

**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): July 22, 2024

ANEBULO PHARMACEUTICALS, INC

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40388
(Commission
File Number)

85-1170950
(IRS Employer
Identification No.)

Anebulo Pharmaceuticals, Inc.
1017 Ranch Road 620 South, Suite 107
Lakeway, TX
(Address of Principal Executive Offices)

78734
(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 July 22, 2024, Anebulo Pharmaceuticals, Inc., a Delaware corporation (the "Company"), issued a press release announcing the award of the first tranche of a two year cooperative grant of up to approximately \$1.9 million from the National Institute on Drug Abuse, part of the National Institutes of Health, to support the development of intravenous selonabant, for the potential use as an emergency treatment of acute cannabis-induced toxicities, including cannabis-induced CNS depression in children. The grant comes in the form of two tranches with the initial award of \$0.9 million and subsequent funding of approximately \$1 million subject to certain milestones. The grant was awarded under NIH award number 1U01DA059995-01.

A copy of the Company's press release is attached 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.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated July 22, 2024
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: July 22, 2024

By: /s/ Richard Anthony Cunningham
Richard Anthony Cunningham
Chief Executive Officer (*Principal Executive Officer*)



Anebulo Pharmaceuticals Awarded NIDA Grant for its Investigational IV Treatment for Acute Cannabis-Induced Toxic Effects

AUSTIN, Texas (July 22, 2024) – **Anebulo Pharmaceuticals, Inc.** (Nasdaq: ANEB), a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabis-induced toxic effects (the “Company” or “Anebulo”), has been awarded the first tranche of a two year cooperative grant of up to approximately \$1.9 million from the National Institute on Drug Abuse (“NIDA”), part of the National Institutes of Health (“NIH”), to support the development of intravenous selonabant, for the potential use as an emergency treatment of acute cannabis-induced toxicities, including cannabis-induced CNS depression in children. The grant comes in the form of two tranches with the initial award of \$0.9 million and subsequent funding of approximately \$1 million subject to certain milestones. The grant was awarded under NIH award number 1U01DA059995-01.

“We are honored to receive this cooperative grant award from NIDA to support the further development of intravenous selonabant,” commented Ken Cundy, CSO of Anebulo Pharmaceuticals. “We believe this provides additional validation of the significant and growing unmet medical need for an emergency antidote to cannabis. Acute cannabis exposure in children represents a potentially life-threatening condition that can result in CNS depression, respiratory depression, coma, and in rare cases death. Research has shown that children are much more sensitive to the toxic effects of cannabis. Younger children have an underdeveloped endocannabinoid system with significantly more of the primary cannabinoid receptor type 1 (CB1) receptors present in their brains. As a direct consequence, pediatric cannabis ingestion can result in much more serious outcomes than in adults, and a much greater risk of hospitalization and admission to intensive care.”

“This important grant from NIDA recognizes the progress we have already made with the successful Phase 2 proof of concept study of oral selonabant and provides further momentum for advancing the intravenous formulation towards clinical testing,” said Richie Cunningham, CEO, Anebulo Pharmaceuticals. “If approved, we believe selonabant has the potential to offer a much-needed targeted therapy for rapidly reversing the serious and life-threatening consequences of accidental cannabis ingestion in children. This grant aligns with our recent decision to prioritize development of the intravenous formulation and we look forward to working closely with NIDA scientific staff on this important program.”

About Selonabant (ANEB-001)

Our lead product candidate is selonabant (ANEB-001), a potent, small molecule antagonist of CB1, under development to address the unmet medical need for a specific antidote for cannabis toxicity, including ACI and unintentional cannabis poisoning. Selonabant is an orally bioavailable, readily absorbed treatment candidate that we anticipate will rapidly reverse key symptoms of ACI. Selonabant is also under development as a parenteral treatment for unintentional cannabis poisoning. Selonabant is protected by two issued patents covering various methods of use of the compound and composition of matter of the crystalline form of selonabant. We also have multiple pending applications covering various methods of use of the compound and delivery systems. An observational study in patients presenting to Emergency Departments with ACI is currently ongoing. The study will determine concentrations of cannabinoids and metabolites in plasma and gather information on signs and symptoms, patients’ disposition and selected subjective assessments.

About Anebulo Pharmaceuticals, Inc.

Anebulo Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabinoid intoxication, unintentional cannabis intoxication and, longer term, for substance use disorders. Its lead product candidate, selonabant, has completed dosing in a Phase 2 clinical trial (www.clinicaltrials.gov/ct2/show/NCT05282797) evaluating its utility in blocking and reversing the negative effects of acute cannabinoid intoxication. Selonabant is a competitive antagonist at the human CB1. For further information about Anebulo, please visit www.anebulo.com.

Forward-Looking Statements

Statements contained in this press release 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,” “designed,” “expect,” “may,” “will,” “should” and other comparable terms. Forward-looking statements include statements regarding the potential use of selonabant as an emergency treatment of acute cannabis-induced toxicities, including cannabis-induced CNS depression in children, the grant providing additional validation of the significant and growing unmet medical need for an emergency antidote to cannabis, acute cannabis exposure in children representing a potentially life-threatening condition that can result in CNS depression, respiratory depression, coma, and in rare cases death, children being much more sensitive to the toxic effects of cannabis, pediatric cannabis ingestion resulting in much more serious outcomes than in adults, and a much greater risk of hospitalization and admission to intensive care and working closely with the NIDA scientific staff and the potential of selonabant to offer a much-needed targeted therapy for rapidly reversing the serious and life-threatening consequences of accidental cannabis ingestion in children. 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: our ability to pursue our regulatory strategy, our ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, our ability to obtain or maintain the capital or grants necessary to fund our research and development activities, our ability to complete clinical trials on time and achieve desired results and benefits as expected, regulatory limitations relating to our ability to promote or commercialize our product candidates for specific indications, acceptance of our product candidates in the marketplace and the successful development, marketing or sale of our products, our ability to maintain our license agreements, the continued maintenance and growth of our patent estate and our ability to retain our key employees or maintain our Nasdaq listing. These risks should not be construed as exhaustive and should be read together with the other cautionary statements included in our Annual Report on Form 10-K for the year ended June 30, 2023, and our subsequent filings with the SEC, including subsequent periodic reports on Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. All forward-looking statements made in this press release speak only as of the date of this press release 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 press release.

Anebulo Pharmaceuticals, Inc.
Dan George
Acting Chief Financial Officer
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