September 20, 2023

Anebulo Pharmaceuticals Reports Fourth Quarter and Fiscal Year 2023 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 and twelve months ended June 30, 2023, and recent updates.

Fourth Quarter Fiscal Year 2023 and Subsequent Highlights:

- Positive feedback from the Type B meeting with the FDA supports advancing ANEB-001 to registrational studies.
- Dosing completed in Part C open-label extension of Phase 2 study evaluating up to a 60 mg challenge of THC with ANEB-001 given simultaneously in healthy volunteers. Data readout anticipated in Q4 2023.
- Observational PK study in patients reporting to the emergency department with ACI is ongoing.
- The Company will present at the following scientific conferences:
    - North American Congress on Clinical Toxicology in Montreal, Quebec: Oral Presentation on September 29 from 1 p.m. to 3 p.m. ET.
    - American Congress of Emergency Physicians in Philadelphia, PA: Poster presentation on October 9 at 10:30 a.m. ET and oral presentation on October 10, 2023, at 3:30 p.m. ET.

Management Commentary

"I am grateful for our team's hard work and diligence in transitioning Anebulo to a Phase 3-ready company, a very important step in our mission to make ANEB-001 available to individuals who present at emergency departments with cannabinoid intoxication," commented Simon Allen, Chief Executive Officer of Anebulo. "We believe ANEB-001 can significantly reduce the treatment time of ACI patients by several hours while providing superior patient outcomes. We are targeting to initiate Phase 3 registrational studies in the first half of 2024."

Financial Results for the three months ended June 30, 2023

- Operating expenses in the fourth quarter of fiscal 2023 were $2.5 million compared with $2.3 million in the same period in fiscal 2022.
- Net loss in the fourth quarter of fiscal 2023 was $2.5 million, or $(0.10) per share, compared with a net loss of $2.3 million, or $(0.10) per share, in the fourth quarter of fiscal 2022.
- Cash was $11.2 million as of June 30, 2023.

Financial Results for the twelve months ended June 30, 2023

- Operating expenses in fiscal year 2023 were $11.8 million compared with $6.8 million in the same period in fiscal 2022. Research and Development increased approximately $2.6 million over the prior year period, primarily due to increased pre-clinical and clinical studies, and direct third-party costs, in the support of ANEB-001. General and Administrative expenses increased approximately $2.3 million over the prior year period, primarily due to compensation and related benefits, and professional and consultant fees, including legal and accounting fees.
- Net loss in fiscal year 2023 was $11.7 million, or $(0.47) per share, compared with a net loss of $6.8 million, or $(0.29) per share, in fiscal year 2022. The increase in the net loss was the result of higher operating expenses in fiscal year 2023, as explained above.

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 2024. In addition, an observational study in patients presenting to Emergency Departments 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 emergency department combined with a larger THC challenge study in volunteers to provide substantial evidence to support a new drug application; Anebulo's intention to file patent applications in the US and foreign jurisdictions to further cover ANEB-001; the expected data read out in Q4 2023 for Anebulo's open-label

Part C extension of its Phase 2 clinical trial; intent to commence phase 3 registrational trials in the first half of 2024; Anebulo's intention to participate in and present at certain conferences; 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 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, as filed with the SEC on May 11, 2023. 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,	
	2023	**2022**
Cash	$ 11,247,403	$ 14,548,471
Total assets	11,670,151	15,579,431
Total liabilities	1,068,801	512,531
Total stockholders' equity	10,601,350	15,066,900

Condensed Statements of Operations

	Three months ended June 30,		Year ended June 30,	
	2023	**2022**	**2023**	**2022**
Research and development	$ 1,417,159	$ 1,118,141	$ 5,600,197	$ 2,961,538
General and administrative	1,077,230	1,207,343	6,183,402	3,869,636
Total operating expenses	2,494,389	2,325,484	11,783,599	6,831,174
Loss from operations	(2,494,389)	(2,325,484)	(11,783,599)	(6,831,174)
Other (income) expenses				
Interest income	(6)	(1,929)	(92,407)	(7,332)
Other	1,197	(813)	41,146	1,777
Total other (income) expenses, net	1,191	(2,742)	(51,261)	(5,555)
Net loss	$ (2,495,580)	$ (2,322,742)	$ (11,732,338)	$ (6,825,619))

Weighted average common shares outstanding, basic and diluted	25,633,217	23,344,567	25,074,481	23,344,567
Net loss per share, basic and diluted	$ (0.10)	$ (0.10)	$ (0.47)	$ (0.29)

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Media Contact
Ignacio Guerrero-Ros, Ph.D.
Russo Partners
(646) 942-5604
ignacio.guerrero-ros@russopartnersllc.com

Investor Relations
Adanna Alexander, Ph.D. or Harrison Seidner, Ph.D.
(646) 942-5603
(646) 942-5599
Adanna@russopr.com
Harrison.seidner@russopartnersllc.com

Anebulo Pharmaceuticals, Inc.
Sandra Gardiner
Acting Chief Financial Officer
(512) 598-0931
Sandra@anebulo.com

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