

Anebulo Pharmaceuticals Reports Fourth Quarter and 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 and twelve months ended June 30, 2025, and recent updates.

Fourth Quarter Fiscal Year 2025 and Subsequent Highlights:

- On September 25, 2025, Anebulo announced the first subjects dosed in a Phase 1 single ascending dose ("SAD") study of an intravenous (IV) formulation of its lead drug candidate selonabant. Selonabant is under development for treatment of acute cannabis-induced toxicity in children. The study will investigate the safety, tolerability, and pharmacokinetics of selonabant administered intravenously in healthy adult subjects aged 18 to 25 years. The randomized, double-blind, placebo-controlled study design was cleared by the FDA and is being conducted at a single Phase 1 clinical study site in Austin, Texas.
- Anebulo has been awarded the second-year tranche (\$994,300) of an ongoing collaborative grant from the National Institute on Drug Abuse (NIDA) of the Nation-al Institutes of Health (NIH), under award number U01DA059995. The award provides support for the ongoing SAD study.

"We have made significant progress towards our goal of providing the first emergency antidote for acute cannabis-induced toxicity in children," commented Richie Cunningham, Chief Executive Officer of Anebulo. "Anebulo previously evaluated selonabant as an oral treatment in a Phase 2 clinical trial, demonstrating potential for blocking and reversing the negative effects of acute cannabinoid intoxication (ACI) in healthy adults challenged with oral THC. The Company has since prioritized the advancement of a selonabant IV formulation as a potential treatment for pediatric patients with acute cannabis-induced toxicity, which it believes is a more serious condition that offers the potential for a faster timeline to approval relative to the adult oral product. 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. Cannabis toxic effects in children can be much more serious than in adults, and there is a much greater risk of hospitalization and admission to intensive care."

Cunningham continued, "In addition to the continuing collaborative support from NIDA, our interactions with the Food and Drug Administration to date have confirmed our belief that there is a significant and growing unmet need for a treatment for children exposed to cannabis toxicity. FDA has suggested a close collaboration with Anebulo to facilitate the development of selonabant 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."

A Special Committee of independent directors has recommended, and the Board of Directors has approved, as part of a proposed going private transaction, an amendment to the Company's Second Amended and Restated Certificate of Incorporation, to effect a reverse stock split (the "Reverse Stock Split") of the Company's common stock, subject to obtaining the requisite approval of the Company's stockholders at a special meeting of stockholders to be held for that purpose, the date of which meeting has not yet been determined. The primary purpose of the Reverse Stock Split is to enable the Company to maintain the number of its record holders of Common Stock below 300, which is the level at or above which the Company is required to file public reports with the SEC. The Board continues to review all strategic alternatives available to the Company. While the strategic review process is ongoing, the Company currently plans to move forward with holding the special meeting of stockholders to approve the Reverse Stock Split. There can be no assurance that this process will result in the Company pursuing a transaction or any other strategic outcome. There is no deadline or definitive timetable set for completion of the strategic alternatives review process. Similarly, even if the Company's stockholders approve the Reverse Stock Split, the Board could determine to abandon the Reverse Stock Split for any reason.

Financial Results for the three months ended June 30, 2025

- Operating expenses in the fourth quarter of fiscal 2025 were \$2.3 million compared with \$1.3 million in the same period in fiscal 2024.
- Net loss in the fourth quarter of fiscal 2025 was \$2.1 million, or \$(0.05) per share, compared with a net loss of \$1.3 million, or \$(0.05) per share, in the fourth quarter of fiscal 2024.
- Cash and cash equivalents were \$11.6 million as of June 30, 2025. The Company also has access to an additional \$3 million in cash through a Loan Agreement.

Financial Results for the twelve months ended June 30, 2025

• Operating expenses in fiscal year 2025 were \$9.2 million compared with \$8.3 million in the same period in fiscal 2024. Research and development expenses increased approximately \$0.9 million from the prior year, primarily due to an increase in activities related to pre-clinical and clinical studies, and direct third-party costs incurred under agreements with CROs and CMOs for selonabant. We completed our Phase 2 proof of concept clinical trial for ACI during the first half of the fiscal year ended June 30, 2024, resulting in less expense than the current year. Rather than proceeding directly with the Phase 3 oral ACI studies in adults, we are prioritizing the advancement of a selonabant IV formulation as a potential treatment for pediatric patients with unintentional cannabis poisoning, which we believe offers the potential for a faster timeline to approval relative to the adult oral product. We have successfully scaled up the IV formulation for initial clinical safety studies. We incurred increased pre-clinical and clinical studies and contract manufacturing expenses in the year ended June 30, 2025 as we began to prepare for our Phase 1 SAD study for IV selonabant. We expect

our research and development expenses to increase as we complete the current study and prepare for further clinical trials. General and Administrative expenses increased \$0.2 million from the prior period. Compensation and related benefits decreased by \$0.3 million, primarily resulting from increased expense recognized in the prior period in connection with the severance agreement entered into with our former CEO during October 2023. Furthermore, professional and consultant fees decreased by \$0.2 million over the same period, resulting from an overall decrease due to strategic cost reductions. These decreases were offset by an increase in stock-based compensation expense of \$0.7 million due to additional option grants.

Net loss in fiscal year 2025 was \$8.5 million, or \$(0.25) per share, compared with a net loss of \$8.2 million, or \$(0.32) per share, in fiscal year 2024. The increase in the net loss and the resulting change in net loss per share was the result of increased operating expenses as discussed above, partially offset by grant income of \$0.9 million in connection with our research and development grant with NIDA.

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-9tetrahydrocannabinol ("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. Another 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 has scaled up the intravenous formulation for initial clinical safety studies, and initiated a Phase 1 SAD study of IV selonabant in September 2025. 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: providing the first emergency antidote for acute cannabis-induced toxicity in children; intravenous selonabant as a potential treatment for pediatric patients with cannabis-induced CNS depression; 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 lifethreatening 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 cannabisinduced toxicity, offering the potential for a faster timeline to approval relative to the adult oral product, statements related to strategic alternatives, and statements related to the proposed going private transaction, the related reverse stock split and the special meeting of stockholders to approve the reverse stock split. You are cautioned that any such forwardlooking 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 its Phase 1 SAD study of intravenous selonabant in healthy adults aged 18 to 25 years which was initiated in the third guarter 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. 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. 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

		June 30, 2024	
	<u>June 30, 2025</u>		
Cash and cash equivalents	\$ 11,627,849	\$	3,094,200
Total assets	12,145,616		4,073,114
Total liabilities	487,688		260,583
Total stockholders' equity	11,657,928		3,812,531

Condensed Statements of Operations

	Three months				
	30,		Year ended June 30,		
	2025	2024	2025	2024	
Research and development	\$ 1,126,223	\$ 467,706	\$ 4,299,941	\$ 3,548,937	
General and administrative	1,204,661	872,661	4,923,540	4,759,818	
Total operating expenses	2,330,884	1,340,367	9,223,481	8,308,755	
Loss from operations	(2,330,884)	(1,340,367)	(9,223,481)	(8,308,755)	
Other (income) expenses:					
Interest expense	17,439	59,696	382,014	151,230	
Interest income	(122,583)	(50,218)	(257,913)	(249,022)	
Grant income	(81,343)	-	(864,014)	-	
Other	431	124	1,195	(9,260)	
Total other (income) expenses, net	(186,056)	9,602	(738,718)	(107,052)	
Net loss	\$ (2,144,828)	\$ (1,349,969)	\$ (8,484,763)	\$ (8,201,703)	
Weighted average common shares outstanding, basic and					
diluted	41,084,731	25,933,217	33,820,306	25,822,258	
Net loss per share, basic and diluted	\$ (0.05)	\$ (0.05)	\$ (0.25)	\$ (0.32)	

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