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 10, 2023

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 Stock Market LLC**

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 10, 2023, Anebulo Pharmaceuticals, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended December 31, 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 February 10, 2023
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: February 10, 2023

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

Exhibit 99.1

Anebulo Pharmaceuticals Reports Second Quarter Fiscal Year 2023 Financial Results and Recent Updates

AUSTIN, Texas (February 10, 2023) – 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, 2022 and recent updates.

Second Quarter Fiscal Year 2023 and Subsequent Highlights:

- **Completed dosing its randomized, double-blind, placebo-controlled Phase 2 trial evaluating ANEB-001's potential in treating acute cannabinoid intoxication ("ACI").**
- **Preliminary data showed that a single 10 mg oral dose of ANEB-001 reduced key symptoms of ACI induced by 30 mg of oral THC.**
- **Final Phase 2 data expected by the end of the first calendar quarter of 2023**
- **End of Phase 2A (EOP2A) meeting with FDA expected second calendar quarter of 2023.**
- **Continued development of an ANEB-001 parenteral formulation**

Management Commentary

"We completed dosing our Phase 2 in December of last year and remain on-track to present final data before the end of this current calendar quarter, a milestone that enables an EOP2A meeting with FDA to determine the next steps in our development path. We have amassed a significant amount of human clinical data since January 2022, having dosed 134 THC challenged subjects with ANEB-001," said Simon Allen, Chief Executive Officer of Anebulo. "Data from an ongoing observational study of ACI patients in the emergency department setting is expected to supplement our efforts to develop the first FDA approved therapy to treat ACI."

Financial Results for the three months ended December 31, 2022

- **Operating expenses in the second quarter of fiscal 2023 were $3.8 million compared with $1.1 million in the same period in fiscal 2022.**
- **Net loss in the second quarter of fiscal 2023 was $3.8 million, or $(0.15) per share, compared with a net loss of $1.1 million, or $(0.05) per share, in the second quarter of fiscal 2022.**
- **Cash was $16.4 million as of December 31, 2022.**

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.

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 expected timing for full data from Anebulo's Phase 2 Study of ANEB-001 by the end of the first calendar quarter of 2023; the targeted timing for an End of Phase 2A meeting with the FDA in the first half of calendar 2023; Anebulo's plans to continue developing an ANEB-001 parenteral formulation; 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-0001 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; clinical trial site challenges that may impact the expected timing of the Company's ongoing clinical trials, including challenges related to COVID-19; 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 September 30, 2022, as filed with the SEC on November 10, 2022, and Anebulo's Quarterly Report on Form 10-Q for the quarter ended December 31, 2022, 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:

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Condensed Balance Sheet Data

	December 31, 2022	June 30, 2022
Cash	$ 16,355,350	$ 14,548,471
Total assets	16,888,256	15,579,431
Total liabilities	1,372,401	512,531
Total stockholders' equity	15,515,855	15,066,900

Condensed Statements of Operations

	Three Months Ended December 31,	
	2022	2021
Research and development	$ 1,869,920	$ 212,936
General and administrative	1,943,202	858,186
Total operating expenses	3,813,122	1,071,122
Loss from operations	(3,813,122)	(1,071,122)
Other expenses, net	(13,830)	(1,869)
Net loss	$ (3,826,952)	$ (1,072,991)
Weighted average common shares outstanding, basic and diluted	25,633,217	23,344,567
Net loss per share, basic and diluted	$ (0.15)	$ (0.05)