

November 12, 2021



# Anebulo Pharmaceuticals Reports First Quarter Fiscal Year 2022 Financial Results and Provides a Business Update

AUSTIN, Texas--(BUSINESS WIRE)-- **Anebulo Pharmaceuticals, Inc.** (Nasdaq: ANEB), a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabinoid intoxication and substance addiction, today announced financial results for the first quarter of its fiscal year ending June 30, 2022 and reported recent business highlights.

Highlights for the quarter ended September 30, 2021 and recent weeks include the following:

- **Method of use U.S. patent issued for ANEB-001 strengthens intellectual property protection.** In October the Company announced the issuance of U.S. patent No. 11,141,404, titled "Formulations And Methods For Treating Acute Cannabinoid Overdose." The patent provides protection through 2040 and describes use of the Company's investigational drug ANEB-001 to treat acute cannabinoid overdose.
- **Completed manufacturing of ANEB-001 capsules for upcoming Phase 2 clinical trial.** In compliance with current Good Manufacturing Practice requirements, the Company delivered ANEB-001's active pharmaceutical ingredient to its contract manufacturer to fill into 10 mg and 50 mg capsules for finished product.
- **Formed Scientific Advisory Board (SAB) with two founding co-chairs.** In August Anebulo formed the SAB to advise the Company on its clinical development programs and product pipeline. The founding co-chairs are Andrew Monte, M.D., Ph.D. and Arjun Chanmugam, M.D., both recognized leaders in emergency medicine.
- **On track to commence Phase 2 proof-of-concept clinical trial with ANEB-001 for the treatment of acute cannabinoid intoxication by year-end.** The planned Phase 2 study at a single site in the Netherlands has been approved by the institution's regulatory and ethics committee. The study is expected to enroll 100 healthy volunteers with each to receive 10 mg of THC orally, and then randomized to one of three doses of ANEB-001 or placebo. The Company expects topline results to be available in the first half of 2022.

## Management Commentary

"We continue to advance ANEB-001's clinical development and are pleased with our progress to date. In addition, we affirm expectations to initiate the Phase 2 clinical study for ANEB-001 by the end of this year and look forward to reporting topline results in the first half of 2022. Furthermore, we plan to speak with the U.S. FDA regarding ANEB-001's domestic regulatory path before year-end," stated Daniel Schneeberger, M.D., Chief Executive Officer

of Anebulo. “We recently announced a key milestone with the issuance of a method of use patent for ANEB-001, providing protection through 2040. We plan to enhance our intellectual property portfolio with additional patent applications in the U.S. and key overseas markets. We believe there is a significant unmet need to treat acute cannabinoid intoxication and that ANEB-001 has the ability to reverse symptoms in a safe and effective manner.”

### **First Quarter Fiscal 2022 Financial Results**

- Operating expenses in the first quarter of fiscal 2022 were \$1,554,924 compared with \$252,346 in the same period in fiscal 2021.
- Net loss in the first quarter of fiscal 2022 was \$1,553,395, or \$(0.07) per share, compared with a net loss of \$256,379, or \$(0.02) per share, in the first quarter of fiscal 2021.
- Cash was approximately \$19.2 million as of September 30, 2021.

### **About ANEB-001**

ANEB-001 is a competitive antagonist at the human CB1 receptor with good oral bioavailability and brain penetration (brain:plasma ratio of approximately = 1.5). ANEB-001 has been shown to antagonize THC-induced hypolocomotion in mice, a CB1 receptor-mediated response.

ANEB-001 is being developed to be administered as an oral treatment, reaches potentially therapeutic blood levels within 30 minutes and is believed to rapidly reverse the signs and symptoms of cannabinoid overdose in as little as one hour. Anebulo believes there is a low likelihood of drug-drug interactions as preclinical testing demonstrated that ANEB-001 does not inhibit the metabolic cytochromes 1A2, 2C9, 2C19, 2D6 and 3A4 at pharmacologically relevant concentrations. No product is approved for acute cannabinoid intoxication and Anebulo is not aware of any competing products to reverse the symptoms of cannabinoid intoxication that are further along in the development process than ANEB-001.

### **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 addiction. Its lead product candidate, ANEB-001, is intended to reverse the negative effects of acute cannabinoid intoxication within one hour of administration. Clinical trials completed to date have shown that ANEB-001 is rapidly absorbed, well tolerated and leads to weight loss, an effect that is consistent with central cannabinoid receptor type 1 antagonism. For further information about Anebulo, please visit [www.anebulo.com](http://www.anebulo.com).

### **Forward-Looking Statements**

This press release contains 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. These forward-looking statements, along with terms such as “anticipate,” “expect,” “intend,” “may,” “will,” “should” and other comparable terms, involve risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. Those statements include statements regarding the intent, belief or current expectations of Anebulo Pharmaceuticals and members of its management, as well as the

assumptions on which such statements are based. Prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, including risks attendant to developing, testing and commercializing the company's product candidates, including funding of clinical trials, and those described in Anebulo Pharmaceutical's 2021 annual report on Form 10-K filed with the SEC, and that actual results may differ materially from those contemplated by such forward-looking statements. Except as required by federal securities law, Anebulo Pharmaceuticals undertakes no obligation to update or revise forward-looking statements to reflect changed conditions.

**Anebulo Pharmaceuticals, Inc.  
Condensed Balance Sheet Data**

	<b>September 30, 2021</b>	<b>June 30, 2021</b>
Cash	\$ 19,207,743	\$ 19,985,645
Total assets	20,500,342	21,653,491
Total liabilities	607,706	241,633
Total stockholders' equity	19,892,636	21,411,858

**Anebulo Pharmaceuticals, Inc.  
Condensed Statements of Operations**

	<b>Three Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
Research and development	\$ 715,098	\$ 20,286
General and administrative	839,826	232,060
Total operating expenses	1,554,924	252,346
Loss from operations	(1,554,924)	(252,346)
Other income (expenses), net	1,529	(4,033)
Net loss	\$ (1,553,395)	\$ (256,379)
Weighted average common shares outstanding, basic and diluted	23,344,567	12,000,000
Net loss per share, basic and diluted	\$ (0.07)	\$ (0.02)

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Source: Anebulo Pharmaceuticals, Inc.