

May 13, 2025



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

AUSTIN, Texas--(BUSINESS WIRE)-- **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 March 31, 2025, and recent updates.

Third Quarter Fiscal Year 2025 and Subsequent Highlights:

- Anebulo is prioritizing the advancement of an intravenous selonabant as a potential treatment for pediatric patients with cannabis-induced Central Nervous System ("CNS") depression.
- The Company plans to begin dosing healthy adult volunteers in its Phase 1 single ascending dose ("SAD") study of intravenous selonabant in the third quarter of calendar 2025.

"We anticipate initiating our Phase 1 SAD study of intravenous selonabant in healthy adults aged 18 to 25 years in the third quarter of calendar 2025," 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 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 and distribution 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 a pre-Investigational New Drug ("IND") application interaction, Food and Drug Administration 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 March 31, 2025

- Operating expenses in the third quarter of fiscal 2025 were \$1.9 million compared with \$1.7 million in the same period in fiscal 2024.

- Net loss in the third quarter of fiscal 2025 was \$1.7 million, or \$(0.04) per share, compared with a net loss of \$1.7 million, or \$(0.06) per share, in the third quarter of fiscal 2024.
- Cash and cash equivalents were \$13.3 million as of March 31, 2025. The Company also has access to an additional \$3 million in cash through a Loan Agreement.

About Selonabant

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 cannabis poisoning in pediatric subjects. The Company anticipates that selonabant will rapidly reverse key symptoms of acute cannabis-induced 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 191 received selonabant. 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. Anebulo also has multiple pending applications 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 and is being amended to focus on pediatric patients. The study is intended to determine concentrations of cannabinoids and metabolites in plasma and gather information on signs and symptoms, treatment, and patient disposition, including hospital/ICU admission.

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: intravenous selonabant as a potential treatment for pediatric patients with cannabis-induced CNS depression; initiating its Phase 1 SAD study of intravenous selonabant in healthy adults aged 18 to 25 years in the third quarter of calendar 2025; 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 initiation of its Phase 1 SAD study of intravenous selonabant in healthy adults aged 18 to 25 years in the third quarter of calendar 2025; the ability of selonabant to be a potential treatment for pediatric patients with cannabis-induced CNS depression; the ability of selonabant to rapidly reverse key symptoms of cannabis toxicity, including acute cannabis-induced toxicity in children; 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.

Condensed Balance Sheets

**March 31,
2025**

**June 30,
2024**

Cash and cash equivalents	\$ 13,279,901	\$ 3,094,200
Total assets	14,008,484	4,073,114
Total liabilities	546,032	260,583
Total stockholders' equity	13,462,452	3,812,531

Condensed Statements of Operations

	Three months ended March 31,	
	2025	2024
Research and development	\$ 638,324	\$ 748,339
General and administrative	1,253,998	915,912
Total operating expenses	1,892,322	1,664,251
Loss from operations	(1,892,322)	(1,664,251)
Other (income) expenses:		
Interest expense	245,182	59,696
Interest income	(102,257)	(68,084)
Grant income	(359,606)	-
Other	528	(2,321)
Total other income, net	(216,153)	(10,709)
Net loss	\$ (1,676,169)	\$ (1,653,542)
Weighted average common shares outstanding, basic and diluted	41,084,731	25,933,217
Net loss per share, basic and diluted	\$ (0.04)	\$ (0.06)

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Source: Anebulo Pharmaceuticals, Inc.