

**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 13, 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 2.02 Results of Operations and Financial Condition.

On February 13, 2024, Anebulo Pharmaceuticals, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended December 31, 2023 and providing a business update. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for 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 incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
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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: February 13, 2024

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

**Anebulo Pharmaceuticals Reports Second Quarter Fiscal Year 2024
Financial Results and Recent Updates**

AUSTIN, Texas (February 13, 2024) – Anebulo Pharmaceuticals, Inc. (Nasdaq: ANEB), a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabinoid intoxication (ACI) and substance abuse (the “Company” or “Anebulo”), today announced financial results for the three months ended December 31, 2023, and recent updates.

Second Quarter Fiscal Year 2024 and Subsequent Highlights:

- Richie Cunningham announced as Chief Executive Officer
- United States Adopted Names (USAN) adopted selonabant as the generic name for ANEB-001
- Advancing selonabant IV formulation as a second product
- Secured a credit facility of up to \$10 million
- Bimal Shah announced as Board Member

“Anebulo continues to make progress towards our goal of becoming the first company to have an approved treatment for acute cannabinoid intoxication. Our current efforts are focused on completion of critical steps needed to support the future Phase 3 studies of selonabant, including efficient scale up of manufacturing, completion of remaining nonclinical activities, and finalizing the designs of our proposed registrational studies for further discussion with the FDA. One important development at Anebulo is the advancement of a selonabant IV formulation, which we are currently scaling-up for initial clinical safety studies as a potential treatment for patients where oral dosing is not an option, such as younger pediatric patients accidentally exposed to cannabis, who may experience serious outcomes like CNS depression, seizures, or coma,” commented Richie Cunningham, Chief Executive Officer of Anebulo.

“We find ourselves at a seminal moment to deliver a meaningfully constructive solution to healthcare providers and to their patients suffering with ACI and associated cannabis toxicities,” Cunningham continued. “Despite the high tolerability of cannabis in the majority of users, a significant number of users who develop ACI may experience moderate to severe neuropsychiatric symptoms such as anxiety, paranoia, and psychosis. In addition to poor patient outcomes, cannabis toxicity places a substantial burden on the healthcare system.”

“We are pleased to report that the USAN Council has adopted selonabant as the generic name for ANEB-001. This is just another step in the journey to delivering a much needed solution to patients.”

“Lastly, the company has recently strengthened its capital structure by executing a credit facility with certain existing investors that will allow us access of up to \$10 million. This facility reflects their on-going confidence and support as we continue to prepare for Phase 3 trials, a very important step in our mission.”

Financial Results for the three months ended December 31, 2023

- Operating expenses in the second quarter of fiscal 2024 were \$2.8 million compared with \$3.8 million in the same period in fiscal 2023.
- Net loss in the second quarter of fiscal 2024 was \$2.7 million, or \$(0.11) per share, compared with a net loss of \$3.8 million, or \$(0.15) per share, in the second quarter of fiscal 2023.
- Cash was \$6.6 million as of December 31, 2023.

About Selonabant (ANEB-001)

Our lead product candidate is selonabant (ANEB-001), a potent, small molecule antagonist of cannabinoid receptor type 1 (CB1), under development to address the unmet medical need for a specific antidote for cannabis toxicity, including ACI. Selonabant is an orally bioavailable, readily absorbed treatment candidate that we anticipate will rapidly reverse key symptoms of ACI. Selonabant is protected by two issued patents and rights to four pending patent applications covering various methods of use of the compound and delivery systems. We are targeting initiation of Phase 3 registrational studies of oral selonabant in the first half of calendar 2024. In addition, 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 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 cannabinoid receptor type 1 (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 Anebulo’s intentions, beliefs, projections, outlook, analyses or current expectations regarding: the targeted commencement of phase 3 registrational trials for selonabant in the first half of calendar 2024; the advancement of a selonabant IV formulation; the observational study of selonabant; pending patent applications; the potential for selonabant to address an unmet medical need for a specific antidote for ACI; Anebulo becoming the first company to have an approved treatment for ACI; and Anebulo’s expectation that selonabant will rapidly reverse key symptoms of ACI or related cannabis toxicities. 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; the ability to obtain regulatory approval; the timing and success of development efforts and clinical trials may be impacted by various factors, including safety and other complications; any negative effects on the Company’s business and product development plans caused by or associated with health crises or geopolitical issues; 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 September 30, 2023, as filed with the SEC on November 14, 2023, and in Anebulo’s Quarterly Report on Form 10-Q for the quarter ended December 31, 2023, being

filed with the SEC on February 13, 2024. 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.

CONTACTS:

Anebulo Pharmaceuticals, Inc.
 Daniel George
 Acting Chief Financial Officer
 (512) 598-0931
Dan@anebulo.com

Condensed Balance Sheets

	<u>December 31,</u>	<u>June 30,</u>
	<u>2023</u>	<u>2023</u>
Cash	\$ 6,644,517	\$ 11,247,403
Total assets	7,500,773	11,670,151
Total liabilities	1,013,556	1,068,801
Total stockholders' equity	6,487,217	10,601,350

Condensed Statements of Operations

	<u>Three Months Ended December 31,</u>	
	<u>2023</u>	<u>2022</u>
Research and development	\$ 1,062,672	\$ 1,869,920
General and administrative	1,697,787	1,943,202
Total operating expenses	<u>2,760,459</u>	<u>3,813,122</u>
Loss from operations	(2,760,459)	(3,813,122)
Other (income) expenses:		
Interest income	(75,522)	(8,816)
Other	32,432	22,646
Total other (income) expenses, net	<u>(43,090)</u>	<u>13,830</u>
Net loss	<u>\$ (2,717,369)</u>	<u>\$ (3,826,952)</u>
Weighted average common shares outstanding, basic and diluted	<u>25,789,739</u>	<u>25,633,217</u>
Net loss per share, basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.15)</u>