# 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 9, 2022**

# 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** **78734**
**(Address of Principal Executive Offices)** **(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 9, 2022, 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, 2022 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 9, 2022 |
| 104 | Cover Page of Interactive Data File (embedded within the Inline XBRL document). |

**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 9, 2022

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

**Exhibit 99.1**

**Anebulo Pharmaceuticals Reports Fourth Quarter and Fiscal Year 2022 Financial Results and Highlights Recent Business Progress**

**AUSTIN, Texas (September 9, 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 and twelve months ended June 30, 2022 and reported recent business updates.

Fourth Quarter Fiscal Year 2022 and Subsequent Highlights:

- **Anebulo to hold its Inaugural R&D Day in New York City on September 26, 2022**
- **Announced positive topline data from Part A of an ongoing Phase 2 clinical trial evaluating the potential of ANEB-001 to treat acute cannabinoid intoxication (ACI)**
- **Company executives are scheduled to participate in the following investor conferences:**
    - H.C. Wainwright 24th Annual Global Investment Conference, September 12-14, 2022
    - Cowen 4th Annual Cannabis Policy Summit, September 12, 2022
    - LD Micro Invitational Main Event XV Investor Conference, October 25-27, 2022

**Business Updates and Upcoming Milestones**

The Company's lead product candidate, ANEB-001, is being developed as a potential treatment to rapidly reverse the negative effects of ACI. The signs and symptoms of ACI include profound sedation, anxiety, panic, hallucinations, and psychosis. More than 1.7 million emergency department visits in the United States were related to cannabinoid use in 2019, which includes ACI and other cannabis-related conditions. There are currently no FDA approved drugs to treat ACI.

In July 2022, the Company announced positive topline data from Part A of its ongoing Phase 2 clinical trial evaluating the potential of ANEB-001 to treat ACI. Part A was a 60-subject randomized, double-blind, placebo-controlled trial designed to evaluate the effectiveness of a single dose of ANEB-001 in treating healthy subjects challenged with delta-9-tetrahydrocannabinol, better known as THC, the primary psychoactive constituent of cannabis. Healthy subjects received a single dose of oral THC (10.5 mg) with a single oral dose of ANEB-001 (50 mg or 100 mg) or placebo.

The topline data demonstrated a significant, robust, and sustained reduction in key symptoms of ACI, including reduction of the VAS feeling high score ($p < 0.0001$) and improvement in the VAS alertness scale ($p < 0.01$). In addition, the proportion of subjects reporting feeling high on the VAS was significantly reduced by ANEB-001 ($p < 0.001$). The effects of a 50 mg ANEB-001 were similar to those of a 100 mg dose, indicating lower doses should be evaluated. ANEB-001 was well tolerated in these healthy volunteers. Preliminary safety information showed all adverse events were mild and transient, except in the case of one subject in the 50 mg ANEB-001 group who experienced transient moderate nausea and vomiting.

Based on the encouraging data from Part A, the Company plans to initiate Part B of the study at CHDR by the end of third quarter 2022 to evaluate lower doses of ANEB-001. Anebulo is currently collaborating with the Model-Informed Drug Development (MIDD) group at FDA to develop a PK/PD model that will potentially allow prediction of optimal doses for treatment of ACI subjects. Preparations are ongoing for an observational study in ACI subjects in the emergency department setting to further support the PK/PD model and ANEB-001 development. Submission of an Investigational New Drug application (IND) for ANEB-001 to initiate U.S. trials is anticipated by the end of 2022.

**Management Commentary**

"2022 has been a time of diligent execution as we continue our efforts to develop the first FDA approved therapy for ACI," stated Simon Allen, Chief Executive Officer of Anebulo. "The positive topline data from Part A of our ongoing Phase 2 trial provided a solid foundation for the continued development of ANEB-001. As such, we look forward to presenting our strategy and vision for this program in greater detail, including new Part B data, during our R&D Day on September 26. Operations and expenditures for this most recent quarter keep us on budget and on target to progress ANEB-001 deeper into the clinic."

**Financial Results for the three months ended June 30, 2022**

- Operating expenses in the fourth quarter of fiscal 2022 were $2.3 million compared with $2.5 million in the same period in fiscal 2021.
- Net loss in the fourth quarter of fiscal 2022 was $2.3 million, or $(0.10) per share, compared with a net loss of $29.1 million, or $(1.59) per share, in the fourth quarter of fiscal 2021.
- Cash burn in the fourth quarter of fiscal 2022 was $2.0 million.
- Cash was $14.5 million as of June 30, 2022.

**Financial Results for the twelve months ended June 30, 2022**

- Operating expenses in fiscal year 2022 were $6.8 million compared with $3.6 million in fiscal year 2021.
- Net loss in fiscal year 2022 was $6.8 million, or $(0.29) per share, compared with a net loss of $30.3 million, or $(2.83) per share, in fiscal year 2021.
- Cash burn in fiscal year 2022 was $5.4 million.

**Anebulo to Host Inaugural R&D Day in New York City on Monday, September 26**

The Company will host its inaugural R&D Day on Monday, September 26, 2022, from 10:00 a.m. to 12:30 p.m. (ET) in Midtown, New York City. Anebulo's CEO, Simon Allen will be joined Dr. Joseph Lawler (Founder and Chairman), Dr. Ken Cundy (CSO) and other senior executives to discuss the Company's vision and strategy for ANEB-001, including new data from Part B of our ongoing Phase 2 trial.

Investors and financial analysts are invited to attend and can register via email at AnebuloIR@mww.com.

**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:**

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**Condensed Balance Sheet Data**

| | June 30, | |
|---|---|---|
| | **2022** | **2021** |
| Cash | $ 14,548,471 | $ 19,985,645 |
| Total assets | 15,579,431 | 21,653,491 |
| Total liabilities | 512,531 | 241,633 |
| Total stockholders' equity | 15,066,900 | 21,411,858 |

**Condensed Statements of Operations**

| | Three months ended June 30, | | Year ended June 30, | |
|---|---|---|---|---|
| | **2022** | **2021** | **2022** | **2021** |
| Research and development | $ 1,118,141 | $ 1,806,692 | $ 2,961,538 | $ 2,269,998 |
| General and administrative | 1,207,343 | 678,013 | 3,869,636 | 1,343,755 |
| Total operating expenses | 2,325,484 | 2,484,705 | 6,831,174 | 3,613,753 |
| Loss from operations | (2,325,484) | (2,484,705) | (6,831,174) | (3,613,753) |
| Other (income) expenses | | | | |
| Interest income | (1,929) | (1,020) | (7,332) | (1,020) |
| Interest expense | - | - | - | 11,767 |
| Fair value adjustments for milestone warrants | - | 26,626,710 | - | 26,626,710 |
| Other | (813) | 1,344 | 1,777 | 1,344 |
| Total other expenses, net | (2,742) | 26,627,034 | (5,555) | 26,638,801 |
| Net loss | $ (2,322,742) | $ (29,111,739) | $ (6,825,619) | $ (30,252,554) |
| Deemed dividends | - | - | - | (8,208,393) |
| Net loss attributable to common stockholders | $ (2,322,742) | $ (29,111,739) | $ (6,825,619) | $ (38,460,947) |
| Weighted average common share outstanding, basic and diluted | 23,344,567 | 18,293,103 | 23,344,567 | 13,612,701 |
| Net loss per share, basic and diluted | $ (0.10) | $ (1.59) | $ (0.29) | $ (2.83) |