

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): March 7, 2024

ALX ONCOLOGY HOLDINGS INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-39386

(Commission File Number)

85-0642577

(IRS Employer
Identification No.)

323 Allerton Avenue,
South San Francisco, California
(Address of Principal Executive Offices)

94080
(Zip Code)

650-466-7125

(Registrant's Telephone Number, Including Area Code)

Not applicable

(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 March 7, 2024, ALX Oncology Holdings Inc. (the "Company"), issued a press release announcing its financial results for the fourth quarter and full year ended December 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 March 7, 2024
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: March 7, 2024

By: /s/ Peter Garcia

Peter Garcia
Chief Financial Officer

ALX Oncology Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Corporate Update

SOUTH SAN FRANCISCO, Calif., March 7, 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 fourth quarter and full year ended December 31, 2023, and provided a corporate update.

“This past year proved to be a profound growth period for ALX Oncology highlighted by evorpaccept’s positive results in the prespecified randomized interim analysis of the ASPEN-06 Phase 2 clinical trial in advanced HER2-positive gastric/GEJ cancer,” said Jason Lettmann, Chief Executive Officer (“CEO”) of ALX Oncology. “Notably, this outcome is particularly important as it represents the first promising activity in a randomized trial in solid tumors in the CD47 space and further underscores evorpaccept’s differentiation. Over the next 12-18 months, we expect to report multiple value inflection datapoints, with the goal of advancing evorpaccept’s potential beyond anti-cancer antibodies through ongoing combination studies with ADCs and checkpoint inhibitors. With nine ongoing trials, our goal is to expand evorpaccept’s value to other tumor types including breast, NHL, multiple myeloma and urothelial cancers as well as accelerate our efforts to identify new indications around this highly differentiated asset.”

Fourth Quarter 2023 Highlights

- Appointed long-standing board member, Jason Lettmann to CEO, while co-founder and previous CEO, Jaume Pons, Ph.D., transitioned to Chief Scientific Officer in September.
- Reported positive results from a prespecified interim analysis of the Phase 2 randomized multi-center international clinical trial of ASPEN-06 for the treatment of advanced HER2-positive gastric/gastroesophageal junction (“GEJ”) cancer in October.
 - o Key findings from the 54 randomized subjects, which included those previously treated with ENHERTU[®] (fam-trastuzumab deruxtecan-nxki) and/or immune checkpoint inhibitors, reported a confirmed overall response rate (“ORR”) of 52 percent in the evorpaccept combination treatment arm compared to 22 percent for the control group of trastuzumab + CYRAMZA[®] (ramucirumab) + paclitaxel (“TRP”).
 - o Median duration of response (“mDOR”) was not reached for the evorpaccept TRP combination treatment arm compared to 7.4 months for the control group of TRP.
 - o The safety profile of evorpaccept was consistent with the Company’s previous clinical trials and remained well-tolerated in this reported treatment combination.
 - o The interim results compared favorably to the efficacy results reported for CYRAMZA + paclitaxel in the RAINBOW study (ORR of 28 percent and mDOR of 4.4 months), which currently serves as the regulatory benchmark and global standard-of-care for second-line gastric/GEJ cancer.
- Executed an oversubscribed underwritten public offering that generated gross proceeds of approximately \$63.2 million during October, which helps to extend the Company’s expected cash runway into early 2026. The follow-on offering closely followed the report of the positive

interim analysis of the Phase 2 ASPEN-06 clinical trial in advanced HER2-positive gastric/GEJ cancer.

- o ALX Oncology 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.

Anticipated 2024 Clinical Milestones for Evorpcept's Maturing Pipeline Development

- Non-Hodgkin Lymphoma – Data from a Phase 1b IST with rituximab + lenalidomide will be presented in an oral presentation in a Clinical Trials Minisymposium session at the AACR Annual Meeting 2024 on Tuesday, April 9, 2024, from 2:30 pm – 4:30 pm PT.
- Urothelial Carcinoma – Data from a Phase 1b ASPEN-07 clinical trial with PADCEV® (enfortumab vedotin-ejfv) (Q2 2024)
- Gastric/GEJ Cancer – Top line results from all 122 subjects in a Phase 2 randomized clinical trial of ASPEN-06 (June-July 2024)
- Breast Cancer – Top line results from a Phase 1b I-SPY TRIAL with ENHERTU (Q4 2024)
- Head and Neck Squamous Cell Carcinoma – Top line results from a Phase 2 randomized clinical trial of ASPEN-03 with KEYTRUDA® (pembrolizumab) (Q4 2024/Q1 2025)
- Head and Neck Squamous Cell Carcinoma – Top line results from a Phase 2 randomized clinical trial of ASPEN-04 with KEYTRUDA and chemotherapy (Q4 2024/Q1 2025)
- Gastric/GEJ Cancer – Initiation of Phase 3 registrational randomized clinical trial for evorpcept (Q4 2024)

2023 Full Year and Fourth Quarter Financial Results:

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of December 31, 2023, were \$218.1 million. The Company 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 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, evorpcept, and R&D employee-related expenses. These expenses for the three months ended December 31, 2023, were \$41.8 million, compared to \$25.2 million for the prior-year period. The increase was primarily attributable to an increase of \$13.6 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 evorpcept. R&D expenses for the year ended December 31, 2023 were \$141.8 million, compared to \$98.4 million for the prior-year period.

- **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 December 31, 2023, were \$6.2 million, compared to \$7.0 million for the prior year period. G&A expenses for the year ended December 31, 2023 were \$28.5 million, compared to \$29.0 million for the prior-year period.
- **Net loss:** GAAP net loss was \$45.5 million for the fourth quarter ended December 31, 2023, or (\$0.93) per basic and diluted share, as compared to a GAAP net loss of \$30.7 million for the fourth quarter ended December 31, 2022, or (\$0.75) per basic and diluted share. GAAP net loss was \$160.8 million for the year ended December 31, 2023, or (\$3.74) per basic and diluted share, as compared to a GAAP net loss of \$123.5 million for the year ended December 31, 2022, or (\$3.03) per basic and diluted share. Non-GAAP net loss was \$38.7 million for the fourth quarter ended December 31, 2023, as compared to a non-GAAP net loss of \$24.4 million for the fourth quarter ended December 31, 2022. Non-GAAP net loss was \$134.3 million for the year ended December 31, 2023, as compared to a non-GAAP net loss of \$99.6 million for the year ended December 31, 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, evorpaccept, is a next generation CD47 blocking therapeutic that combines a high-affinity CD47 binding domain with an inactivated, proprietary Fc domain. To date, evorpaccept has been dosed in over 500 subjects and has demonstrated promising activity and a 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 evorpaccept with anti-cancer antibodies, ADCs, and PD-1/PD-L1 immune checkpoint inhibitors.

Evorpaccept’s Unique Profile: Anchored by a Rational Design and Dual Development Pillars

Rationally engineered with an inactive Fc effector function, evorpaccept’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):** evorpaccept 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):** evorpaccept 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.
Consolidated Statements of Operations
(unaudited for the three months ended December 31, 2023 and 2022)
(in thousands, except share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 41,784	\$ 25,197	\$ 141,795	\$ 98,400
General and administrative	6,239	7,022	28,483	29,036
Total operating expenses	48,023	32,219	170,278	127,436
Loss from operations	(48,023)	(32,219)	(170,278)	(127,436)
Interest income	2,995	1,807	10,649	4,278
Interest expense	(415)	(231)	(1,565)	(238)
Other income (expense), net	(29)	(2)	389	(22)
Loss before income taxes	(45,472)	(30,645)	(160,805)	(123,418)
Income tax (provision) benefit	—	(64)	—	(64)
Net loss	\$ (45,472)	\$ (30,709)	\$ (160,805)	\$ (123,482)
Net loss per share, basic and diluted	\$ (0.93)	\$ (0.75)	\$ (3.74)	\$ (3.03)
Weighted-average shares of common stock used to compute net loss per shares, basic and diluted	48,995,998	40,755,520	42,987,767	40,699,612

Consolidated Balance Sheet Data
(in thousands)

	December 31, 2023	December 31, 2022
Cash, cash equivalents and investments	\$ 218,147	\$ 282,906
Total assets	\$ 242,553	\$ 306,489
Total liabilities	\$ 52,841	\$ 43,025
Accumulated deficit	\$ (486,272)	\$ (325,467)
Total stockholders' equity	\$ 189,712	\$ 263,464

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
GAAP net loss, as reported	\$ (45,472)	\$ (30,709)	\$ (160,805)	\$ (123,482)
Adjustments:				
Stock-based compensation expense	6,721	6,295	26,273	23,839
Accretion of term loan discount and issuance costs	64	44	250	44
Total adjustments	6,785	6,339	26,523	23,883
Non-GAAP net loss	\$ (38,687)	\$ (24,370)	\$ (134,282)	\$ (99,599)

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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