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): September 22, 2021

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

Delaware	001-40388	85-1170950
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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, $.0.001 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 September 22, 2021, Anebulo Pharmaceuticals, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the fiscal quarter and year ended June 30, 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
99.1	Press Release dated September 22, 2021

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: September 22, 2021

By: */s/ Daniel Schneeberger*
Daniel Schneeberger
Chief Executive Officer

Exhibit 99.1

September 22, 2021

Anebulo Pharmaceuticals Reports Fourth Quarter and Fiscal Year 2021 Financial Results and Provides a Business Update

AUSTIN, Texas (September 22, 2021) – 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 three and 12 months ended June 30, 2021 and reported recent business highlights.

Business highlights for the fourth quarter of fiscal year 2021 and recent weeks include the following:

- **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 2021, the Company 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.

- **Closed initial public offering (IPO) of common stock.** The Company completed its IPO of 3,078,224 shares of common stock at $7.00 per share for gross proceeds to Anebulo of $21.5 million. On May 7, 2021, the Company's common stock began trading on the Nasdaq Capital Market under the symbol ANEB.

- **Raised sufficient capital to fund operations through calendar year 2022.** Management believes the IPO net proceeds of $19.8 million provide adequate funding for the Company's planned business operations and clinical studies through the end of calendar year 2022.

- **On track to commence Phase 2 proof-of-concept clinical trial with ANEB-001 for the treatment of acute cannabinoid intoxication in the fourth quarter of 2021**. The planned Phase 2 study will take place at a single site in the Netherlands and 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 are pleased with our progress toward initiating the Phase 2 clinical study of ANEB-001 for the treatment of patients with acute cannabinoid intoxication later this year. As the number of emergency department visits related to cannabis intoxication continues to increase by approximately 15% annually, we believe there is a significant unmet medical need for our drug candidate," stated Daniel Schneeberger, M.D., Chief Executive Officer of Anebulo. "The manufacture of finished product for ANEB-001 was a critical step in preparation for our proof-of-concept study in the Netherlands. In addition, we were delighted to announce the formation of our SAB with founding members who bring significant expertise in emergency medicine and medical toxicology. We intend to expand the SAB over time and look forward to their valuable contributions for our initial indication, as well as in the exploration of other potential indications to expand our addressable market."

Financial Results

Anebulo Pharmaceuticals commenced operations in May 2020. As such, all prior-year comparisons reflect approximately one month of operations.

- Operating expenses in the fourth quarter of fiscal 2021 were $2,484,705 compared with $173,351 in the same period in fiscal 2020. Operating expenses in fiscal 2021 were $3,613,753 compared with $173,351 in fiscal 2020.
- Net loss in the fourth quarter of fiscal 2021 was $29,111,739, or $(1.59) per share, compared with a net loss of $174,637, or $(0.01) per share, in the fourth quarter of fiscal 2020. Net loss in fiscal 2021 was $30,252,554, or $(2.83) per share, compared with a net loss of $174,637, or $(0.01) per share, in fiscal 2020. The number of shares outstanding has been adjusted to reflect the 6:1 stock split effected prior to the Company's May 6, 2021 IPO.
- Cash was approximately $20 million as of June 30, 2021.

About ANEB-001

Anebulo believes ANEB-001 is an asset with a well-understood mechanism of action. ANEB-001 is a competitive antagonist at the human CB1 receptor with an affinity of 0.6nM with good oral bioavailability and brain penetration (brain:plasma ratio = 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.

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.

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Condensed Balance Sheet Data

	June 30,	
	2021	2020
Cash	$ 19,985,645	$ 3,024,980
Total assets	21,653,491	3,028,480
Total liabilities	241,633	223,865
Series A convertible preferred stock	-	2,975,752
Total stockholders' equity (deficit)	21,411,858	(171,137)

Condensed Statements of Operations

	Three months ended June 30,		Year ended June 30,	
	2021	2020	2021	2020
Research and development	$ 1,806,692	$ 150,000	$ 2,269,998	$ 150,000
General and administrative	678,013	23,351	1,343,755	23,351
Total operating expenses	2,484,705	173,351	3,613,753	173,351
Loss from operations	(2,484,705)	(173,351)	(3,613,753)	(173,351)
Other (income) expenses				
Interest income	(1,020)	-	(1,020)	-
Interest expense	-	1,286	11,767	1,286
Fair value adjustments for milestone warrants	26,626,710	-	26,626,710	-
Other	1,344	-	1,344	-
Total other expenses, net	26,627,034	1,286	26,638,801	1,286
Net loss	$ (29,111,739)	$ (174,637)	$ (30,252,554)	$ (174,637)
Deemed dividends	-	-	(8,208,393)	-
Net loss attributable to common stockholders	$ (29,111,739)	$ (174,637)	$ (38,460,947)	$ (174,637)
Weighted average common share outstanding, basic and diluted	18,293,103	12,000,000	13,612,701	12,000,000
Net loss per share, basic and diluted	$ (1.59)	$ (0.01)	$ (2.83)	$ (0.01)