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): February 12, 2024

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 Number)**

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	Name of each exchange on which registered
Common Stock, $0.00001 par value per share	ANTX	The Nasdaq Stock Market LLC (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 8.01 Other Events.

On February 12, 2024, AN2 Therapeutics, Inc. (the "Company") announced its decision to voluntarily pause Phase 3 enrollment in the Company's seamless Phase 2/3 clinical trial ("EBO-301") evaluating epetraborole in treatment-refractory *Mycobacterium avium* complex ("MAC") lung disease, pending further data review. The double-blind, placebo-controlled trial has two arms comparing epetraborole plus optimized background regimen ("OBR") versus placebo plus OBR. The voluntary pause was instituted following a blinded aggregate analysis of the ongoing Phase 2 study, including pooled patients from both treatment arms, which showed potentially lower than expected efficacy. The decision was not due to safety concerns. The Phase 2 part of the trial is intended to inform the Phase 3 part of the trial. The Company continues to expect to announce topline data from the Phase 2 part of the trial in summer 2024.

The Company's decision to pause enrollment is expected to enable time to further evaluate study data and for the independent Data Safety Monitoring Board (the "DSMB") to conduct an unblinded assessment and recommend next steps, which could include changes to the Phase 3 part of the study protocol. The Phase 2 part of the trial completed enrollment in September 2023 with 80 patients. The Phase 3 part of the trial has enrolled nearly 100 patients to date, a faster enrollment rate than previously anticipated. Patients already enrolled in the Phase 2/3 trial will be allowed to continue on study.

About the Epetraborole Pivotal Phase 2/3 Trial (EBO-301)

This double-blind, placebo-controlled superiority trial uses an adaptive design to evaluate the safety and efficacy of epetraborole in patients with treatment-refractory MAC lung disease. The Phase 2 part of the trial (n=80) assesses clinical response using various patient-reported outcome tools as well as the safety, efficacy, and pharmacokinetics of epetraborole plus an OBR, when compared to a placebo plus an OBR. The Phase 2 findings are expected to be utilized to inform the clinical response measures evaluated in the Phase 3 part of the trial and confirm the final sample size. The primary objective in Phase 3 (n=at least 234) will be to determine if epetraborole plus an OBR, consisting of two or more standard-of-care drugs, is superior to placebo plus an OBR.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this report that are not historical facts may be considered "forward-looking statements," including, without limitation, statements regarding: further evaluation of the Company's study data and DSMB review; potential changes to the Company's Phase 3 study protocol; anticipated impact of clinical studies and timing for announcing results; timing of completion of the Company's analysis of study data; and continuation of enrolled patients in the Company's Phase 2/3 trial. Forward-looking statements are typically, but not always, identified by the use of words such as "may," "will," "would," "believe," "intend," "plan," "anticipate," "estimate," "expect," and other similar terminology indicating future results. Such forward-looking statements are subject to substantial risks and uncertainties that could cause the Company's studies, trials, and development programs, future results, performance, or achievements to differ materially from those anticipated in the forward-looking statements. Such risks and uncertainties include, without limitation: the recommendations of the DSMB following its review of blinded data; the number of patients who remain enrolled in the Company's Phase 2/3 trial; the ability of the Company to resume enrollment in its Phase 2/3 trial, in the event the determination to resume enrollment is made; the Company's ability 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 feedback from the U.S. Food and Drug Administration; possible changes to the Company's plans or priorities as it assesses study data; potential for protocol modifications, redesign or study termination; timely enrollment of patients in the Company's existing and future clinical trials; the Company'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 the Company's product candidate; the significant uncertainty associated with the Company's product candidate ever receiving any regulatory approvals; the Company's ability to obtain, maintain, or protect intellectual property rights related to its current and future product candidates; implementation of the Company's strategic plans for its business and current and future product candidates; the sufficiency of the Company's capital resources and need for additional capital to achieve its goals; and global macroeconomic conditions and global conflicts. For a further description of the risks and uncertainties that could cause actual results to differ from those anticipated in these forward-looking statements, as well as risks relating to the business of the Company in general, see the Company's reports filed with the U.S. Securities and Exchange Commission (the "SEC"), including the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, and its future periodic reports to be filed with the SEC. Forward-looking statements contained in this Current Report on Form 8-K are made as of the date of this report, and the Company undertakes no duty to update such information except as required under applicable law.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AN2 Therapeutics, Inc.

Date: February 12, 2024

By: /s/ Eric Easom
Eric Easom
Chief Executive Officer