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): May 11, 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 May 11, 2023, Anebulo Pharmaceuticals, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended March 31, 2023 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 May 11, 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: May 11, 2023

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

Exhibit 99.1

Anebulo Pharmaceuticals Reports Third Quarter Fiscal 2023 Financial Results and Recent Updates

AUSTIN, Texas (May 11, 2023) – Anebulo Pharmaceuticals, Inc. (Nasdaq: ANEB), a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabinoid intoxication (ACI) and substance abuse (the "Company" or "Anebulo"), today announced financial results for the three months ended March 31, 2023, and recent updates.

Third Quarter Fiscal Year 2023 and Subsequent Highlights:

- Anebulo announced positive Phase 2 clinical data demonstrating the potential of ANEB-001 as a treatment for ACI.
- Anebulo to host a KOL event in the second quarter CY2023.
- Company executives will participate in the BIO International Convention on June 5-8, 2023, in Boston, Massachusetts.
- Type B meeting with FDA granted for July 2023.

Management Commentary

"We are very encouraged by the progress our team has made in developing what has the potential to be the first FDA approved therapy to treat patients suffering from acute cannabinoid intoxication," said Simon Allen, Chief Executive Officer of Anebulo. "In March, we announced the full positive data from Part B of our Phase 2 study of ANEB-001 in healthy volunteers challenged with THC. We believe these data, in conjunction with our observational study of ACI patients in the emergency room setting, will provide a solid foundation for discussing a registrational path for ANEB-001 with FDA. That meeting has now been scheduled for July."

Financial Results for the three months ended March 31, 2023

- Operating expenses in the third quarter of fiscal 2023 were $2.9 million compared with $1.9 million in the same period in fiscal 2022.
- Net loss in the third quarter of fiscal 2023 was $2.8 million, or $(0.11) per share, compared with a net loss of $1.9 million, or $(0.08) per share, in the third quarter of fiscal 2022.
- Cash was $14.2 million as of March 31, 2023.

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. On March 28, 2023, we announced complete results from Part A and Part B of our Phase 2 clinical trial. A Type B meeting to discuss these data with FDA is scheduled for July 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 Type B meeting scheduled with FDA in July 2023; the Company's plans to host a KOL event in the second calendar quarter of 2023; the Company's participation at the BIO International Convention in June 2023; 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; the ability to obtain regulatory approval; the FDA's scheduling of the Type B meeting should not be relied on as an indication that ANEB-001 will ultimately be approved; the outcome of the Type B meeting is uncertain; 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 December 31, 2022, as filed with the SEC on February 10, 2023, and Anebulo's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, 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.

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Condensed Balance Sheets

	March 31, 2023	June 30, 2022
Cash	$ 14,164,805	$ 14,548,471
Total assets	14,432,606	15,579,431
Total liabilities	1,491,085	512,531
Total stockholders' equity	12,941,521	15,066,900

Condensed Statements of Operations

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2023	2022	2023	2022
Research and development	$ 1,089,342	$ 915,363	$ 4,183,038	$ 1,843,397
General and administrative	1,774,699	964,281	5,106,172	2,662,293
Total operating expenses	2,864,041	1,879,644	9,289,210	4,505,690
Loss from operations	(2,864,041)	(1,879,644)	(9,289,210)	(4,505,690)
Other income, net	66,070	3,153	52,452	2,813
Net loss	$ (2,797,971)	$ (1,876,491)	$ (9,236,758)	$ (4,502,877)
Weighted average common shares outstanding, basic and diluted	25,633,217	23,344,567	24,888,916	23,344,567
Net loss per share, basic and diluted	$ (0.11)	$ (0.08)	$ (0.37)	$ (0.19)