

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 11, 2022

ANEBULO PHARMACEUTICALS, INC
(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40388
(Commission
File Number)

85-1170950
(IRS Employer
Identification No.)

Anebulo Pharmaceuticals, Inc.
1415 Ranch Road 620 South, Suite 201
Lakeway, TX
(Address of Principal Executive Offices)

78734
(Zip Code)

Registrant's Telephone Number, Including Area Code: (512) 598-0931

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$.0001 par value per share	ANEB	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On February 11, 2022, Anebulo Pharmaceuticals, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended December 31, 2021 and providing a business update. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ANEBULO PHARMACEUTICALS, INC.

Date: February 11, 2022

By: /s/ Simon Allen
Simon Allen
Chief Executive Officer
(Principal Executive Officer)



Anebulo Pharmaceuticals Reports Second Quarter Fiscal Year 2022 Financial Results and Recent Updates

AUSTIN, Texas (February 11, 2022) – **Anebulo Pharmaceuticals, Inc.** (Nasdaq: ANEB), a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabinoid intoxication and substance abuse (the “Company” or “Anebulo”), today announced financial results for the three months ended December 31, 2021 and recent updates.

Highlights from the fiscal year 2022 second quarter and recent weeks include the following:

- **Initiated a Phase 2 proof-of-concept clinical study to investigate ANEB-001 as a potential treatment for acute cannabinoid intoxication.** The Phase 2 clinical trial is a randomized, double-blind, placebo-controlled study at the Centre for Human Drug Research in, Leiden, the Netherlands to evaluate ANEB-001 in the inhibition of THC-induced effects. The Company expects topline results to be available in the first half of calendar year 2022.
 - **Participated in a pre-IND (Investigational New Drug) meeting with the U.S. Food and Drug Administration (FDA) during which the company received guidance regarding the clinical development of ANEB-001 in the United States.** The FDA noted that a challenge model whereby subjects are exposed to THC in a controlled clinical setting, as an essential alternative to patient studies, may be acceptable. FDA also suggested we submit a model-informed drug development (MIDD) paired-meeting request, potentially allowing for more frequent contact with the FDA to improve our path to clinical development and intended registration.
 - **Named Simon Allen as Chief Executive Officer and a member of the Board of Directors.** Mr. Allen joined Anebulo on February 1, 2022. Previously he served as Chief Business Officer of Ambrx Biopharma Inc., where he helped prepare and conclude its NYSE IPO and establishing multiple partnerships with pharmaceutical companies such as Bristol Myers Squibb, Pfizer, Merck, Eli Lilly, Astellas, BeiGene and Sino Biopharma. These partnerships generated over \$270 million in non-dilutive revenue with the potential to earn over a billion dollars in future milestones plus royalties for the company. From 2016 to 2018 he was Chief Executive Officer of CohBar where he transitioned the company from preclinical to clinical, managed the listing of its shares on Nasdaq, and included the company into the Russell 2000 Index. Mr. Allen started his career in the lab at Gilead Sciences working on antiviral drugs for HIV and Influenza prior to spending over two decades in sell-side biotech business development at companies such as Skyepharma, CovX and Kalypsos.
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- **Appointed Scott L. Anderson as Head of Investor Relations and Public Relations.** Mr. Anderson joined Anebulo on January 1, 2022 and is responsible for Anebulo’s global investor relations and public relations programs. With more than 20 years of public company IR and PR experience, Mr. Anderson continues to enhance the Companies outreach programs while managing investor and corporate relationships. Mr. Anderson began his career in similar capacities at companies such as Qualcomm, Qorvo (formerly RF Micro Devices), Actavis plc (formerly Watson Pharmaceuticals) and O2Micro International.
 - **Issued U.S. method-of-use patent for ANEB-001.** The Company strengthened its intellectual property with 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 the use of ANEB-001 to treat acute cannabinoid overdose.

Management Commentary

“I am thrilled to join the Anebulo team at such an exciting time in the company’s development. There is a significant and pressing need to treat acute cannabinoid intoxication as hospital emergency department visits for this condition reached 1.7 million in 2018 and continue to increase by approximately 15% annually as more states legalize the use of marijuana,” stated Simon Allen, Chief Executive Officer of Anebulo. “In January, we announced the initiation of our Phase 2 clinical study of ANEB-001 in the Netherlands and expect to report topline results in the first half of this year, an important step in achieving our goal of developing the first FDA-approved therapy for acute cannabinoid intoxication.”

Second Quarter Fiscal 2022 Financial Results

- Operating expenses in the second quarter of fiscal 2022 were \$1.1 million compared with \$0.3 million in the same period in fiscal 2021.
- Net loss in the second quarter of fiscal 2022 was \$1.1 million, or \$(0.05) per share, compared with a net loss of \$0.3 million, or \$(0.03) per share, in the second quarter of fiscal 2021.
- Cash burn in the second quarter of fiscal 2022 was \$1.2 million compared with \$0.4 million in the same period in fiscal 2021.
- Cash and cash equivalents were \$18.0 million as of December 31, 2021.

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. Its lead product candidate, ANEB-001, is intended to reverse the negative effects of acute cannabinoid intoxication within one hour of administration. ANEB-001 is a competitive antagonist at the human cannabinoid receptor type 1 (CB1). For further information about Anebulo, please visit 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, and those described in Anebulo Pharmaceutical’s most recent annual report on Form 10-K and in other periodic reports 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.

CONTACTS:**Anebulo Pharmaceuticals, Inc.**

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Head of Investor Relations and Public Relations

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scott@anebulo.com

Rex Merchant

Chief Financial Officer

(512) 598-0931

IR@anebulo.com**Anebulo Pharmaceuticals, Inc.
Condensed Balance Sheet Data**

	December 31, 2021	June 30, 2021
Assets		
Cash	\$ 18,008,990	\$ 19,985,645
Total assets	<u>\$ 18,963,871</u>	<u>\$ 21,653,491</u>
Liabilities and stockholders' equity		
Total liabilities	49,944	241,633
Total stockholders' equity	18,913,927	21,411,858
Total liabilities and stockholders' equity	<u>\$ 18,963,871</u>	<u>\$ 21,653,491</u>

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

	Three Months Ended December 31,	
	2021	2020
Research and development	\$ 212,936	\$ 169,982
General and administrative	858,186	154,589
Total operating expenses	<u>1,071,122</u>	<u>324,571</u>
Loss from operations	(1,071,122)	(324,571)
Other expenses, net	(1,869)	(4,033)
Net loss	<u>\$ (1,072,991)</u>	<u>\$ (328,604)</u>
Weighted average common shares outstanding, basic and diluted	23,344,567	12,982,500
Net loss per share, basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.03)</u>

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