# 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): June 29, 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<br>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 8.01 Other Events.**

On June 29, 2022, AN2 Therapeutics, Inc. (the "Company") issued a press release entitled "AN2 Therapeutics Initiates Pivotal Phase 2/3 Trial Evaluating Epetraborole for Treatment-Refractory MAC Lung Disease."

A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release of AN2 Therapeutics Inc. dated June 29, 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: June 29, 2022

By: /s/ Eric Easom

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

**AN2 Therapeutics Initiates Pivotal Phase 2/3 Trial Evaluating Epetraborole for Treatment-Refractory MAC Lung Disease**

- ***AN2 is developing epetraborole*** *as a once-daily, orally administered treatment with a novel mechanism of action for patients with NTM lung disease, with an initial focus on treatment-refractory MAC lung disease*
- *Phase 2/3 pivotal trial expected to support regulatory approval for treatment-refractory MAC lung disease; Plan to use LPAD pathway*

**Menlo Park, CA** – June 29, 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 announced it has 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.

“Initiating this pivotal Phase 2/3 trial marks an important step towards delivering a new treatment option to patients with treatment-refractory MAC lung disease, an area which has seen little innovation,” said Eric Easom, President and Chief Executive Officer of AN2 Therapeutics. “As a once-daily oral therapy, epetraborole has the potential to become an important component of a multi-drug treatment regimen for patients with treatment-refractory MAC lung disease. We look forward to sharing clinical data from the Phase 2 portion of this trial in mid-2023, when we expect to get our first clinical readout on the impact of epetraborole added to a standard of care regimen.”

AN2 Therapeutics believes that compelling data from this pivotal Phase 2/3 clinical trial could allow the company to seek approval for epetraborole with the U.S. Food and Drug Administration (FDA) using the Limited Population Pathway for Antibacterial and Antifungal drugs (LPAD) and in other geographies. Under the LPAD pathway, the FDA may approve and review new antibacterial drugs to treat serious bacterial diseases in patients with an unmet medical need and for which effective bacterial drugs are limited or lacking, potentially resulting in a New Drug Application submission based on streamlined development. Epetraborole has been granted Qualified Infectious Disease Product and Fast Track status by the FDA for treatment-refractory MAC lung disease, as well as orphan drug designation for the treatment of infections caused by NTM.

**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. In total, this multi-center trial is expected to enroll approximately 314 patients across North America, Europe and potentially other geographies. The Phase 2 part of the trial (n=80) will assess the clinical response using various patient-reported outcome tools as well as to determine the safety, efficacy and pharmacokinetics of epetraborole plus an optimized background regimen (OBR), when compared to a placebo plus an OBR. The Phase 2 findings will 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 the Phase 3 part of the trial (nâ‰^ 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. The Company expects to report topline data from the Phase 2 part of the trial in mid-2023 and from the Phase 3 part in mid-2024, pending any sample size adjustments. For more information, please visit: www.clinicaltrials.gov (NCT05327803).

**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 epetraborole, 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.

**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; AN2’s plans to initiate its Phase 2/3 pivotal clinical trial and the timing thereof; the potential clinical benefits

and therapeutic potential of epetraborole; the timing of initial data from AN2's Phase 2/3 pivotal clinical trial; the ability of AN2's Phase 2/3 pivotal clinical trial to support regulatory approval; 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 those described under the heading "Risk Factors" in AN2's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 filed with the U.S. Securities and Exchange Commission (SEC). 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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