

**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 17, 2021

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.)

866 Malcolm Road, Suite 100
Burlingame, California
(Address of Principal Executive Offices)

94010
(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, \$0.001 par value 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 17, 2021, ALX Oncology Holdings Inc. (the "Company"), issued a press release announcing its financial results for the first quarter ended March 31, 2021. 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 17, 2021

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 17, 2021

By: /s/ Peter Garcia

Peter Garcia
Chief Financial Officer

ALX Oncology Reports First Quarter 2021 Financial Results and Provides Clinical Development and Operational Highlights

BURLINGAME, Calif., May 17, 2021 -- 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, 2021 and provided recent clinical development and operational highlights.

“Having achieved important milestones in the first quarter of 2021, we look forward to what we expect will be another exciting year of substantial progress for our lead candidate, ALX148, as we prepare to initiate several clinical trials in combination with other agents in a variety of indications, as well as multiple anticipated data readouts during the year,” said Jaume Pons, Ph.D., Founder, President and Chief Executive Officer of ALX Oncology.

“We recently dosed the first patient in our Phase 2 study (ASPEN-03) to evaluate ALX148 in combination with KEYTRUDA® in first line treatment of patients with PD-L1 expressing metastatic or unresectable, recurrent head and neck squamous cell carcinoma (“HNSCC”) and we are preparing to initiate a second Phase 2 study (ASPEN-04) in the coming weeks with ALX148 in combination with KEYTRUDA and standard chemotherapy in a similar patient population but regardless of PD-L1 expression status. We also look forward to presenting additional results from a Phase 1b study (ASPEN-01) of ALX148 in combination with trastuzumab, ramucirumab and paclitaxel in patients with HER2-positive gastric/gastroesophageal junction cancer (“G/GEJ”) at the upcoming ESMO 23rd World Congress on Gastrointestinal Cancer in July,” Dr. Pons continued.

Recent Clinical Developments for ALX148:

- **Phase 2 ASPEN-03 study**

In May 2021, dosed first patient in the Phase 2 ASPEN-03 study evaluating the combination of ALX148, a next generation CD47 blocker, with KEYTRUDA® (pembrolizumab), Merck’s anti-PD-1 therapy, for the treatment of patients with HNSCC.

- **Strengthened IP Portfolio Covering ALX148**

In April 2021, ALX Oncology announced that the post-grant review period for granted U.S. Patent No. 10,696,730 ended on March 30, 2021. This patent covers the lead product candidate ALX148, a next generation CD47-blocking therapeutic that combines a high-affinity signal regulatory protein-alpha (“SIRPα”) CD47-binding domain fused with an inactivated, proprietary Fc domain. The U.S. patent is not expected to expire before August 5, 2036, excluding patent term adjustments or extensions.

Recent Operational Highlights:

- In May 2021, reported the appointment of Shelly Pinto as VP Finance and Chief Accounting Officer. Ms. Pinto was most recently VP of Finance and Operations at Tizona Therapeutics and is a Certified Public Accountant.

First Quarter 2021 Financial Results:

- **Cash and Cash Equivalents:** Cash and cash equivalents as of March 31, 2021 were \$429.9 million. ALX Oncology believes its cash and cash equivalents is sufficient to fund planned operations through 2024.
 - **Net loss:** Generally accepted accounting principles (GAAP) net loss attributable to common stockholders was \$14.2 million, or \$0.35 per basic and diluted share and \$7.4 million, or \$2.37 per basic and diluted share for the three months ended March 31, 2021, and 2020, respectively. Non-GAAP net loss attributable to common stockholders was \$12.4 million for the three months ended March 31, 2021, as compared to \$7.1 million for the three months ended March 31, 2020. A reconciliation of GAAP to non-GAAP financial results can be found at the end of this news release.
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- **Related-party Revenue:** There was no related-party revenue for the three months ended March 31, 2021, compared to \$0.7 million for the same prior-year period. The decrease in related-party revenue relates to the termination of the research and development agreement with Tallac Therapeutics, Inc. in July 2020.
- **Research and Development (“R&D”) Expenses:** R&D expenses consist primarily of pre-clinical, clinical and manufacturing expenses related to the development of ALX148. These expenses for the three months ended March 31, 2021, were \$9.8 million, compared to \$3.8 million for the same prior-year period. The increase of \$6.0 million was primarily attributable to an increase of \$5.1 million in clinical and development costs due to higher expenses associated with increased pre-clinical, clinical and other research costs in advancement of our current lead product candidate, ALX148, as well as an increase of \$0.5 million in stock-based compensation expense primarily resulting from additional stock option award grants at higher fair values. In addition, we incurred increased personnel-related costs of \$0.4 million due to headcount growth.
- **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, 2021, were \$4.4 million, compared to \$1.5 million for the same prior-year period. The increase of \$2.9 million was primarily due to a \$1.2 million increase in stock-based compensation expense primarily resulting from additional stock option award grants at higher fair values, an increase of \$0.7 million in personnel-related costs due to headcount growth, an increase of \$0.5 million of directors and officers liability insurance premium, and an increase of \$0.3 million in professional service fees associated with increased accounting and compliance activities.

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, ALX148, is a next generation CD47 blocking therapeutic that combines a high-affinity CD47 binding domain with an inactivated, proprietary Fc domain. ALX148 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 ALX148 for the treatment of a range of solid tumor indications as well as myelodysplastic syndromes (“MDS”) and acute myeloid leukemia (“AML”). For more information, please visit ALX Oncology’s website at www.alxoncology.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. 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 statements include, but are not limited to, statements regarding ALX Oncology’s financial condition, results of operations and sufficiency of its cash and cash equivalents to fund its planned operations as well as statements about ALX Oncology’s clinical pipeline, including the timing of clinical trial initiations and data releases, and the expectations regarding the beneficial characteristics, safety, efficacy and therapeutic effects of ALX148. 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 Report on Form 10-K, filed with the SEC on March 18, 2021, and other documents ALX Oncology subsequently 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 and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended	
	March 31,	
	2021	2020
Related-party revenue	\$ —	\$ 655
Operating expenses:		
Research and development	9,849	3,828
General and administrative	4,359	1,473
Cost of services for related-party revenue	—	596
Total operating expenses	<u>14,208</u>	<u>5,897</u>
Loss from operations	<u>(14,208)</u>	<u>(5,242)</u>
Interest expense	(3)	(215)
Other income, net	26	7
Loss before income taxes	<u>(14,185)</u>	<u>(5,450)</u>
Income tax provision	—	(4)
Net loss and comprehensive loss	<u>(14,185)</u>	<u>(5,454)</u>
Cumulative dividends allocated to preferred stockholders	—	(1,983)
Net loss attributable to common stockholders	<u>\$ (14,185)</u>	<u>\$ (7,437)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.35)</u>	<u>\$ (2.37)</u>
Weighted-average shares of common stock used to compute net loss per share attributable to common stockholders, basic and diluted	<u>40,055,435</u>	<u>3,143,159</u>

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

	March 31, 2021	December 31, 2020
Cash and cash equivalents	\$ 429,855	\$ 434,219
Total assets	\$ 432,910	\$ 436,054
Total liabilities	\$ 14,426	\$ 6,209
Total stockholders' equity	\$ 418,484	\$ 429,845

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

	Three Months Ended March 31,	
	2021	2020
GAAP net loss attributable to common stockholders, as reported	\$ (14,185)	\$ (7,437)
Adjustments:		
Stock-based compensation expense	1,800	151
Accretion of term loan	—	108
Mark-to-market adjustment on financial instruments	—	100
Total adjustments	1,800	359
Non-GAAP net loss attributable to common stockholders	<u>\$ (12,385)</u>	<u>\$ (7,078)</u>

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 Securities and Exchange Commission 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 attributable to common stockholders” is not based on any standardized methodology prescribed by GAAP and represent GAAP net loss adjusted to exclude (1) stock-based compensation expense, (2) accretion of term loan (interest expense related to ALX Oncology’s amortization of debt discount) and (3) mark-to-market adjustment on financial instruments (which include preferred stock warrants and derivatives). 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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