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 14, 2025

ANEBULO PHARMACEUTICALS, INC

(Exact name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation)

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

001-40388 (Commission File Number) 85-1170950 (IRS Employer Identification No.)

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 \boxtimes

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 14, 2025, Anebulo Pharmaceuticals, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended December 31, 2024 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

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: February 14, 2025

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



Anebulo Pharmaceuticals Reports Second Quarter Fiscal Year 2025 Financial Results and Recent Updates

AUSTIN, Texas (February 14, 2025) – Anebulo Pharmaceuticals, Inc. (Nasdaq: ANEB), a clinical-stage pharmaceutical company developing novel solutions for people suffering from acute cannabis-induced toxic effects (the "Company" or "Anebulo"), today announced financial results for the three months ended December 31, 2024, and recent updates.

Second Quarter Fiscal Year 2025 and Subsequent Highlights:

- In December 2024, Anebulo met with FDA to discuss the development of intravenous selonabant and the initial plan for clinical testing. FDA acknowledged the unmet
 need for a treatment for children exposed to cannabis toxicity, and proposed a close, ongoing collaboration to efficiently advance the selonabant program for the pediatric
 indication. Anebulo plans to begin its Phase 1 single ascending dose ("SAD") study of intravenous selonabant in healthy adults in 1H25
- In December 2024, Anebulo entered into a definitive stock purchase agreement with 22NW Fund, LP ("22NW"), a company controlled by one of its directors, and existing investors for the issuance and sale of 15.2 million shares of common stock for gross proceeds of \$15 million in a private placement offering
- In February 2025, Anebulo amended the Loan and Security Agreement ("LSA") with 22NW and JFL Capital Management by reducing the maximum loan size to
 approximately \$3 million and removing all securitization provisions

"We are grateful to have the continued support from current investors. Having secured such meaningful financing is indicative of the confidence these highly respected institutional investors have in the Company's future," commented Richie Cunningham, Chief Executive Officer of Anebulo.

Cunningham continued, "There is a significant and growing unmet medical need for an emergency antidote to acute cannabis-induced toxicity. In particular, acute cannabis exposure in children can result in serious and potentially life-threatening consequences, including Central Nervous System ("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, due in part to age-related differences in the abundance of cannabis receptors in their brains. As a consequence, cannabis ingestion in children can result in much more serious outcomes than in adults, and a much greater risk of hospitalization and admission to intensive care.

In recent interactions, FDA confirmed our belief that there is an unmet need for a treatment for children exposed to cannabis toxicity and suggested a close collaboration with Anebulo to facilitate an efficient development plan for this important pediatric condition. 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 acute cannabis-induced toxicity in children."

Financial Results for the three months ended December 31, 2024

- Operating expenses in the second quarter of fiscal 2025 were \$2.6 million compared with \$2.8 million in the same period in fiscal 2024.
- Net loss in the second quarter of fiscal 2025 was \$2.5 million, or \$(0.09) per share, compared with a net loss of \$2.7 million, or \$(0.11) per share, in the second quarter of fiscal 2024.
- Cash and cash equivalents were \$15.0 million as of December 31, 2024. The Company also has access to an additional \$3 million in cash through a Loan Agreement.

About Selonabant (ANEB-001)

The Company's lead product candidate is selonabant (ANEB-001), a potent, small molecule antagonist of the cannabinoid receptor type-1 ("CB1"), under development to address the unmet medical need for a specific antidote for acute cannabis-induced toxicity, including acute cannabinoid intoxication ("ACI") in adults and unintentional cannabis poisoning in pediatric subjects. The Company anticipates that selonabant will rapidly reverse key symptoms of cannabis toxicity. Selonabant has been successfully formulated for oral administration in clinical studies and as a potential intravenous treatment for clinical testing. In a Phase 2 proof-of-concept study in adult subjects challenged with oral delta-9-tetrahydrocannabinol ("THC") (www.clinicaltrials.gov/ct2/show/NCT05282797), oral selonabant blocked or reversed key CNS effects of THC. Selonabant was well tolerated in this study and there were no serious adverse events. In the open-label extension of the study, THC challenge doses of 40 mg and 60 mg were well-tolerated when dosed in combination with oral selonabant, and all treatment-related adverse events were mild and transient. The prior Phase 1 and Phase 2 studies of oral selonabant have together enrolled a total of 250 subjects, of which 189 received selonabant. Selonabant is protected by two issued patents covering various methods of use of the compound and delivery systems. An observational study in patients presenting to Emergency Departments with cannabis toxicity is currently ongoing. The study is intended to determine concentrations of cannabinotids 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 pharmaceutical company developing novel solutions for people suffering from cannabis-induced toxicity. Its lead product candidate, selonabant, has completed a Phase 2 clinical trial evaluating its utility in blocking and reversing the negative effects of acute cannabinoid intoxication in healthy adults challenged with oral THC. Rather than proceeding directly with Phase 3 studies of oral selonabant in adults with ACI, the Company is prioritizing the advancement of a selonabant IV formulation as a potential treatment for pediatric patients with acute cannabis-induced toxicity, which it believes offers the potential for a faster timeline to approval relative to the adult oral product. Anebulo is currently scaling up the intravenous formulation for initial clinical safety studies. Selonabant is a competitive antagonist at the human CB1 receptor. 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: plans to begin its Phase 1 single ascending dose ("SAD") study of intravenous selonabant in healthy adults in 1H25; securing such meaningful financing being indicative of the confidence these highly respected institutional investors have in the company's future; the belief that there is an unmet need for a treatment for children exposed to cannabis toxicity; selonabant having the potential to offer a much-needed targeted therapy for rapidly reversing the serious and life-threatening consequences of acute cannabis-induced toxicity in children; selonabant rapidly reversing key symptoms of cannabis toxicity; the observational study determining concentrations of cannabinoids and metabolites in plasma and gathering information on signs and symptoms, patients' disposition and selected subjective assessments; and a selonabant IV formulation as a potential treatment for pediatric patients with acute cannabis-induced toxicity, offering the potential for a faster timeline to approval relative to the adult oral product. 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: Anebulo's ability to pursue its regulatory strategy including the ability to begin the Phase 1 single ascending dose ("SAD") study of intravenous selonabant in healthy adults in 1H25; the ability of selonabant to rapidly reverse key symptoms of cannabis toxicity; the ability of a selonabant IV formulation as a potential treatment for pediatric patients with acute cannabis-induced toxicity, offering the potential for a faster timeline to approval relative to the adult oral product; Anebulo's ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, Anebulo's ability to obtain or maintain the capital or grants necessary to fund its research and development activities, its ability to complete clinical trials on time and achieve desired results and benefits as expected, regulatory limitations relating to the ability to promote or commercialize product candidates for specific indications, acceptance of product candidates in the marketplace and the successful development, marketing or sale of Anebulo's products, Anebulo's ability to maintain its license agreements, the continued maintenance and growth of its patent estate and Anebulo's ability to retain its key employees or maintain its Nasdaq listing. These risks should not be construed as exhaustive and should be read together with the other cautionary statements included in Anebulo's Annual Report on Form 10-K for the year ended June 30, 2024, and its subsequent filings with the Securities and Exchange Commission, 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.

CONTACTS:

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

Condensed Balance Sheets

	December 31, 2024		June 30, 2024	
Cash and cash equivalents	\$ 14,998	467	\$ 3,094,200	
Total assets	15,841,	220	4,073,114	
Total liabilities	878.	,799	260,583	
Total stockholders' equity	14,962	421	3,812,531	

Condensed Statements of Operations

	 Three months ended December 31,			
	2024		2023	
Research and development	\$ 1,220,535	\$	1,062,672	
General and administrative	1,367,616		1,697,787	
Total operating expenses	 2,588,151		2,760,459	
Loss from operations	(2,588,151)		(2,760,459)	
Other (income) expenses:				
Interest expense	59,696		31,838	
Interest income	(7,067)		(75,522)	
Grant income	(177,703)		-	
Other	(47)		594	
Total other income, net	(125,121)		(43,090)	
Net loss	\$ (2,463,030)	\$	(2,717,369)	
Weighted average common shares outstanding, basic and diluted	 27,415,430		25,789,739	
Net loss per share, basic and diluted	\$ (0.09)	\$	(0.11)	