

**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): August 11, 2022

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 August 11, 2022, AN2 Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the second quarter ended June 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 August 11, 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: August 11, 2022

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

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

- *Enrolling U.S. Patients in the EBO-301 Pivotal Phase 2/3 Trial of Epetraborole in Treatment-Refractory MAC Lung Disease; Topline Results from Phase 2 Part of Trial Expected in Mid-2023*
- *Completed Enrollment in Phase 1 PK/Safety Study of Epetraborole in Healthy Volunteers in Japan*
- *Plan to Include Japanese Patients in EBO-301 Pivotal Phase 2/3 Trial; Gained Alignment with the PMDA on the Use of a Microbiological Primary Endpoint to Support Potential Registration in Japan*

Menlo Park, CA – August 11, 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 June 30, 2022.

“We’ve made significant strides with the epetraborole clinical program, initiating the pivotal Phase 2/3 trial in treatment-refractory MAC lung disease in the U.S., and completing enrollment in a Phase 1 study in healthy volunteers in Japan. Furthermore, we recently gained alignment with the PMDA on the registrational path in Japan, including the use of a microbiological endpoint as the basis for potential approval. As a result, the company is planning to include Japanese patients in our ongoing pivotal Phase 2/3 trial,” said Eric Easom, President and Chief Executive Officer. “Initiating the pivotal study for epetraborole in the U.S. and paving the way to add Japanese patients to the study is an important milestone for AN2 and patients suffering from NTM lung disease. With the highest incidence of NTM globally, Japan is an important part of our epetraborole strategy.”

Second Quarter & Recent Business Updates:

Initiated Pivotal Phase 2/3 Trial for Epetraborole in Treatment-Refractory MAC Lung Disease. In June 2022, AN2 Therapeutics reported that it screened its first patient in its pivotal Phase 2/3 clinical trial evaluating once-daily, oral epetraborole for treatment-refractory Mycobacterium avium complex (MAC) lung disease, the most common form of nontuberculous mycobacterial (NTM) lung disease.

Expanded Company’s Board of Directors. During the second quarter of 2022, AN2 Therapeutics announced that Maggie FitzPatrick, a corporate affairs, communications and business operations leader, was appointed to its Board of Directors. Ms. FitzPatrick previously served as Global Chief Communications Officer and led public affairs at Johnson & Johnson.

Advancing Epetraborole Clinical Development. AN2 Therapeutics has completed enrollment in the Phase 1 safety and pharmacokinetics (PK) study of oral epetraborole in healthy volunteers in Japan. The Company recently met with the Japanese Pharmaceutical and Medical Devices Agency (PMDA) and gained alignment on the use of a microbiological primary endpoint to support potential registration in Japan. The Company is planning to include Japanese patients in the EBO-301 pivotal Phase 2/3 clinical trial and expects that data from the ongoing pivotal Phase 2/3 clinical trial of oral epetraborole for treatment-refractory MAC lung disease, if positive, will serve as the basis for the application for marketing approval in Japan.

Financial Results for Second Quarter 2022:

- **Research and Development (R&D) Expenses:** R&D expenses increased for the three months ended June 30, 2022, compared to the same period during 2021 due to higher clinical trial activity, additional R&D personnel and related expenses, increased outside consultant costs and research studies related to our research and development activities. These increases were partially offset by lower clinical manufacturing costs for our clinical trials and lower related party license fees.
 - **General and Administrative (G&A) Expenses:** G&A expenses increased for the three months ended June 30, 2022, compared to the same period during 2021 due to additional G&A personnel and related expenses, higher
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outside legal and accounting professional service costs and increased consulting services, as we expanded our post-initial public offering (IPO) activities.

- **Cash Position:** Cash, cash equivalents and investments totaled \$115.8 million on June 30, 2022. The Company expects that current cash, cash equivalents and investments, including net proceeds from the underwriters' IPO over-allotment option exercised in April, 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. AN2 is developing epetaborole, a once-daily oral treatment 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 recently initiated Phase 2/3 pivotal clinical trial; the potential clinical benefits and therapeutic potential of epetaborole; 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 markets and initiate clinical trials in other jurisdictions; 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; AN2's ability to continue enrollment in its Phase 2/3 pivotal clinical trial of epetaborole and the ability to enable epetaborole development in Japan, the anticipated timing of development in Japan or at all; the ability of AN2 to effectively and timely make amendments to the Phase 2/3 pivotal trial design pursuant to additional FDA feedback; initiation of planned clinical trials and enrollment of patients in its future clinical trials; AN2's ability to procure sufficient supply of its product candidate for its future clinical trials; the preclinical profiles of AN2's product candidate not translating in 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 June 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.

Company Contacts:

Lucy O. Day
Chief Financial Officer
l.day@an2therapeutics.com

Anne Bowdidge
Investor Relations
abowdidge@an2therapeutics.com

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

	Three Months Ended	
	June 30,	
	2022	2021
Operating expenses:		
Research and development	\$ 6,698	\$ 3,850
Research and development—related party	—	250
General and administrative	3,635	898
Total operating expenses	<u>10,333</u>	<u>4,998</u>
Loss from operations	(10,333)	(4,998)
Interest income	228	15
Other expense	(15)	(24)
Net loss	<u>(10,120)</u>	<u>(5,007)</u>
Accretion to redemption value and cumulative dividends on preferred stock	—	(1,904)
Net loss attributable to common stockholders	<u>\$ (10,120)</u>	<u>\$ (6,911)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.53)</u>	<u>\$ (2.62)</u>
Weighted-average number of shares used in computing net loss per share, basic and diluted	<u>19,258,066</u>	<u>2,633,954</u>
Other comprehensive loss:		
Unrealized loss on investments	(202)	—
Comprehensive loss	<u>\$ (10,322)</u>	<u>\$ (5,007)</u>

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

	June 30,	December 31,
	2022	2021
	(unaudited)	
Assets		
Cash and cash equivalents	\$ 40,616	\$ 12,097
Short-term investments	72,773	46,458
Prepaid expenses and other current assets	3,488	1,551
Deferred offering costs	—	1,724
Long-term investments	2,419	3,486
Other assets, long-term	720	—
Total assets	<u>\$ 120,016</u>	<u>\$ 65,316</u>
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Accounts payable	\$ 1,612	\$ 1,063
Other current liabilities	2,537	2,332
Other liabilities, long-term	4	13
Total liabilities	<u>4,153</u>	<u>3,408</u>
Redeemable convertible preferred stock	—	109,319
Stockholders' equity (deficit)	<u>115,863</u>	<u>(47,411)</u>
Total liabilities, redeemable convertible preferred stock, and stockholders' equity	<u>\$ 120,016</u>	<u>\$ 65,316</u>

