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): March 28, 2023

ANEBULO PHARMACEUTICALS, INC
(Exact name of registrant as specified in its charter)

Delaware	**001-40388**	**85-1170950**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1415 Ranch Road 620 South, Suite 201 Lakeway, TX	**78734**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (512) 598-0931

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, $0.001 par value per share	ANEB	The Nasdaq Stock Market LLC

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 March 28, 2023, Anebulo Pharmaceuticals, Inc. (the "Company" or "Anebulo") announced complete results from its randomized, double-blind, placebo-controlled Phase 2 clinical trial evaluating ANEB-001 as a potential treatment for ACI in healthy volunteers challenged with oral delta-9-tetrahydrocannabinol ("THC"). Part B of the study was an adaptive design that included six cohorts of up to 15 healthy adults to examine different doses of THC and ANEB-001, and the impact of delayed dosing of ANEB-001 or placebo. In total, Parts A and B of the Phase 2 study enrolled 134 healthy subjects.

Data from Part A of the study previously showed positive protective effects of a single oral dose of 50 or 100 mg ANEB-001 when co-administered with an oral challenge dose of 10.5 mg THC. In Part B of the study, subjects were challenged with substantially higher oral doses of THC (21, 30, or 40 mg) and treated with lower doses of ANEB-001 (10 or 30 mg) or a matching placebo. Delayed dosing of ANEB-001 was also examined by introducing a one-hour pause between the THC challenge and treatment with the ANEB-001 or placebo. The final cohort of the study included the administration of a high-fat meal prior to the THC challenge.

Based on the final data for Part B of the study, a single low oral dose of ANEB-001 (10 mg) administered 1 hour after a THC challenge rapidly and statistically significantly reversed key psychotropic effects of THC doses as high as 30 mg, including a reduction in the visual analog scale (VAS) for feeling high (p=<0.0001) and improvement in VAS alertness (p=0.0042) and reduced body sway (p=0.0196). In a pre-specified pooled analysis of data for the combined 21 mg or 30 mg THC dose levels, a single 10 mg of ANEB-001 administered one hour after THC achieved statistical significance on all primary outcomes, including a reduction in VAS feeling high (p=<0.0001), improvement in VAS alertness (p=0.0024), reduced body sway (p=0.0014), and reduction in heart rate (p=0.0125). ANEB-001 also reduced the time required for the THC effects to normalize back to baseline.

The Phase 2 study was conducted in the Netherlands by the Centre for Human Drug Research. A total of 134 healthy subjects were enrolled. All subjects received oral THC challenge doses. In total, 91 subjects received single oral doses of ANEB-001. Pharmacodynamic outcomes were assessed by mixed-effect model repeated measures (MMRM) analysis of covariance (ANCOVA) through 8 hours post-ANEB-001 dosing. Safety was assessed by continuous observation through 24 hours and followed up at 7 to 14 days after treatment. ANEB-001 was well tolerated in this study and there were no serious adverse events. At the 30 mg THC dose, prior to dosing ANEB-001 or placebo, subjects developed mild to moderate THC-related symptoms including moderate euphoria, nausea, and/or vomiting, and mild bradyphrenia, dizziness, paresthesia, and/or feeling emotional. After delayed dosing of 10 mg ANEB-001 or placebo following a 21 mg or 30 mg THC challenge dose, the adverse events considered possibly or probably related to ANEB-001 were mild except for one case of moderate nausea/vomiting at THC doses of 21 mg and 30 mg; the incidence of dizziness and euphoria was greater in the placebo treated subjects. Administration of a high-fat meal delayed the absorption of THC resulting in blunted effects of a 30 mg THC dose on many of the outcomes. However, delayed dosing of 10 mg ANB-001 still significantly reduced VAS feeling high in fed subjects (p=0.0030).

Forward-Looking Statements

Statements contained in this Current Report on Form 8-K that are not statements of historical fact are forward-looking statements as defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, these forward-looking statements can be identified by words such as "anticipate," "believe," "targeting," "expect," "will," "should" and other comparable terms. Forward-looking statements include statements regarding Anebulo's intentions, beliefs, projections, outlook, analyses or current expectations regarding: the targeted timing for an End of Phase 2A meeting with the FDA by mid 2023; the expected timing for a response from the FDA on the request for an End of Phase 2A meeting; the timing for presenting further details of the Phase 2 clinical trial; the potential for ANEB-0001 to address an unmet medical need for a specific

antidote for ACI; and Anebulo's expectation that ANEB-001 will rapidly reverse key symptoms of ACI. You are cautioned that any such forward-looking statements are not guarantees of future performance and are subject to a number of risks, uncertainties and assumptions, including, but not limited to: initial and interim results from clinical studies are not necessarily indicative of results that may be observed in the future; clinical trial site challenges that may impact the expected timing of the Company's ongoing clinical trials; the timing and success of clinical trials and potential safety and other complications thereof; and Anebulo's need for additional capital. These and other risks are described under the "Risk Factors" heading of Anebulo's Quarterly Report on Form 10-Q for the quarter ended December 31, 2022, as filed with the SEC on February 10, 2023, and other filings Anebulo makes with the Securities and Exchange Commission from time to time (which are available at http://www.sec.gov). All forward-looking statements made in this Current Report on Form 8-K speak only as of the date of this Current Report on Form 8-K and are based on management's assumptions and estimates as of such date. Except as required by law, Anebulo undertakes no obligation to update or revise forward-looking statements to reflect new information, future events, changed conditions or otherwise after the date of this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
104	Cover Page of 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 hereunto duly authorized.

ANEBULO PHARMACEUTICALS, INC.

Date: March 28, 2023

By: */s/ Simon Allen*
Simon Allen
Chief Executive Officer