatory benchmark and global standard of care for second line gastric/GEJ cancer.

Upcoming Clinical Milestones for Evorpacept’s Development Pipeline

- 1H 2024
  - Non-Hodgkin Lymphoma – Phase 1b investigator-sponsored trial with rituximab + lenalidomide top line results (Q1/Q2 2024)
  - Gastric/GEJ Cancer – Phase 2 ASPEN-06 randomized top line final results (Q2 2024)
- 2H 2024
  - Head and Neck Squamous Cell Carcinoma – Phase 2 ASPEN-03 with KEYTRUDA randomized top line results
  - Head and Neck Squamous Cell Carcinoma – Phase 2 ASPEN-04 with KEYTRUDA + chemotherapy randomized top line results
  - Gastric/GEJ Cancer – Phase 3 ASPEN-06 study initiation

- Urothelial Carcinoma – Phase 1b ASPEN-07 with PADCEV® (enfortumab vedotin-ejfv) top line results
- Breast Cancer – Phase 1b I-SPY study with ENHERTU top line results

Corporate Update

ALX Oncology achieved a significant corporate development milestone during the third quarter with the realignment of the Company's leadership team. Jason Lettmann, who has been involved with ALX Oncology for nearly a decade since its founding, having co-led the Company's first institutional financing and serving as a member of its Board of Directors since 2015, was appointed Chief Executive Officer in September 2023. In turn, Dr. Jaume Pons who founded ALX Oncology and served as its Chief Executive Officer since inception, transitioned to the role of President and Chief Scientific Officer. This represents an important growth milestone for the Company as it signifies the clinical maturity of evorpacept's portfolio of therapeutic candidates and enables Dr. Pons to focus on pipeline extension opportunities while continuing to generate scientific support for the platform asset.

An additional recent highlight was the closing of an underwritten public offering of common stock and pre-funded warrants in October 2023 which provided ALX Oncology with gross proceeds of approximately $63.2 million. The Company sold 8,663,793 shares of common stock, which included 1,293,103 shares of common stock pursuant to the full exercise of the underwriters' option to purchase additional shares and, in lieu of common stock to certain investors, pre-funded warrants to purchase 1,250,000 shares of common stock in the offering. The shares of common stock were sold at a public offering price of $6.38 per share (the closing price on October 4, 2023), and the pre-funded warrants were sold at a public offering price of $6.379 per pre-funded warrant.

Third Quarter 2023 Financial Results:

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of September 30, 2023, were $196.4 million. ALX Oncology believes its cash, cash equivalents, and investments along with the ability to draw down an additional $40 million of its term loan and the net proceeds from its recent public offering are sufficient to fund planned operations into early 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, 2023, were $45.8 million, compared to $29.4 million for the prior-year period. The increase was primarily attributable to an increase of $16.4 million in clinical costs from an increase in the 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 the advancement of evorpacept.
- **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, 2023, were $7.5 million, compared to $7.3 million for the prior year period.
- **Net loss:** GAAP net loss was $51.0 million for the third quarter ended September 30, 2023, or $1.24 per basic and diluted share, as compared to a GAAP net loss of $35.3 million for the third quarter ended September 30, 2022, or $0.87 per basic and diluted share. Non-GAAP net loss was $44.0 million for the third quarter ended September 30, 2023, as compared to a non-GAAP net loss of $29.1 million for the third quarter ended September 30, 2022. 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. Evorpacept has demonstrated promising clinical responses across a range of hematologic and solid malignancies in combination with a number of 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.

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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 45,766	$ 29,382	$ 100,011	$ 73,203
General and administrative	7,509	7,299	22,244	22,014
Total operating expenses	53,275	36,681	122,255	95,217
Loss from operations	(53,275)	(36,681)	(122,255)	(95,217)
Interest income	2,677	1,370	7,654	2,471
Interest expense	(391)	(2)	(1,150)	(7)
Other income (expense), net	(1)	(7)	418	(20)
Loss before income taxes	(50,990)	(35,320)	(115,333)	(92,773)
Income tax (provision) benefit	—	—		
Net loss	$ (50,990)	$ (35,320)	$ (115,333)	$ (92,773)
Net loss per share, basic and diluted	$ (1.24)	$ (0.87)	$ (2.82)	$ (2.28)
Weighted-average shares of common stock used to compute net loss per shares, basic and diluted	41,147,938	40,747,026	40,963,015	40,684,172

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

	September 30, 2023	December 31, 2022
Cash, cash equivalents and investments	$ 196,444	$ 282,906
Total assets	$ 220,107	$ 306,489
Total liabilities	$ 51,355	$ 43,025
Accumulated deficit	$ (440,800)	$ (325,467)
Total stockholders' equity	$ 168,752	$ 263,464

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
GAAP net loss, as reported	$ (50,990)	$ (35,320)	$ (115,333)	$ (92,773)
Adjustments:				
Stock-based compensation expense	6,964	6,207	19,552	17,544
Accretion of term loan discount and issuance costs	63	—	186	—
Total adjustments	7,027	6,207	19,738	17,544
Non-GAAP net loss	$ (43,963)	$ (29,113)	$ (95,595)	$ (75,229)

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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