

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 28, 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 March 28, 2024, AN2 Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2023. 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 March 28, 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: March 28, 2024

By: _____ /s/ Eric Easom
Eric Easom
Chief Executive Officer and Director
(Principal Executive Officer)

AN2 Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Recent Business and Scientific Highlights

Phase 2/3 trial (EBO-301) in treatment-refractory Mycobacterium avium Complex (TR-MAC) continues with Phase 2 topline results expected in summer 2024 and Phase 3 enrollment pause in place during continued analysis of incoming data; plan to discuss with FDA

Cash, cash equivalents and investments of \$134.5 million at December 31, 2023

Menlo Park, CA – March 28, 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 fourth quarter and year ended December 31, 2023.

“AN2’s cash position remains strong as we advance our innovative boron-based pipeline. Following the recent meeting of the independent Data Safety Monitoring Board, we continue to believe in the potential of epetraborole to become an important component of the backbone therapy for NTM lung disease,” said Eric Easom, Co-Founder, President and Chief Executive Officer. “Patients enrolled in the epetraborole Phase 2/3 trial in treatment refractory lung disease caused by MAC continue to be dosed while new enrollment in the Phase 3 part of the trial remains paused. Patients in the Phase 2 trial have reached the six-month mark, and we plan to report topline results this summer. Analysis of the baseline patient demographics from the trial show a highly complex and refractory patient population, which we plan to discuss with the FDA in the coming months.”

Easom continued, “We are pleased with the momentum across our boron chemistry pipeline. We signed a licensing agreement last fall with the University of Georgia Research Foundation to develop a novel therapy for chronic Chagas disease, which is in late preclinical development and we are also progressing an IV formulation of epetraborole for melioidosis, in addition to advancing other research programs. We believe epetraborole, along with these other promising boron therapy candidates, has the opportunity to help address significant unmet patient need.”

Fourth Quarter & Recent Business Updates:

Epetraborole Pivotal Phase 2/3 Clinical Study in TR-MAC Lung Disease. This double-blind, placebo-controlled trial is comparing epetraborole 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. 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. The aggregate baseline characteristics reveal patients with complex comorbidities, prolonged NTM lung disease, and high levels of cavitory disease, as well as patients who are refractory to Arikayce, the only FDA-approved drug for refractory NTM caused by MAC, as part of their background regimen. The decision to pause Phase 3 enrollment was not due to safety concerns. While the Phase 3 part of the trial is paused for new enrollment (n=97), the Company is continuing to dose existing patients enrolled in the Phase 2/3 trial under the existing protocol.

The Company plans to provide further details on the epetraborole development strategy after discussion with FDA and continued review of the accumulated blinded data. The Company expects to announce topline data from the Phase 2 part of the trial in summer 2024.

Presented New Epetraborole Data at Infectious Disease Society of America (IDSA) IDWeek 2023 Conference. In October 2023, three poster presentations and two oral presentations were presented at the IDWeek 2023 conference that detailed the potential of epetraborole in treating NTM (nontuberculous mycobacteria) lung disease caused by MAC and Mycobacterium abscessus. The Company also presented data on its melioidosis program.

Executed License from University of Georgia Research Foundation to Develop Boron-Containing Product Candidates for Chagas Disease. In October 2023, AN2 announced that it had executed an exclusive license from the

University of Georgia Research Foundation to advance the development of a boron-containing small molecule, AN2-502998 (formerly AN15368), for Chagas disease. This boron-based molecule was originally discovered by researchers at Anacor Pharmaceuticals, Inc. (a wholly owned subsidiary of Pfizer), which included some of the current AN2 team, and the University of Georgia, with grant funding from the Wellcome Trust. AN2-502998 has advanced into late preclinical development for chronic Chagas disease.

Received Grant from Bill & Melinda Gates Foundation. In September 2023, AN2 announced that it received a grant from the Bill & Melinda Gates Foundation to discover novel, boron containing small molecules for the treatment of tuberculosis and malaria.

Selected Fourth Quarter and Full Year 2023 Financial Results

- **Research and Development (R&D) Expenses:** R&D expenses for the full year 2023 were \$54.9 million, compared to \$29.5 million in the prior year. R&D expenses for the fourth quarter of 2023 were \$14.9 million, compared to \$8.8 million for the same period during 2022 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.
- **General and Administrative (G&A) Expenses:** G&A expenses for the full year 2023 were \$14.8 million, compared to \$12.8 million in the prior year. G&A expenses for the fourth quarter of 2023 were \$3.9 million, compared to \$3.7 million for the same period during 2022 due to increased personnel-related expenses and professional service fees, partially offset by a decrease in insurance expenses.
- **Other Income, Net:** Other income, net for the full year 2023 was \$4.9 million, compared to \$1.3 million in the prior year. Other income, net for the fourth quarter of 2023 was \$1.9 million, compared to \$0.6 million for the same period in 2022 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 full year 2023 was \$64.7 million, compared to \$41.0 million in the prior year. Net loss for the fourth quarter of 2023 was \$16.9 million, compared to \$11.8 million for the same period during 2022.
- **Cash Position:** The Company had cash, cash equivalents and investments of \$134.5 million at December 31, 2023.

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 epetraborole, 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: continued analysis of incoming data; continuation of the Phase 2 and 3 parts of the EBO-301 trial; continuation of the enrollment pause in Phase 3 of the EBO-301 trial; FDA meetings and discussions; reporting of topline data from Phase 2 of the EBO-301 trial and other updates; potential of epetraborole, AN-502998, and the Company's boron chemistry pipeline; timing and initiation of preclinical and clinical studies; the advancement of candidates for Chagas disease and melioidosis; 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 recommendations of the Data Safety Monitoring Board following future reviews of unblinded data; 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; meetings 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 December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 14,919	\$ 8,752	\$ 54,871	\$ 28,511
Research and development—related party	—	—	—	1,000
General and administrative	3,896	3,724	14,764	12,751
Total operating expenses	18,815	12,476	69,635	42,262
Loss from operations	(18,815)	(12,476)	(69,635)	(42,262)
Other income, net	1,917	634	4,903	1,306
Net loss	(16,898)	(11,842)	(64,732)	(40,956)
Accretion to redemption value and cumulative dividends on preferred stock	—	—	—	(1,820)
Net loss attributable to common stockholders	\$ (16,898)	\$ (11,842)	\$ (64,732)	\$ (42,776)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.57)	\$ (0.61)	\$ (2.74)	\$ (2.79)
Weighted-average number of shares used in computing net loss per share, basic and diluted	29,735,397	19,352,854	23,600,107	15,340,134
Other comprehensive loss:				
Unrealized gain (loss) on investments	397	167	649	(347)
Comprehensive loss	\$ (16,501)	\$ (11,675)	\$ (64,083)	\$ (41,303)

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

	December 31,	
	2023	2022
Assets		
Cash and cash equivalents	\$ 15,647	\$ 27,219
Short-term investments	91,648	68,840
Prepaid expenses and other current assets	3,212	2,562
Long-term investments	27,194	3,219
Other assets, long-term	1,043	720
Total assets	\$ 138,744	\$ 102,560
Liabilities and stockholders' equity		
Accounts payable	\$ 2,676	\$ 2,122
Other current liabilities	11,367	5,064
Other liabilities, long-term	—	2
Total liabilities	14,043	7,188
Stockholders' equity	124,701	95,372
Total liabilities and stockholders' equity	\$ 138,744	\$ 102,560

