

**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): October 6, 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 7.01 Regulation FD Disclosure.**

On October 6, 2022, AN2 Therapeutics, Inc. (the “Company”) issued a press release entitled “AN2 Therapeutics Provides Update on Epetraborole Ex-U.S. Development Plan in Treatment-Refractory MAC Lung Disease”. A copy of the Company’s press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed subject to the requirements of amended Item 10 of Regulation S-K, nor shall it be deemed incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing. The furnishing of this information hereby shall not be deemed an admission as to the materiality of any such information.

**Item 9.01 Financial Statements and Exhibits.**

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release of AN2 Therapeutics Inc. dated October 6, 2022</a>
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: October 6, 2022

By: /s/ Eric Easom

**Eric Easom**

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

**AN2 Therapeutics Provides Update on Epetraborole Ex-U.S. Development Plan in Treatment-Refractory MAC Lung Disease**

- **Epetraborole Data from Recently Completed Phase 1 Study in Japanese Subjects Supports Use of Once Daily, 500 mg Dose in Japanese Patients**
- **Treatment-Refractory MAC Lung Disease Clinical Development Strategy to Focus Initially on Japan and U.S., Two Countries with Highest Prevalence of MAC Lung Disease**
- **Epetraborole Granted Orphan Medicinal Product Designation in NTM Lung Disease in European Union**

**Menlo Park, CA** – October 6, 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 provided an update on the ex-U.S. development plan for epetraborole in treatment-refractory *Mycobacterium avium* complex (MAC) lung disease, the most common form of non-tuberculous mycobacterial (NTM) lung disease.

“We believe that epetraborole has the potential to provide significant benefit to patients with NTM lung disease and are pleased with the progress we’ve made globally across our epetraborole development program, including, most recently, the results from our Phase 1 trial in Japan (EBO-103) that further validate data from our previous studies and support our recommended Phase 2/3 dose in the ongoing EBO-301 pivotal trial in treatment-refractory MAC patients,” said Eric Easom, Co-Founder, President and Chief Executive Officer of AN2 Therapeutics. “These data are an important step towards including patients in our ongoing EBO-301 pivotal Phase 2/3 trial from Japan, a country with one of the highest prevalence rates of MAC lung disease in the world.”

Easom added, “In addition, the European Commission’s decision to adopt the orphan medicinal product designation for epetraborole for NTM lung disease is an important milestone. After discussion with the European Medicines Agency, we believe the clearest path to address the unmet medical need in Europe is through further development of epetraborole in patients with treatment-naïve MAC lung disease, which is in scope of this designation. We expect to provide further updates on our approach to this important patient population in the future.”

***Results from Phase 1 PK/Safety Study of Oral Epetraborole in Japan (EBO-103)***

This Phase 1 study was 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 Phase 2/3 study. Epetraborole exposures were similar amongst patients with different ADH genotypes, and consistent with those observed in non-Japanese subjects in a previously reported Phase 1 study (EBO-101).

## ***European Union Orphan Medicinal Product Designation***

In August, the Company received the orphan medicinal product designation for epetaborole 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, with a prevalence in the European Union of not more than five in 10,000 people, and where either no satisfactory method of diagnosis, prevention or treatment of the condition in question exists, or if such method exists that the medicinal product will be of significant benefit to those affected by that condition. The designation provides various incentives, including ten-year market exclusivity upon regulatory approval, if received, fee reductions, and access to protocol assistance.

## **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 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](http://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 ability to provide significant benefits to patients with NTM lung disease, anticipated progress, business plans, business strategy and planned clinical trials; AN2's plans to include Japan in its Phase 2/3 pivotal clinical trial and the timing thereof; the potential clinical benefits and therapeutic potential of epetaborole; the ability to receive market exclusivity in the European Union; the ability of AN2's clinical trials 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 June 30, 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](http://investor.an2therapeutics.com) and on the SEC's website at [www.sec.gov](http://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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