

**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): November 09, 2023

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 November 9, 2023, AN2 Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the third quarter ended September 30, 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 November 9, 2023
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: November 9, 2023

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

AN2 Therapeutics Reports Third Quarter 2023 Financial Results and Recent Business and Scientific Highlights

- Enrollment well underway in Phase 3 part of pivotal Phase 2/3 study of epetraborole in treatment-refractory *Mycobacterium avium* complex (MAC) lung disease
- On track to announce Phase 2 clinical data summer 2024
- Cash and investments of \$150.2 million at September 30, 2023; cash runway anticipated to fund operations through summer 2025

Menlo Park, CA – November 9, 2023 – 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 September 30, 2023.

“We are incredibly proud of the significant milestones achieved recently and over the past quarter. In September, we initiated enrollment in the Phase 3 part of our pivotal Phase 2/3 clinical trial for epetraborole in treatment-refractory MAC lung disease after fully enrolling the Phase 2 part of the trial. At IDWeek in October 2023, we presented preclinical data showing the potential for epetraborole to address unmet needs for patients with *Mycobacterium abscessus* lung infections, for whom current treatment guidelines recommend four or more antibiotics, some of which are IV-only. There is an urgent need for more effective, novel, oral agents for this difficult-to-treat disease,” said Eric Easom, Co-Founder, President and Chief Executive Officer. “In addition to our promising progress on the epetraborole program, and consistent with our company’s mission to support global health programs, we signed key agreements during the quarter that leverage our boron-based platform for global health. Notably, in September, we received a grant from the Bill and Melinda Gates Foundation to discover novel small molecules for the treatment of tuberculosis and malaria, and in October, we announced a license agreement with the University of Georgia Research Foundation to advance the development of AN2-502998, a novel, boron-containing small molecule for Chagas disease.”

Third Quarter & Recent Business Updates:

Initiated Phase 3 Part of Pivotal Phase 2/3 Clinical Trial for Epetraborole. In September, the Company announced that it had commenced the Phase 3 part of the Phase 2/3 clinical trial after fully enrolling 80 patients in the Phase 2 part of the trial evaluating once-daily, oral epetraborole for treatment-refractory MAC lung disease. The trial is being conducted at over 100 clinical sites across the U.S., Japan, South Korea, and Australia. AN2 expects to announce top-line data from the Phase 2 portion of the trial in summer 2024.

Presented New Epetraborole Data at Infectious Disease Society of America (IDSA) IDWeek 2023 Conference. In October, three poster presentations and two oral presentations were presented at the IDWeek 2023 conference that detailed the potential of epetraborole in treating NTM lung disease and melioidosis.

Executed License from University of Georgia Research Foundation to Develop Boron-Containing Product Candidates for Chagas Disease. In October, 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) and the University of Georgia, with grant funding from Wellcome. To date, AN2’s preclinical activities have been supported using non-dilutive grant funding from Wellcome and are conducted in partnership with Professor Rick Tarleton, Ph.D., from the University of Georgia, an expert in Chagas disease and *Trypanosoma cruzi* biology.

Received Grant from Bill & Melinda Gates Foundation. In September, 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 Third Quarter Financial Results

- **Research and Development (R&D) Expenses:** R&D expenses increased for the three months ended September 30, 2023, compared to the same period during 2022 due to increased clinical trial expenses, personnel-related expenses, consulting and outside services and preclinical and research study expenses, partially offset by lower chemistry manufacturing and controls costs and other expenses.
- **General and Administrative (G&A) Expenses:** G&A expenses increased for the three months ended September 30, 2023, compared to the same period during 2022 due to increased personnel-related expenses and professional service fees, partially offset by a decrease in insurance costs.
- **Other Income, Net:** Other income, net was \$1.5 million for the three months ended September 30, 2023, compared to \$0.4 million in 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 was \$16.7 million for the three months ended September 30, 2023, compared to \$11.3 million in the same period during 2022.
- **Cash Position:** On August 15, 2023, the Company sold an aggregate of 7,777,778 shares of the Company's common stock at a purchase price of \$9.00 per share under an underwritten offering. This resulted in aggregate gross proceeds to the Company of approximately \$70.0 million, before deducting underwriting discounts and commissions and offering expenses. The Company expects that current cash and investments of \$150.2 million at September 30, 2023 will be sufficient to fund its operating expenses through summer 2025.

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: the timing, progress, and anticipated results from AN2's Phase 2/3 pivotal clinical trial; anticipated timing of the data readout of the Phase 2 portion of AN2's pivotal Phase 2/3 trial; timing of enrollment in the Phase 3 portion of AN2's pivotal Phase 2/3 trial; AN2's anticipated progress, business plans, business strategy and planned clinical trials; the potential clinical benefits and therapeutic potential of epetraborole to address unmet needs for patients with NTM lung disease and melioidosis; AN2's estimated cash runway, and planned usage and the timing of use of its capital resources; ability of AN2 to expand into other geographies; 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: AN2's ability to progress enrollment in its Phase 2/3 pivotal clinical trial of epetraborole; the ability of AN2 to effectively and timely make amendments to the Phase 2/3 pivotal trial design pursuant to additional FDA feedback; timely enrollment of patients in its current 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 reports to be filed with the SEC, including AN2's Report on Form 10-Q for the quarter ended

September 30, 2023. These filings, when available, are available on the investor relations section of our website at investor.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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 14,429	\$ 7,428	\$ 39,952	\$ 19,759
Research and development—related party	—	1,000	—	1,000
General and administrative	3,751	3,342	10,868	9,027
Total operating expenses	<u>18,180</u>	<u>11,770</u>	<u>50,820</u>	<u>29,786</u>
Loss from operations	(18,180)	(11,770)	(50,820)	(29,786)
Other income, net	1,473	431	2,986	672
Net loss	<u>(16,707)</u>	<u>(11,339)</u>	<u>(47,834)</u>	<u>(29,114)</u>
Accretion to redemption value and cumulative dividends on preferred stock	—	—	—	(1,820)
Net loss attributable to common stockholders	<u>\$ (16,707)</u>	<u>\$ (11,339)</u>	<u>\$ (47,834)</u>	<u>\$ (30,934)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.65)</u>	<u>\$ (0.59)</u>	<u>\$ (2.22)</u>	<u>\$ (2.21)</u>
Weighted-average number of shares used in computing net loss per share, basic and diluted	<u>25,645,421</u>	<u>19,347,148</u>	<u>21,532,537</u>	<u>13,987,862</u>
Other comprehensive loss:				
Unrealized gain (loss) on investments	(3)	(181)	252	(514)
Comprehensive loss	<u>\$ (16,710)</u>	<u>\$ (11,520)</u>	<u>\$ (47,582)</u>	<u>\$ (29,628)</u>

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

	September 30, 2023 (unaudited)	December 31, 2022
Assets		
Cash and cash equivalents	\$ 32,616	\$ 27,219
Short-term investments	91,202	68,840
Prepaid expenses and other current assets	2,591	2,562
Long-term investments	26,356	3,219
Other assets, long-term	1,043	720
Total assets	<u>\$ 153,808</u>	<u>\$ 102,560</u>
Liabilities and stockholders' equity		
Accounts payable	\$ 4,877	\$ 2,122
Other current liabilities	9,962	5,064
Other liabilities, long-term	—	2
Total liabilities	<u>14,839</u>	<u>7,188</u>
Stockholders' equity	<u>138,969</u>	<u>95,372</u>
Total liabilities and stockholders' equity	<u>\$ 153,808</u>	<u>\$ 102,560</u>

