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 29, 2023

AN2 Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-41331**	**82-0606654**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1800 El Camino Real, Suite D **Menlo Park, California**	**94027**
(Address of Principal Executive Offices)	**(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 29, 2023, AN2 Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2022. 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 29, 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: March 29, 2023

By: /s/ Eric Easom

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

Exhibit 99.1

AN2 Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Recent Highlights

- Approaching 60 clinical sites participating in pivotal Phase 2/3 trial of epetraborole in treatment-refractory *Mycobacterium avium* complex (MAC) lung disease to date
- Opened up sites in three additional countries -- Japan, South Korea, and Australia in addition to the U.S.; Japan has some of the highest rates of MAC lung disease in the world
- Activities underway to advance development of epetraborole for acute systemic melioidosis using non-dilutive funding

Menlo Park, CA – March 29, 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 fourth quarter and year ended December 31, 2022.

"2022 was a transformative year for AN2 as we transitioned from a private company into a public company and initiated a single pivotal Phase 2/3 clinical trial, EBO-301, for epetraborole in treatment-refractory MAC lung disease. We continued to generate data that support the potential of epetraborole to meet an ideal target product profile for NTM lung disease caused by MAC. Importantly, based on discussions with FDA and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), we believe that our pivotal trial, if positive, will be sufficient to support regulatory filings in these two major markets. We also gained alignment with the PMDA on the use of a microbiological primary endpoint to support potential registration and received orphan medicinal product designation from the European Union," said Eric Easom, Co-Founder, President and Chief Executive Officer. "Enrollment is ongoing in the Phase 2/3 pivotal trial of epetraborole. We are approaching 60 clinical sites worldwide, including new sites in Japan, South Korea and Australia. Japan has some of the highest rates of MAC lung disease in the world, making it and the broader Asia-Pacific region an area of particular importance as we look to make a significant impact on the lives of patients worldwide."

Highlighting the company's commitment to global health using non-dilutive funding, AN2 was awarded a contract in the third quarter of 2022 valued up to $17.8M from the National Institute of Allergy and Infectious Disease to develop epetraborole for acute systemic melioidosis and other biothreat pathogens. "Melioidosis affects an estimated 165,000 patients globally with an unacceptably high mortality rate of up to 60% left untreated. We believe epetraborole can play a key role in reducing mortality as well as provide a countermeasure to a serious biothreat agent," said Easom.

Fourth Quarter & Recent Business Updates:

Advanced Epetraborole Pivotal Phase 2/3 Clinical Study.
The Company is currently enrolling its Phase 2/3 pivotal trial evaluating once-daily, oral epetraborole for treatment-refractory MAC lung disease. We expect to complete enrollment in the Phase 2 portion of the pivotal Phase 2/3 clinical trial in mid-2023 and plan to seamlessly begin enrollment of the Phase 3 portion of the trial immediately thereafter. We expect to announce top-line data for each of the Phase 2 and Phase 3 portions of the trial approximately nine months after the completion of enrollment in each respective portion of the trial.

In 2022, the FDA granted epetraborole Fast Track designation for treatment-refractory MAC lung disease, Qualified Infectious Disease Product designation for treatment-refractory MAC lung disease, and orphan-drug designation for the treatment of infections caused by NTM.

Announced Epetraborole Data from Phase 1 Study in Japanese Subjects that Supports Use of Once-Daily 500 mg Dose in Japanese Patients.
In October, the Company announced results from a Phase 1 study designed to evaluate the pharmacokinetics, safety, and tolerability of oral epetraborole administered as a single 500 mg dose to healthy Japanese volunteers with different alcohol dehydrogenase (ADH) genotypes. The study showed that epetraborole was well tolerated at this dosage and supports use in Japanese patients enrolled in the ongoing Phase 2/3 pivotal trial.

Presented New Epetraborole Data at the Infectious Disease Society of America (IDSA) IDWeek 2022 Conference.
In October, the Company presented one oral presentation and nine data poster presentations at the ID Week Conference highlighting new data supporting the potential for epetraborole in nontuberculous mycobacteria (NTM) lung disease.

Granted Orphan Medicinal Product Designation in NTM Lung Disease in European Union.
In October, the Company announced that it received the orphan medicinal product designation for epetraborole in NTM lung disease from the European Commission, which grants orphan medicinal product designation to medicines intended for the treatment, prevention or diagnosis of a life-threatening or very serious condition. The designation provides various incentives, including ten-year market exclusivity upon regulatory approval, if received, fee reductions, and access to protocol assistance.

Selected Fourth Quarter and Full Year 2022 Financial Results

- **Research and Development (R&D) Expenses:** R&D expenses for the full year 2022 were $29.5 million, compared to $16.9 million in the prior year. R&D expenses for the fourth quarter of 2022 were $8.7 million, compared to $5.8 million for the same period last year.
- **General and Administrative (G&A) Expenses:** G&A expenses for the full year 2022 were $12.8 million, compared to $4.7 million in the prior year. General and administrative expenses for the fourth quarter of 2022 were $3.7 million, compared to $1.8 million for the same period last year. Most of the increase is attributable to being a publicly-traded company.
- **Interest and Other Income:** Interest and other income, net for the full year 2022 was $1.3 million, compared to $0.03 million in the prior year. Interest and other income, net for the fourth quarter of 2022 was $0.6 million, compared to $0.05 million for the fourth quarter of 2021.
- **Net loss:** For the three months and full year ended December 31, 2022 net loss was $11.8 million and $41.0 million, respectively.
- **Cash Position:** Cash, cash equivalents and investments totaled $99.3 million at December 31, 2022, which the company expects will be sufficient to fund its operating expenses through mid-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 epetraborole, which we are studying as a once-daily, oral treatment with a novel mechanism of action for patients with 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; AN2's anticipated progress, business plans, business strategy and planned clinical trials; the potential clinical benefits and therapeutic potential of epetraborole; AN2's estimated cash runway 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: the continuing effects of the COVID-19 pandemic; macro-economic conditions; 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; 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-K for the year ended December 31, 2022. 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 amounts)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 8,752	$ 5,312	$ 28,511	$ 16,156
Research and development—related party	—	500	1,000	750
General and administrative	3,724	1,782	12,751	4,668
Total operating expenses	12,476	7,594	42,262	21,574
Loss from operations	(12,476)	(7,594)	(42,262)	(21,574)
Interest income	630	27	1,351	69
Other (expense) income	4	22	(45)	(38)
Net loss	(11,842)	(7,545)	(40,956)	(21,543)
Accretion to redemption value and cumulative dividends on preferred stock	—	(1,925)	(1,820)	(6,515)
Net loss attributable to common stockholders	$ (11,842)	$ (9,470)	$ (42,776)	$ (28,058)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.61)	$ (3.57)	$ (2.79)	$ (10.64)
Weighted-average number of shares used in computing net loss per share, basic and diluted	19,352,854	2,653,858	15,340,134	2,638,197
Other comprehensive loss:				
Unrealized loss on investments	167	(24)	(347)	(27)
Comprehensive loss	$ (11,675)	$ (7,569)	$ (41,303)	$ (21,570)

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

	December 31,	
	2022	**2021**
Assets		
Cash and cash equivalents	$ 27,219	$ 12,097
Short-term investments	68,840	46,458
Prepaid expenses and other current assets	2,562	1,551
Deferred offering costs	—	1,724
Long-term investments	3,219	3,486
Other assets, long-term	720	—
Total assets	$ 102,560	$ 65,316
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Accounts payable	$ 2,122	$ 1,063
Other current liabilities	5,064	2,332
Other liabilities, long-term	2	13
Total liabilities	7,188	3,408
Redeemable convertible preferred stock	—	109,319
Stockholders' equity (deficit)	95,372	(47,411)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 102,560	$ 65,316