November 13, 2024

Anebulo Pharmaceuticals Reports First 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 September 30, 2024, and recent updates.

First Quarter Fiscal Year 2025 and Subsequent Highlights:

- Anebulo announced it 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”), under award number 1U01DA059995-01.
- With the support of NIDA, Anebulo aims to complete IND-enabling activities and the scale up of its intravenous (IV) formulation of selonabant around calendar year end 2024 as it prepares for clinical studies and the Company expects to enroll the first healthy adult volunteer in the first half of calendar 2025.

“We are excited to have the support of NIDA to advance our development of a rapid and clinically impactful emergency treatment for acute cannabis-induced toxicities, including cannabis-induced Central Nervous System (CNS) depression in children,” commented Richie Cunningham, Chief Executive Officer of Anebulo.

“We believe this important grant from NIDA recognizes the significant progress we have already made with the successful Phase 2 proof of concept study of oral selonabant. This grant, along with our access to an additional $10 million in cash through the recent Loan and Security Agreement, provides further momentum for advancing the intravenous formulation towards clinical testing. We also believe the grant further validates the 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 of cannabis receptors in their brains. As a direct 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. 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.”

Financial Results for the three months ended September 30, 2024

- Operating expenses in the first quarter of fiscal 2025 were $2.4 million compared with

$2.5 million in the same period in fiscal 2024.

- Net loss in the first quarter of fiscal 2025 was $2.2 million, or $(0.08) per share, compared with a net loss of $2.5 million, or $(0.10) per share, in the first quarter of fiscal 2024.
- Cash and cash equivalents were $1.4 million as of September 30, 2024. The Company has access to an additional $10 million in cash through the Loan and Security Agreement executed on November 13, 2023.

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 t as a potential IV treatment. 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 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. The study is intended to 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 pharmaceutical company developing novel solutions for people suffering from acute cannabinoid intoxication and unintentional cannabis intoxication. 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: completion of IND-enabling activities and the scale up of Anebulo’s intravenous formulation of selonabant around year end 2024 as Anebulo prepares for clinical studies; enrollment of the first healthy adult volunteer in the first half of 2025; the grant from NIDA recognizing the significant progress the Company has already made with the successful Phase 2 proof of concept study of oral selonabant; the grant further validating the significant and growing unmet medical need for an emergency antidote to acute cannabis-induced toxicity; 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; 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 advancement 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. 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: the Company’s ability to pursue its regulatory strategy including completion of IND enabling activities and scale up of the intravenous formulation of selonabant around year end 2024 and enrolling the first healthy adult volunteer in the first half of 2025, its ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, the Company’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, the Company’s ability to maintain its license agreements, the continued maintenance and growth of its patent estate and the Company’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 the Company’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

	September 30, 2024	June 30, 2024
Cash and cash equivalents	$ 1,404,211	$ 3,094,200

Total assets	2,467,940	4,073,114
Total liabilities	569,225	260,583
Total stockholders' equity	1,898,715	3,812,531

Condensed Statements of Operations

	Three months ended September 30,	
	2024	**2023**
Research and development	$ 1,314,859	$ 1,270,220
General and administrative	1,097,265	1,273,458
Total operating expenses	2,412,124	2,543,678
Loss from operations	(2,412,124)	(2,543,678)
Other (income) expenses:		
Interest expense	59,697	-
Interest income	(26,006)	(55,198)
Grant income	(245,362)	-
Other	283	(7,657)
Total other income, net	(211,388)	(62,855)
Net loss	$ (2,200,736)	$ (2,480,823)
Weighted average common shares outstanding, basic and diluted	25,933,217	25,633,217
Net loss per share, basic and diluted	$ (0.08)	$ (0.10)

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

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