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): October 3, 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 8.01 Other Events.

On October 3, 2023, ALX Oncology Holdings Inc. (the "Company"), issued a press release announcing its ASPEN-06 interim data results.

As a follow-up to these ASPEN-06 interim data results, the Company would like to disclose additional information on the study protocol and interim analysis. In particular, it is important to note the following stratification factors are prespecified in the study:

- 2nd vs 3rd line
- Prior ENHERTU exposure

As defined stratification factors in the protocol, there is no population bias by arm due to either factor. Each factor is balanced by arm.

A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated October 3, 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: October 4, 2023

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

ALX Oncology Reports Positive Interim Phase 2 ASPEN-06 Clinical Trial Results of Evorpacept for the Treatment of Advanced HER2-Positive Gastric Cancer

— Evorpacept is the first CD47 blocker to show activity in a global randomized study in solid tumors

— Interim efficacy results showed the confirmed overall response rate for evorpacept combination treatment was 52% compared to 22% for control treatment

— Company to host conference call and webcast today at 8:00 AM EDT

SOUTH SAN FRANCISCO, Calif., October 3, 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 announced positive prespecified interim Phase 2 data from its ASPEN-06 clinical trial, a randomized multi-center international study evaluating evorpacept, the Company's CD47 blocking therapeutic, in combination with trastuzumab, CYRAMZA® (ramucirumab) and paclitaxel for the treatment of patients with HER2-positive gastric/gastroesophageal junction ("GEJ") cancer. This prespecified interim analysis represents 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.

Phase 2 ASPEN-06 Interim Analysis Results:

- A confirmed overall response rate ("ORR") of 52% was demonstrated for evorpacept in combination with trastuzumab + CYRAMZA + paclitaxel 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.
- The safety profile of evorpacept was consistent with previous clinical trials and was well-tolerated.
- These 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.

"The ASPEN-06 clinical trial validates the potential of evorpacept both in solid tumors and in combination with anti-cancer antibodies and these data highlight the drug's potential as a first-in-class foundational immunotherapy," said Sophia Randolph, M.D., Ph.D., Chief Medical Officer, ALX Oncology. "We are highly encouraged by these initial randomized efficacy and safety results in gastric cancer that build upon the activity previously seen in our first-in-human study and represent the first positive randomized clinical

trial data presented for any CD47 blocker. In addition, ASPEN-06 is the first global randomized study in HER2-positive gastric cancer where prior KEYTRUDA® (pembrolizumab) and ENHERTU were allowed. We look forward to reporting the final analysis from the ongoing Phase 2 ASPEN-06 study in Q2 2024 and plan to initiate the Phase 3 portion of ASPEN-06 in late 2024."

"These data in gastric cancer represent the first positive initial result in a randomized trial setting of blocking the CD47 immune checkpoint pathway with a CD47 blocker that has an inactive Fc effector function in order to treat patients living with advanced gastric cancer," said Keun Wook Lee, M.D., Ph.D., Professor at Seoul National University College of Medicine and ASPEN-06 Principal Investigator. "Patients with advanced disease face poor outcomes following progression on initial treatment with HER2-directed therapy. Evorpacept could represent a breakthrough in therapy and a potential paradigm shift in the gastric cancer care continuum."

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

Conference Call on October 3 at 8:00 am EDT

The Company will host a conference call and webcast today at 8:00 AM EDT that will feature ASPEN-06 investigator Dr. Josep Tabernero, Director of the Vall d'Hebron Institute of Oncology and Head of the Medical Oncology Department at the Vall d'Hebron University Hospital in Barcelona, Spain and past President of the European Society of Medical Oncology.

To access the live conference call, please dial (800) 715-9871 (U.S./Canada) or +44.800.260.6466 (internationally) at least 10 minutes prior to the start time and refer to conference ID 7797378. The link to the live webcast of the conference call will be posted in the News & Events section (see "Events") of the Company's website at www.alxoncology.com. An archived replay will be accessible for 90 days following the event.

About the ASPEN-06 Study

ASPEN-06 is a randomized Phase 2 (open-label) / Phase 3 (double-blinded), multi-center international study of patients with second or third line metastatic HER2-overexpressing gastric/GEJ adenocarcinoma that has progressed on or after prior HER2-directed therapy and fluoropyrimidine- or platinum-containing chemotherapy. While trastuzumab 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 fluoropyrimidine and/or platinum-containing regimens. To determine the activity of evorpacept + trastuzumab + CYRAMZA + paclitaxel, in the Phase 2 portion of ASPEN-06, patients are randomized to receive either a four-drug combination regimen (evorpacept + trastuzumab + CYRAMZA + paclitaxel) or a three-drug combination regimen (trastuzumab + CYRAMZA + paclitaxel). This design enables the assessment of evorpacept's contribution to the standard of care plus trastuzumab and to global standard of care, CYRAMZA + paclitaxel. 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.

About Gastric Cancer and Gastroesophageal Junction Cancer

Gastric cancer ("GC") begins in the cells lining the inner wall of the stomach and spreads through the outer layers and eventually the body as it grows. GC is the fifth most common cancer worldwide and the third leading cause of cancer mortality as reported by GLOBOCAN. The American Cancer Society estimates there will be 26,500 newly diagnosed cases of GC at all stages in the U.S. in 2023, and approximately 17 percent of all GC patients have HER2-positive disease. The five-year survival rate is only 5.5 percent for those patients diagnosed with metastatic disease. GC is more common in East Asian countries, with incidence rates 4 to 10 times higher than in the U.S.

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.

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.

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