November 14, 2023

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

AUSTIN, Texas--(BUSINESS WIRE)--**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 September 30, 2023, and recent updates.

First Quarter Fiscal Year 2024 and Subsequent Highlights:

- Richie Cunningham announced as Chief Executive Officer and Board Member
- Positive Type B meeting with the United States Food and Drug Administration (FDA), focusing on finalizing our registrational study designs
- The Company presented at two major scientific meetings: the American College of Emergency Physicians Research Forum and the North American Congress of Clinical Toxicology
- Secured a credit facility of up to $10 million
- Bimal Shah announced as Board Member

"Anebulo continues to make progress towards becoming the first company to have an approved treatment for ACI. During my brief tenure at Anebulo, I have been profoundly impressed with the team and their expertise in the field of cannabis overdose. I have also had the opportunity to speak with key subject matter experts and key opinion leaders, who have shared their growing enthusiasm for the work we are doing in this area of unmet need," commented Richie Cunningham, Chief Executive Officer of Anebulo.

"The Company is at a critical juncture in its history as we endeavor to pioneer a much-needed solution to this large and growing problem. Data collected has been encouraging both on safety and efficacy, resulting in positive feedback from the FDA following a Type B meeting in July. The FDA indicated that a single, well-controlled study of ANEB-001 in ACI patients presenting to the emergency department (ED), combined with a larger THC challenge study in volunteers, could potentially provide substantial evidence to support a new drug application. Furthermore, recent data presented at the American College of Emergency Physicians Research Forum, included a pharmacokinetic / pharmacodynamic model of data from the THC challenge study of ANEB-001 in healthy volunteers. The model predicted that 10 mg ANEB-001 can rapidly reverse the effects of feeling high on THC doses up to 100 mg, a dose that cannot be directly tested in healthy volunteers, but may be relevant to the ED setting.

"The potential of being first to market with an ACI treatment, offers Anebulo shareholders a tremendous opportunity for potential value creation. In preparation for initiation of the two Phase 3 studies, we are focusing on finalizing our registrational study designs, while

continuing our dialogue with the FDA. We aim to confirm our belief that ANEB-001 can significantly reduce the treatment time of ACI patients by several hours, while providing superior patient outcomes.

“Based on our company sponsored survey of 27 U.S. emergency room physicians, who on average each saw 10.5 patients per month with ACI, indicated there is a real need for a cannabinoid antagonist such as ANEB-001 to treat ACI in the ED setting. In addition to poor patient outcomes, ACI places a substantial burden on the healthcare system, especially for patients who present with concomitant neuropsychiatric symptoms. When you consider the deregulation of cannabis, this growing trend, has the potential to result in more patients, both young and old, showing up in EDs with moderate to severe ACI.

“Lastly, the Company has recently strengthened its capital structure by executing a credit facility with certain existing investors, that will allow us access up to $10 million. This facility reflects their on-going confidence and support as we prepare to initiate Phase 3 trials.”

Financial Results for the three months ended September 30, 2023

- Operating expenses in the first quarter of fiscal 2024 were $2.5 million compared with $2.6 million in the same period in fiscal 2023.
- Net loss in the first quarter of fiscal 2024 was $2.5 million, or $(0.10) per share, compared with a net loss of $2.6 million, or $(0.11) per share, in the first quarter of fiscal 2023.
- Cash was $8.5 million as of September 30, 2023.

About Anebulo Pharmaceuticals, Inc.

Anebulo Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabinoid intoxication and substance abuse disorder. Its lead product candidate, ANEB-001, 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. ANEB-001 is a competitive antagonist at the human cannabinoid receptor type 1 (CB1). For further information about Anebulo, please visit www.anebulo.com.

About ANEB-001

Our lead product candidate is ANEB-001, a potent, small molecule cannabinoid receptor antagonist, under development to address the unmet medical need for a specific antidote for ACI. ANEB-001 is an orally bioavailable, readily absorbed treatment candidate that we anticipate will rapidly reverse key symptoms of ACI. ANEB-001 is protected by one issued patent and rights to one patent application covering various methods of use of the compound and delivery systems. We are targeting initiation of Phase 3 registrational studies of ANEB-001 in the first half of calendar 2024. In addition, an observational study in patients presenting to EDs 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.

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 potential for a single well-controlled study of ANEB-001 in ACI patients presenting to the ED combined with a larger THC challenge study in volunteers to provide substantial evidence to support a new drug application; Anebulo's ability to become the first company to have an approved treatment for ACI; the potential value that ANEB-001 may create for stockholders if approved; intent to commence phase 3 registrational trials in the first half of 2024; the potential for ANEB-001 to address an unmet medical need for a specific antidote for ACI; and Anebulo's expectation that ANEB-001 will rapidly reverse key symptoms of ACI. 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 stockholder value anticipated to be created if ANEB-001 is approved may not materialize or be as significant as anticipated; the Type B feedback should not be relied on as an indication that ANEB-001 will ultimately be approved; the timing and success of clinical trials and potential safety and other complications thereof; 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 Annual Report on form 10-K for the fiscal year ending June 30, 2023, filed with the SEC on September 22, 2023, and Anebulo's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, being filed with the SEC later today. 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, 2023	June 30, 2023
Cash	$ 8,520,578	$ 11,247,403
Total assets	9,047,884	11,670,151
Total liabilities	716,560	1,068,801
Total stockholders' equity	8,331,324	10,601,350

Condensed Statements of Operations

	Three Months Ended September 30,	
	2023	2022

Research and development	$ 1,270,220	$ 1,223,776
General and administrative	1,273,458	1,388,271
Total operating expenses	2,543,678	2,612,047
Loss from operations	(2,543,678)	(2,612,047)
Other (income) expenses:		
Interest income	(55,198)	-
Other	(7,657)	212
Total other (income) expenses, net	(62,855)	212
Net loss	$ (2,480,823)	$ (2,611,835)
Weighted average common shares outstanding, basic and diluted	25,633,217	23,416,495
Net loss per share, basic and diluted	$ (0.10)	$ (0.11)

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