UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 11, 2023

ALX ONCOLOGY HOLDINGS INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39386**	**85-0642577**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
323 Allerton Avenue, South San Francisco, California		**94080**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (650) 466-7125

N/A

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	ALXO	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 11, 2023, ALX Oncology Holdings Inc. (the "Company"), issued a press release announcing its financial results for the first quarter ended March 31, 2023. A copy of this press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1 hereto shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly stated by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated May 11, 2023
104	Cover Page Interactive Data File (formatted as Inline XBRL)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ALX ONCOLOGY HOLDINGS INC.

Date: May 11, 2023

By: /s/ Peter Garcia
Peter Garcia
Chief Financial Officer

Exhibit 99.1

ALX Oncology Reports First Quarter 2023 Financial Results and Provides Clinical Development and Operational Highlights

SOUTH SAN FRANCISCO, Calif., May 11, 2023 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc., ("ALX Oncology") (Nasdaq: ALXO), a clinical-stage immuno-oncology company developing therapies that block the CD47 checkpoint pathway, today reported financial results for the first quarter ended March 31, 2023 and provided clinical development and operational highlights.

"In the first quarter of 2023, we continued to make significant progress in advancing our lead program, evorpacept, through new collaborations and clinical trial starts," said Dr. Jaume Pons, Founder, President and Chief Executive Officer of ALX Oncology. "This included our recently announced clinical trial collaboration with Sanofi to evaluate evorpacept in combination with SARCLISA® in patients with multiple myeloma, and the initiation of three new clinical studies. These studies encompass our initiation of a Phase 1 trial in urothelial cancer in combination with PADCEV®, the initiation of a Phase 1 I-SPY-PI TRIAL for the treatment of patients with unresectable or metastatic HER-positive and HER2-low breast cancer in combination with ENHERTU® in partnership with Quantum Leap Healthcare Collaborative ("Quantum Leap"), and the recently announced initiation of a Phase 2 investigator-sponsored trial of evorpacept, in combination with liposomal doxorubicin and KEYTRUDA® in patients with recurrent platinum-resistant ovarian cancer."

Dr. Pons added, "We look forward to important readouts in the second half of 2023 from ASPEN-06, a randomized Phase 2 trial of evorpacept in combination with trastuzumab, paclitaxel and CYRAMZA® (ramucirumab) for the treatment of patients with HER2-positive gastric/gastroesophageal junction cancer, and from ASPEN-02, a Phase 1b clinical trial of evorpacept in combination with azacitidine in patients with myelodysplastic syndromes. Additionally, in collaboration with Tallac Therapeutics, we remain on track to file an Investigational New Drug application in the first half of this year for ALTA-002, a SIRPa Toll-like receptor agonist antibody conjugate, that will broaden our immuno-oncology pipeline beyond evorpacept."

Recent Clinical Developments for Evorpacept

- **First patient dosed in Phase 2 investigator-sponsored trial of evorpacept in combination with KEYTRUDA in patients with ovarian cancer.**
  - In May 2023, we announced the initiation of a Phase 2 investigator-sponsored trial of evorpacept in combination with liposomal doxorubicin and KEYTRUDA (pembrolizumab) in patients with recurrent platinum-resistant ovarian cancer at the UPMC Hillman Cancer Center. This is an open-label, single-arm Phase 2 clinical trial. The study is being led by Haider Mahdi, M.D., M.P.H., Assistant Professor, Department of Obstetrics, Gynecology and Reproductive Sciences, The University of Pittsburgh and UPMC Magee-Womens Research Institute.

- **Announced clinical trial collaboration with Sanofi to evaluate evorpacept in combination with SARCLISA in patients with multiple myeloma.**
    - In April 2023, we entered into a clinical trial collaboration and supply agreement with Sanofi to evaluate evorpacept and SARCLISA (isatuximab-irfc), Sanofi's monoclonal antibody that targets a specific epitope on the CD38 receptor on multiple myeloma cells, for the treatment of patients with relapsed or refractory multiple myeloma ("RRMM"). Under the terms of the agreement, Sanofi will conduct a Phase 1/2 study to evaluate the safety, efficacy, pharmacokinetics and biomarker data of evorpacept in combination with SARCLISA and dexamethasone in patients with RRMM.
- **First patient dosed in I-SPY-PI TRIAL evaluating evorpacept in combination with ENHERTU, a HER2 directed antibody-drug conjugate ("ADC"), in breast cancer.**
    - In March 2023, we announced the dosing of the first patient in the I-SPY-PI TRIAL for the treatment of patients with breast cancer. Sponsored by Quantum Leap, this Phase 1 (open label), multi-center study arm is investigating evorpacept in combination with ENHERTU (fam-trastuzumab deruxtecan-nxki) to determine the safety, tolerability and efficacy of this drug combination in patients with unresectable or metastatic HER2-positive and HER2-low breast cancer.
- **First patient dosed in ASPEN-07 study evaluating evorpacept in combination with PADCEV, an ADC, in patients with urothelial cancer ("UC").**
    - In February 2023, we announced the first patient was dosed in the Phase 1 ASPEN-07 study evaluating evorpacept in combination with PADCEV (enfortumab vedotin-ejfv), an ADC, in patients with UC. ASPEN-07 is a Phase 1, open-label, multi-center study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of evorpacept in combination with PADCEV in subjects with unresectable locally advanced or metastatic UC.

First Quarter 2023 Financial Results:

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of March 31, 2023 were $256.2 million. ALX Oncology believes its cash, cash equivalents, investments along with the ability to draw down an additional $40 million of its term loan are sufficient to fund planned operations through mid-2025.
- **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, 2023 were $24.8 million, compared to $17.1 million for the prior-year period. The increase was primarily due to an increase of $5.3 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, an increase of $1.5 million in personnel and related costs primarily driven by headcount growth, and an increase of $1.1 million in stock-based compensation expense due to additional awards granted since March 31, 2022 offset by a decrease of $0.6 million related to the Tallac Collaboration for costs related to the IND filing planned for 2023 in which the primary work was completed in 2022.

- **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, 2023 were $7.4 million, compared to $7.7 million for the prior-year period. The small decrease year over year was primarily attributable to reduced stock-based compensation expense primarily due to forfeited stock options during the quarter and a decrease in other general and administrative costs due primarily to corporate legal and patent costs.
- **Net loss:** GAAP net loss was $30.2 million for the first quarter ended March 31, 2023, or $0.74 per basic and diluted share, as compared to GAAP net loss of $24.5 million for the first quarter ended March 31, 2022, or $0.60 per basic and diluted share. Non-GAAP net loss was $23.8 million for the first quarter ended March 31, 2023, as compared to a non-GAAP net loss of $19.0 million for the first quarter ended March 31, 2022. A reconciliation of GAAP to non-GAAP financial results can be found at the end of this press 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 checkpoint pathway 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 agents. ALX Oncology intends to continue clinical development of evorpacept for the treatment of multiple solid tumor indications and hematologic malignancies.

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,	
	2023	**2022**
Operating expenses:		
Research and development	$ 24,763	$ 17,073
General and administrative	7,440	7,674
Total operating expenses	32,203	24,747
Loss from operations	(32,203)	(24,747)
Interest income	2,311	225
Interest expense	(387)	(3)
Other income (expense), net	95	(8)
Net loss	$ (30,184)	$ (24,533)
Net loss per share, basic and diluted	$ (0.74)	$ (0.60)
Weighted-average shares of common stock used to compute net loss per shares, basic and diluted	40,862,513	40,616,302

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

	March 31, 2023	**December 31, 2022**
Cash, cash equivalents and investments	$ 256,164	$ 282,906
Total assets	$ 278,138	$ 306,489
Total liabilities	$ 37,750	$ 43,025
Accumulated deficit	$ (355,651)	$ (325,467)
Total stockholders' equity	$ 240,388	$ 263,464

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

	Three Months Ended March 31,	
	2023	**2022**
GAAP net loss, as reported	$ (30,184)	$ (24,533)
Adjustments:		
Stock-based compensation expense	6,351	5,501
Accretion of term loan discount and issuance costs	61	—
Total adjustments	6,412	5,501
Non-GAAP net loss	$ (23,772)	$ (19,032)

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 represent 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 Contact:

Peter Garcia
Chief Financial Officer, ALX Oncology
(650) 466-7125 Ext. 113
peter@alxoncology.com

Argot Partners
(212) 600-1902
alxoncology@argotpartners.com

Media Contact:

Karen Sharma
MacDougall
(781) 235-3060
alx@macbiocom.com