

May 11, 2023



Anebulo Pharmaceuticals Reports Third Quarter Fiscal 2023 Financial Results and Recent Updates

AUSTIN, Texas, May 11, 2023 /PRNewswire/ -- **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 March 31, 2023, and recent updates.



Third Quarter Fiscal Year 2023 and Subsequent Highlights:

- Anebulo announced positive Phase 2 clinical data demonstrating the potential of ANEB-001 as a treatment for ACI.
- Anebulo to host a KOL event in the second quarter CY2023.
- Company executives will participate in the BIO International Convention on June 5-8, 2023, in Boston, Massachusetts.
- Type B meeting with FDA granted for July 2023.

Management Commentary

"We are very encouraged by the progress our team has made in developing what has the potential to be the first FDA approved therapy to treat patients suffering from acute cannabinoid intoxication," said Simon Allen, Chief Executive Officer of Anebulo. "In March, we announced the full positive data from Part B of our Phase 2 study of ANEB-001 in healthy volunteers challenged with THC. We believe these data, in conjunction with our observational study of ACI patients in the emergency room setting, will provide a solid foundation for discussing a registrational path for ANEB-001 with FDA. That meeting has now been scheduled for July."

Financial Results for the three months ended March 31, 2023

- Operating expenses in the third quarter of fiscal 2023 were \$2.9 million compared with \$1.9 million in the same period in fiscal 2022.
- Net loss in the third quarter of fiscal 2023 was \$2.8 million, or \$(0.11) per share, compared with a net loss of \$1.9 million, or \$(0.08) per share, in the third quarter of fiscal 2022.
- Cash was \$14.2 million as of March 31, 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 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, 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 began a Phase 2 proof-of-concept trial for ANEB-001 in December 2021 in the Netherlands and announced positive Phase 2 Part A proof-of-concept topline data on July 5, 2022, positive Part B data on September 26, 2022, completed dosing of all subjects in mid-December 2022, and announced preliminary Phase 2 Part B data on January 09, 2023. On March 28, 2023, we announced complete results from Part A and Part B of our Phase 2 clinical trial. A Type B meeting to discuss these data with FDA is scheduled for July 2023.

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," "believe," "designed," "expect," "intend," "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 Type B meeting scheduled with FDA in July 2023; the Company's plans to host a KOL event in the second calendar quarter of 2023; the Company's participation at the BIO International Convention in June 2023; future results that may be implied by prior results; Anebulo's belief that the data from its Phase 2 Study of ANEB-001, together with data from its planned observational study in ACI subjects, will provide support for the potential approval of ANEB-001; 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 FDA's scheduling of the Type B meeting should not be relied on as an indication that ANEB-001 will ultimately be approved; the outcome of the Type B meeting is uncertain; 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 COVID-19 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 December 31, 2022, as filed with the SEC on February 10, 2023, and Anebulo's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, which is 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.

CONTACTS:

Media Contact

Ignacio Guerrero-Ros, Ph.D.

Russo Partners

(646) 942-5604

ignacio.guerrero-ros@russopartnersllc.com

Investor Relations

Adanna Alexander, PhD

(646) 942-5603

Adanna@RussoPR.com

Anebulo Pharmaceuticals, Inc.

Sandra Gardiner

Acting Chief Financial Officer

(512) 598-0931

Sandra@anebulo.com

Condensed Balance Sheets

	March 31, 2023	June 30, 2022
Cash	\$ 14,164,805	\$ 14,548,471
Total assets	14,432,606	15,579,431
Total liabilities	1,491,085	512,531
Total stockholders' equity	12,941,521	15,066,900

Condensed Statements of Operations

	2022	2021	2022	2021
	Three Months Ended		Nine Months Ended	
	March 31,		March 31,	
	2023	2022	2023	2022
Research and development	\$ 1,089,342	\$ 915,363	\$ 4,183,038	\$ 1,843,397
General and administrative	1,774,699	964,281	5,106,172	2,662,293
Total operating expenses	2,864,041	1,879,644	9,289,210	4,505,690

Loss from operations	(2,864,041)	(1,879,644)	(9,289,210)	(4,505,690)
Other income, net	66,070	3,153	52,452	2,813
Net loss	<u>\$ (2,797,971)</u>	<u>\$ (1,876,491)</u>	<u>\$ (9,236,758)</u>	<u>\$ (4,502,877)</u>
Weighted average common shares outstanding, basic and diluted	<u>25,633,217</u>	<u>23,344,567</u>	<u>24,888,916</u>	<u>23,344,567</u>
Net loss per share, basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.08)</u>	<u>\$ (0.37)</u>	<u>\$ (0.19)</u>

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