
**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 14, 2024

AN2 Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-41331
(Commission File Number)

82-0606654
(IRS Employer
Identification No.)

1800 El Camino Real, Suite D
Menlo Park, California
(Address of Principal Executive Offices)

94027
(Zip Code)

Registrant's Telephone Number, Including Area Code: 650 331-9090

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	ANTX	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 14, 2024, AN2 Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2024. The full text of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

All of the information furnished in this Item 2.02 and Item 9.01 (including Exhibit 99.1) shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be 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 set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press Release of AN2 Therapeutics Inc. dated May 14, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

AN2 Therapeutics, Inc.

Date: May 14, 2024

By: _____ /s/ Eric Easom

Eric Easom
Chief Executive Officer and Director
(Principal Executive Officer)

AN2 Therapeutics Reports First Quarter 2024 Financial Results and Recent Business and Scientific Highlights

Plan to report Phase 2 topline results in August 2024 from ongoing Phase 2/3 trial (EBO-301) in treatment-refractory Mycobacterium avium Complex (TR-MAC)

Phase 3 continues for 97 patients enrolled before the voluntary enrollment pause; lifting of the Phase 3 enrollment pause to be determined after review of unblinded Phase 2 data and discussions with the FDA

Cash, cash equivalents, and investments of \$118.1 million at March 31, 2024

Menlo Park, CA – May 14, 2024 – AN2 Therapeutics, Inc. (Nasdaq: ANTX), a clinical-stage biopharmaceutical company focused on developing treatments for rare, chronic, and serious infectious diseases with high unmet needs, today reported financial results for the quarter ended March 31, 2024.

“The Phase 2 topline data, expected to be available in August, will include the first clinical efficacy data for eptraborole in patients with treatment-refractory MAC. The patients enrolled in EBO-301 are highly refractory with limited to no treatment options; and background regimens available provide little if any benefit,” said Eric Easom, Co-Founder, President and Chief Executive Officer. “We hope to see data demonstrating that eptraborole on top of background therapy will show benefit in these toughest to treat patients. The Phase 2 data package will be critical to informing the path forward for eptraborole in patients with treatment refractory MAC.”

First Quarter & Recent Business Updates:

Eptraborole Pivotal Phase 2/3 Clinical Study in TR-MAC Lung Disease

This double-blind, placebo-controlled trial is comparing eptraborole plus a background regimen versus placebo plus background regimen in patients with TR-MAC lung disease. In February 2024, the Company announced that it had voluntarily paused Phase 3 enrollment in the seamless Phase 2/3 clinical trial, pending further data review. While the Phase 3 part of the trial is paused for new enrollment, the Company is continuing to dose currently enrolled patients (n=97) under the existing protocol. The voluntary pause was instituted following an analysis of blinded aggregate data from the ongoing Phase 2 study, which showed potentially lower than expected efficacy. A blinded review of the aggregate baseline patient demographics points to a highly refractory patient population with high incidence of resistance to background regimens, prolonged nontuberculous mycobacteria (NTM) lung disease and high levels of cavitory disease; the study population also includes patients who are refractory to Arikayce, the only FDA-approved drug for refractory NTM caused by MAC. The decision to pause Phase 3 enrollment was not due to safety concerns.

The Company expects to announce topline data from the Phase 2 part of the trial in August 2024. Continuation of enrollment in the Phase 3 part of the study will be determined after reviewing the unblinded Phase 2 data and following discussions with FDA.

Selected First Quarter Financial Results

- **Research and Development (R&D) Expenses:** R&D expenses for the first quarter of 2024 were \$14.7 million compared to \$12.0 million for the same period during 2023 due to increased clinical trial expenses, personnel-related expenses, consulting and outside services, and other expenses, partially offset by lower chemistry manufacturing and controls expenses and lower costs associated with research studies.
 - **General and Administrative (G&A) Expenses:** G&A expenses for the first quarter of 2024 were \$3.6 million, compared to \$4.1 million for the same period during 2023 due to a decrease in professional and outside services related to IPO expenses in 2023 and a decrease in insurance expenses, partially offset by an increase in personnel-related expenses.
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- **Other Income, Net:** Other income, net for the first quarter of 2024 was \$1.7 million, compared to \$0.7 million for the same period during 2023 due to increased interest and investment income based on higher interest rates and higher cash, cash equivalents, and investment balances.
- **Net loss:** Net loss for the first quarter of 2024 was \$16.6 million, compared to \$15.3 million for the same period during 2023.
- **Cash Position:** The Company had cash, cash equivalents, and investments of \$118.1 million at March 31, 2024.

About AN2 Therapeutics, Inc.

AN2 Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing treatments for rare, chronic, and serious infectious diseases with high unmet needs. Our initial candidate is epetaborole, which we are studying as a once-daily, oral treatment with a novel mechanism of action for patients with nontuberculous mycobacteria (NTM) lung disease, a rare, chronic, and progressive infectious disease caused by bacteria known as mycobacteria, that leads to irreversible lung damage and can be fatal. For more information, please visit our website at www.an2therapeutics.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements expressed or implied in this press release include, but are not limited to, statements regarding: reporting topline data from Phase 2 of the EBO-301 trial; continued analysis and expectations regarding incoming data; continuation of the enrollment pause in Phase 3 of the EBO-301 trial; the occurrence and outcome of FDA discussions; potential of epetaborole; and other statements that are not historical fact. These statements are based on AN2's current estimates, expectations, plans, objectives, and intentions, are not guarantees of future performance and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, but are not limited to, risks and uncertainties related to: the number of patients who remain enrolled in the Phase 2/3 trial; the ability of AN2 to resume enrollment in the Phase 2/3 trial, in the event the determination to resume enrollment is made; discussions with FDA; the ability of AN2 to effectively and timely make amendments to the Phase 2/3 pivotal trial design based on its analysis of the Phase 2 portion of the study and/or pursuant to additional FDA feedback; possible changes to AN2's plans or priorities as it assesses study data; potential for protocol modifications, redesign, or study termination; timely enrollment of patients in AN2's existing and future clinical trials; AN2's ability to procure sufficient supply of its product candidate for its existing and future clinical trials; the potential for results from clinical trials to differ from preclinical, early clinical, preliminary, or expected results; significant adverse events, toxicities, or other undesirable side effects associated with AN2's product candidate; the significant uncertainty associated with AN2's product candidate ever receiving any regulatory approvals; AN2's ability to obtain, maintain, or protect intellectual property rights related to its current and future product candidates; implementation of AN2's strategic plans for its business and current and future product candidates; the sufficiency of AN2's capital resources and need for additional capital to achieve its goals; global macroeconomic conditions and global conflicts; and other risks, including those described under the heading "Risk Factors" in AN2's Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, and AN2's other reports filed with the U.S. Securities and Exchange Commission (SEC). These filings, when made, are available on the investor relations section of AN2's website at www.an2therapeutics.com and on the SEC's website at www.sec.gov. Forward-looking statements contained in this press release are made as of this date, and AN2 undertakes no duty to update such information except as required under applicable law.

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AN2 THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended	
	March 31,	
	2024	2023
Operating expenses:		
Research and development	\$ 14,655	\$ 11,985
General and administrative	3,641	4,054
Total operating expenses	<u>18,296</u>	<u>16,039</u>
Loss from operations	(18,296)	(16,039)
Other income, net	1,679	716
Net loss attributable to common stockholders	<u>\$ (16,617)</u>	<u>\$ (15,323)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.56)</u>	<u>\$ (0.79)</u>
Weighted-average number of shares used in computing net loss per share, basic and diluted	<u>29,763,278</u>	<u>19,385,646</u>
Other comprehensive loss:		
Unrealized (loss) gain on investments	(222)	199
Comprehensive loss	<u>\$ (16,839)</u>	<u>\$ (15,124)</u>

AN2 THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(in thousands)

	March 31,	December 31,
	2024	2023
	(unaudited)	
Assets		
Cash and cash equivalents	\$ 24,693	\$ 15,647
Short-term investments	89,517	91,648
Prepaid expenses and other current assets	2,103	3,212
Long-term investments	3,904	27,194
Other assets, long-term	1,043	1,043
Total assets	<u>\$ 121,260</u>	<u>\$ 138,744</u>
Liabilities and stockholders' equity		
Accounts payable	\$ 2,433	\$ 2,676
Other current liabilities	8,230	11,367
Total liabilities	<u>10,663</u>	<u>14,043</u>
Stockholders' equity	110,597	124,701
Total liabilities and stockholders' equity	<u>\$ 121,260</u>	<u>\$ 138,744</u>

