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, 2022

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 November 9, 2022, AN2 Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 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 November 9, 2022
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 thereunto duly authorized.

AN2 Therapeutics, Inc.

Date: November 9, 2022

By: /s/ Eric Easom

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

Exhibit 99.1

AN2 Therapeutics Reports Third Quarter 2022 Financial Results and Provides Business Updates

- *U.S. Enrollment Ongoing in EBO-301 Pivotal Phase 2/3 Clinical Trial of Epetraborole in Treatment-Refractory MAC Lung Disease; Plan to Include Japanese Patients in Trial*
- *Awarded Contract from NIAID Valued Up to $17.8 Million to Advance Development of Epetraborole for Acute Systemic Melioidosis*

Menlo Park, CA – November 9, 2022 – 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, 2022.

“Chronic lung infections, such as Mycobacterium avium complex (MAC) lung disease, are debilitating and can be fatal. AN2 Therapeutics is committed to developing more effective solutions for patients and healthcare providers that are seeking new treatment options. Over the past several months we’ve continued to advance our epetraborole development strategy. Enrollment is ongoing in our pivotal Phase 2/3 clinical trial in treatment-refractory (MAC) lung disease, and we’ve taken important steps to include Japanese patients in the pivotal trial based on data from our recent Phase 1 trial conducted in Japanese subjects, which supports the use of a single 500-mg daily oral dose of epetraborole and validated data from previous studies. Also, new data recently presented at IDWeek further validates the potential of epetraborole,” said Eric Easom, Co-Founder, President and Chief Executive Officer. "Finally, the recent decision by the National Institutes of Allergy and Infectious Diseases (NIAID) to award AN2 Therapeutics a contract for the development of epetraborole in acute systemic melioidosis, an infectious disease with unacceptably high mortality that also poses a serious biothreat, underscores the potential of epetraborole, which has shown significant promise across preclinical models of infection. We will continue to explore the utility of epetraborole in areas with urgent unmet global health needs that will allow us to capture synergies with our existing epetraborole program.”

Third Quarter & Recent Business Updates:

Advanced Epetraborole Clinical Development. Enrollment is ongoing in the Company’s pivotal Phase 2/3 clinical trial evaluating once-daily, oral epetraborole for treatment-refractory MAC lung disease, the most common form of nontuberculous mycobacterial (NTM) lung disease. The Company expects to complete enrollment in the Phase 2 part of the pivotal Phase 2/3 clinical trial in mid-2023 and plans 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.

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. Results of the study showed that no subjects experienced treatment-emergent adverse events and support use of AN2’s recommended dose in Japanese patients enrolled in its ongoing pivotal Phase 2/3 clinical trial, regardless of ADH genotype.

Received Orphan Medicinal Product Designation for Epetraborole in the European Union. In August, the Company received the orphan medicinal product designation for epetraborole in NTM lung disease from the European Commission.

Presented New Epetraborole Data at Infectious Disease Society of America (IDSA) IDWeek 2022 Conference. In October, AN2 presented nine poster presentations and one oral presentation that advance the understanding of epetraborole in NTM lung disease.

Awarded Contract by National Institute of Allergy and Infectious Diseases (NIAID) to Advance Development of Epetraborole for Acute Systemic Melioidosis. In September, AN2 announced the award of a contract valued up to $17.8 million from the NIAID, part of the National Institutes of Health (NIH), to advance the development of epetraborole for acute systemic melioidosis and other biothreat pathogens.

Strengthened Senior Leadership Team. In September, Joshua M. Eizen was appointed Chief Legal Officer and Secretary. Mr. Eizen brings significant industry experience to AN2, including as counsel to Jazz Pharmaceuticals, GW Pharmaceuticals and the U.S. Food and Drug Administration.

Financial Results for Third Quarter 2022:

- **Research and Development (R&D) Expenses:** R&D expenses increased for the three months ended September 30, 2022, compared to the same period during 2021 due to a related party license fee associated with dosing of the first patient in our pivotal Phase 2/3 clinical trial, increased clinical trial activity, additional R&D personnel and related expenses, and increased outside services and consultant costs. These increases were partially offset by lower outside research and toxicology study costs related to our development activities.
- **General and Administrative (G&A) Expenses:** G&A expenses increased for the three months ended September 30, 2022, compared to the same period during 2021 due to additional G&A personnel and related expenses, increased insurance and other expenses, and increased outside legal and consulting services costs as we conducted business as a public company. These increases were partially offset by lower accounting professional fees compared to 2021 fees related to preparation for AN2's Initial Public Offering.
- **Cash Position:** Cash, cash equivalents and investments totaled $106.4 million on September 30, 2022. The Company expects that current cash, cash equivalents and investments 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 lead candidate is epetraborole, which we are studying in a pivotal Phase 2/3 clinical trial 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: AN2's anticipated progress, business plans, business strategy and planned clinical trials; the timing of anticipated results from AN2's pivotal Phase 2/3 clinical trial; the potential clinical benefits and therapeutic potential of epetraborole; AN2's estimated cash runway and the timing of use of its capital resources; the timing of initial data from AN2's research and development programs; ability of AN2 to expand into other geographies; and other statements that are not historical fact. These statements are based on AN2's current plans, objectives, estimates, expectations 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 effects of the evolving COVID-19 pandemic and macro-economic conditions; AN2's ability to continue enrollment in its pivotal Phase 2/3 clinical trial of epetraborole and the ability to enable epetraborole development in Japan; the ability of AN2 to effectively and timely make amendments to the pivotal Phase 2/3 clinical 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 prospectus filed with the U.S. Securities and Exchange Commission (SEC) on March 24, 2022 and in AN2's reports to be filed with the SEC, including AN2's Quarterly Report on Form 10-Q for the quarter ended September 30, 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 September 30,	
	2022	**2021**
Operating expenses:		
Research and development	$ 7,428	$ 5,345
Research and development—related party	1,000	—
General and administrative	3,342	1,587
Total operating expenses	11,770	6,932
Loss from operations	(11,770)	(6,932)
Interest income	466	25
Other expense	(35)	(36)
Net loss	(11,339)	(6,943)
Accretion to redemption value and cumulative dividends on preferred stock	—	(1,925)
Net loss attributable to common stockholders	$ (11,339)	$ (8,868)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.59)	$ (3.35)
Weighted-average number of shares used in computing net loss per share, basic and diluted	19,347,148	2,643,879
Other comprehensive loss:		
Unrealized loss on investments	(181)	(3)
Comprehensive loss	$ (11,520)	$ (6,946)

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

	September 30, 2022 (unaudited)	**December 31, 2021**
Assets		
Cash and cash equivalents	$ 28,802	$ 12,097
Short-term investments	75,580	46,458
Prepaid expenses and other current assets	2,914	1,551
Deferred offering costs	—	1,724
Long-term investments	1,992	3,486
Other assets, long-term	720	—
Total assets	$ 110,008	$ 65,316
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Accounts payable	$ 1,440	$ 1,063
Other current liabilities	2,992	2,332
Other liabilities, long-term	3	13
Total liabilities	4,435	3,408
Redeemable convertible preferred stock	—	109,319
Stockholders' equity (deficit)	105,573	(47,411)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 110,008	$ 65,316