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): August 10, 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 August 10, 2023, ALX Oncology Holdings Inc. (the "Company"), issued a press release announcing its financial results for the second quarter ended June 30, 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 August 10, 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: August 10, 2023

By: /s/ Peter Garcia

Peter Garcia

Chief Financial Officer

Exhibit 99.1

ALX Oncology Reports Second Quarter 2023 Financial Results and Provides Clinical Program Update

Advancing Phase 2/3 ASPEN-06 gastric cancer trial with data update expected in Q423

Terminating azacitidine combination development programs: ASPEN-02 in MDS and ASPEN-05 in AML

Continuing focus on combinations with anti-cancer antibodies, antibody-drug conjugates, and PD-1/PD-L1 immune checkpoint inhibitors

SOUTH SAN FRANCISCO, Calif., August 10, 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 second quarter ended June 30, 2023, and provided an update on the Company's portfolio of clinical programs in development.

During the second quarter, ALX Oncology continued to advance evorpacept's mid-stage clinical development programs highlighted by ASPEN-06 in HER2-positive gastric cancer which is on track to report data in Q423. In addition, the Company is transitioning its development strategy to purely focus on combinations with anti-cancer antibodies, antibody-drug conjugates ("ADCs"), and PD-1/PD-L1 immune checkpoint inhibitors. While well tolerated, the Company is terminating the ASPEN-02 program which evaluated evorpacept in combination with azacitidine for myelodysplastic syndromes ("MDS"), as the evorpacept combination did not substantially improve upon the historical activity of azacitidine alone. Patients currently on trial may continue in the study and the Company plans to present the full data set from the forty-five subjects at an upcoming scientific conference. Moreover, based on the initial results of ASPEN-02 and the close connection between the mechanism of action with azacitidine in MDS and acute myeloid leukemia ("AML"), the Company will also terminate the ASPEN-05 program in AML and will not initiate a Phase 1b dose optimization clinical evaluation of evorpacept in combination with azacitidine and venetoclax. Based upon this decision, resources originally earmarked for these trials will be allocated to support the Company's ongoing programs evaluating combinations with anti-cancer antibodies and PD-1/PD-L1 immune checkpoint inhibitors.

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 superior safety profile allows us to dose higher 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. ALX Oncology will focus evorpacept development with the standard-of-care agents as originally designed revolving around these two cell types, including:

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-cell"* 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.

"The second quarter proved to be an important period of progress as we advanced key programs and refined the development strategy for evorpacept, our platform asset," commented Dr. Jaume Pons, Founder, President and Chief Executive Officer of ALX Oncology. "While the efficacy results from ASPEN-02 do not warrant further sponsored clinical evaluation in MDS, we remain steadfast in our conviction that the primary mechanism of action of evorpacept is unique compared to other CD47 blockers when combined with anti-cancer antibodies, ADCs, or immune checkpoint inhibitors. Evorpacept was rationally designed with an inactive Fc domain for improved safety and synergies with anti-cancer antibody-based regimens like Herceptin, antibody-drug conjugates, as well as PD-1/PD-L1 immune checkpoint inhibitors like KEYTRUDA® (pembrolizumab). Moving forward the Company will conduct clinical trials where this mechanistic rationale is fulfilled. We move into the second half of 2023 with sufficient funding and with the momentum needed to advance our pipeline of therapeutic candidates led by ASPEN-06, a randomized Phase 2 trial combining Herceptin, CYRAMZA® and paclitaxel for the treatment of patients with HER2-positive gastric or gastroesophageal junction ("GEJ") cancer."

Clinical Highlights for Evorpacept

- **ASPEN-06 Advanced HER2-Positive Gastric/GEJ Cancer**
  - The Phase 2 (open-label)/Phase 3 (double-blind) trial of evorpacept for the treatment of patients with HER-2-positive over-expressing metastatic gastric or GEJ adenocarcinomas continues to progress. While Herceptin is currently approved in combination with cisplatin or capecitabine for HER2-positive gastric/GEJ cancers, it is not yet approved with the standard-of-care of CYRAMZA + paclitaxel. The Phase 2 portion of the ASPEN-06 study is designed to enroll 122 patients who have progressed on, or after prior HER2-directed therapy and/or platinum-containing regimens. To assess the activity of evorpacept on top of Herceptin in the Phase 2 portion of ASPEN-06, patients are randomized to receive either a four-drug combination regimen (evorpacept + Herceptin + CYRAMZA + paclitaxel) or a three-drug combination regimen (Herceptin + CYRAMZA + paclitaxel). This design enables the assessment of evorpacept's contribution to the standard of care plus Herceptin. Should the Phase 2 portion of the trial demonstrate proof of concept, the trial will progress to the Phase 3 portion where the evorpacept containing four-drug regimen will be tested against the two-drug global standard of care of CYRAMZA + paclitaxel. The mechanistic rationale of the evorpacept combination in this setting is supported by clinical data from a Phase 1 clinical trial in 18 patients with >2L HER2 positive gastric/GEJ cancer, in combination with Herceptin plus CYRAMZA and paclitaxel which demonstrated an initial ORR of 72.2% with a median duration of response (mDOR) of 14.8 months, and a median overall survival (mOS) of 17.1 months. Positive data from ASPEN-06 would support evorpacept's mechanism of action in combination with anti-cancer antibodies and provide additional developmental opportunities with other anti-cancer antibodies and ADCs.
- **Orphan drug designation ("ODD") received from the European Commission for evorpacept for the treatment of patients with gastric cancer.**
  - In June 2023, ALX Oncology received ODD from the European Commission for evorpacept for the treatment of patients with gastric/GEJ cancer. The U.S. Food and Drug Administration ("FDA") also granted ODD to evorpacept for the treatment of patients with gastric/GEJ cancer as previously announced in January 2022.

- **First patient dosed in Phase 2 investigator-sponsored trial of evorpacept in combination with KEYTRUDA® in patients with ovarian cancer.**
    - In May 2023, the Company announced the 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 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 CD38-targeting monoclonal antibody SARCLISA® in patients with multiple myeloma.**
    - In April 2023, ALX Oncology 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.

Upcoming Milestones in 2023

- Update of data from a randomized Phase 2 trial of evorpacept in combination with Herceptin, CYRAMZA and paclitaxel for the treatment of patients with HER2-positive gastric/GEJ cancer (ASPEN-06) in the second half of 2023.
- The investigational new drug ("IND") filing for ALTA-002, originally expected in the first half of 2023, has been delayed due to chemistry, manufacturing, and controls ("CMC") related issues and is planned for the first quarter of 2024.
- Expansion of the ADC platform acquired from ScalmiBio to identify clinical development candidates by the fourth quarter of 2023.

Second Quarter 2023 Financial Results

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of June 30, 2023, were $224.5 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 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 June 30, 2023, were $29.5 million, compared to $26.7 million for the prior-year period. The increase was primarily attributable to an increase of $3.9 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, offset by a decrease of $1.0 million related to the Tallac Collaboration for costs related to the IND filing planned for 2023, for 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 June 30, 2023, were $7.3 million, compared to $7.0 million for the prior year period. The increase was primarily attributable to an increase in personnel and related costs primarily driven by headcount growth.
- **Net loss:** GAAP net loss was $34.2 million for the second quarter ended June 30, 2023, or $0.84 per basic and diluted share, as compared to a GAAP net loss of $32.9 million for the second quarter ended June 30, 2022, or $0.81 per basic and diluted share. Non-GAAP net loss was $27.9 million for the second quarter ended June 30, 2023, as compared to a non-GAAP net loss of $27.1 million for the second quarter ended June 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, antibody-drug conjugates, 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,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 29,482	$ 26,748	$ 54,245	$ 43,821
General and administrative	7,295	7,041	14,735	14,715
Total operating expenses	36,777	33,789	68,980	58,536
Loss from operations	(36,777)	(33,789)	(68,980)	(58,536)
Interest income	2,666	876	4,977	1,101
Interest expense	(372)	(2)	(759)	(5)
Other income (expense), net	324	(5)	419	(13)
Net loss	$ (34,159)	$ (32,920)	$ (64,343)	$ (57,453)
Net loss per share, basic and diluted	$ (0.84)	$ (0.81)	$ (1.57)	$ (1.41)
Weighted-average shares of common stock used to compute net loss per shares, basic and diluted	40,875,457	40,687,751	40,869,021	40,652,224

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

	June 30, 2023	December 31, 2022
Cash, cash equivalents and investments	$ 224,483	$ 282,906
Total assets	$ 245,932	$ 306,489
Total liabilities	$ 33,240	$ 43,025
Accumulated deficit	$ (389,810)	$ (325,467)
Total stockholders' equity	$ 212,692	$ 263,464

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
GAAP net loss, as reported	$ (34,159)	$ (32,920)	$ (64,343)	$ (57,453)
Adjustments:				
Stock-based compensation expense	6,237	5,836	12,588	11,337
Accretion of term loan discount and issuance costs	61	—	123	—
Total adjustments	6,298	5,836	12,711	11,337
Non-GAAP net loss	$ (27,861)	$ (27,084)	$ (51,632)	$ (46,116)

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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