UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2024

or

□ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File No. 001-40388

ANEBULO PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**85-1170950** **(I.R.S. Employer Identification No.)**
1017 Ranch Road 620 South, Suite 107 **Lakeway, Texas** **(Address of principal executive offices)**	**78734** **(Zip Code)**

(512) 598-0931
(Registrant's telephone number, including area code)

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	ANEB	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No □

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No □

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	□	Accelerated filer	□
Non-accelerated filer	☒	Smaller reporting company	☒
		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. □

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes □ No ☒

As of November 6, 2024, the registrant had 25,933,217 shares of common stock, par value $0.001 per share, outstanding.

Anebulo Pharmaceuticals, Inc.
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In this report, unless otherwise stated or as the context otherwise requires, references to "Anebulo Pharmaceuticals," "Anebulo," "Company," "we," "us," "our" and similar references refer to Anebulo Pharmaceuticals, Inc. The Anebulo logo, and other trademarks or service marks of Anebulo Pharmaceuticals, Inc. appearing in this report are the property of Anebulo Pharmaceuticals, Inc. This report also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this report are the property of their respective holders. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (the "Quarterly Report") contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are subject the "safe harbor" created by those sections. These forward-looking statements about us and our industry involve substantial risks and uncertainties and our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under Part II, Item 1A, "Risk Factors" in this Quarterly Report and the "Risk Factors" as set forth in the Company's Annual Report on Form 10-K for the year ended June 30, 2024 filed with the Securities and Exchange Commission (the "SEC") on September 25, 2024 (the "2024 Form 10-K"). All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "seek," "plan," "expect," "should," "would," "potentially" or the negative of these terms or similar expressions in this Quarterly Report.

We have based these forward-looking statements largely on our current expectations, beliefs, estimates and projections, and various assumptions, many of which, by their nature, are inherently uncertain and beyond our control. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These forward-looking statements include, but are not limited to, statements about:

- our expectations regarding our capital requirements, expenses and other operating results, and needs for additional financing;
- the timing or outcome of any of our regulatory submissions;
- the timing and conduct of our clinical trials, including statements regarding the timing, progress and results of current and future nonclinical studies and clinical trials, and our research and development programs;
- the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of selonabant (formerly ANEB-001)
- our expectations regarding future growth;
- our ability to obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights;
- our ability to maintain our existing licensing arrangements and enter into and maintain other collaborations or licensing arrangements;
- our estimates regarding the commercial potential and market opportunity for our product candidates;
- the performance of our third-party suppliers and manufacturers;
- our ability to compete effectively with existing competitors and new market entrants;
- the impact on our business of economic or political events or trends; and
- the impact of governmental laws and regulations.

You should not place undue reliance on these forward-looking statements. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should carefully read this Quarterly Report, including the section titled "Risk Factors" and the documents that we reference in this Quarterly Report and have filed as exhibits to this Quarterly Report as well as the 2024 Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this report by these cautionary statements.

PART I. FINANCIAL INFORMATION

Anebulo Pharmaceuticals, Inc.
Condensed Balance Sheets
(unaudited)

	September 30, 2024	June 30, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 1,404,211	$ 3,094,200
Grant receivable	245,362	-
Prepaid expenses	312,940	413,790
Total current assets	$ 1,962,513	$ 3,507,990
Other assets:		
Loan commitment fees	505,427	565,124
Total assets	2,467,940	4,073,114
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 252,142	$ 156,426
Accrued expenses	317,083	104,157
Total liabilities	569,225	260,583
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 2,000,000 shares authorized, no shares issued or outstanding at September 30, 2024 and June 30, 2024	-	-
Common stock, $0.001 par value; 50,000,000 authorized at September 30, 2024 and June 30, 2024; 25,933,217 shares issued and outstanding at September 30, 2024 and June 30, 2024	25,934	25,934
Additional paid-in capital	69,477,261	69,190,341
Accumulated deficit	(67,604,480)	(65,403,744)
Total stockholders' equity	1,898,715	3,812,531
Total liabilities and stockholders' equity	$ 2,467,940	$ 4,073,114

The accompanying notes are an integral part of these condensed financial statements.

Anebulo Pharmaceuticals, Inc.
Condensed Statements of Operations
(unaudited)

	Three Months Ended September 30,	
	2024	**2023**
Research and development	$ 1,314,859	$ 1,270,220
General and administrative	1,097,265	1,273,458
Total operating expenses	2,412,124	2,543,678
Loss from operations	(2,412,124)	(2,543,678)
Other (income) expenses:		
Interest expense	59,697	-
Interest income	(26,006)	(55,198)
Grant income	(245,362)	-
Other	283	(7,657)
Other income, net	(211,388)	(62,855)
Net loss	$ (2,200,736)	$ (2,480,823)
Weighted average common shares outstanding, basic and diluted	25,933,217	25,633,217
Net loss per share, basic and diluted	$ (0.08)	$ (0.10)

The accompanying notes are an integral part of these condensed financial statements.

Anebulo Pharmaceuticals, Inc.
Condensed Statements of Stockholders' Equity
(unaudited)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at June 30, 2023	25,633,217	$ 25,634	$ 67,777,757	$ (57,202,041)	$ 10,601,350
Stock-based compensation expense	-	-	210,797	-	210,797
Net loss	-	-	-	(2,480,823)	(2,480,823)
Balance at September 30, 2023	25,633,217	$ 25,634	$ 67,988,554	$ (59,682,864)	$ 8,331,324
Balance at June 30, 2024	25,933,217	25,934	69,190,341	(65,403,744)	3,812,531
Stock-based compensation expense	-	-	286,920	-	286,920
Net loss	-	-	-	(2,200,736)	(2,200,736)
Balance at September 30, 2024	25,933,217	$ 25,934	$ 69,477,261	$ (67,604,480)	$ 1,898,715

The accompanying notes are an integral part of these condensed financial statements.

Anebulo Pharmaceuticals, Inc.
Condensed Statements of Cash Flows
(unaudited)

	Three Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (2,200,736)	(2,480,823)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	286,920	210,797
Amortization of loan commitment fee	59,697	-
Changes in operating assets and liabilities:		
Grant receivable	(245,362)	-
Prepaid expenses	100,850	(104,558)
Accounts payable	95,716	31,404
Accrued expenses	212,926	(383,645)
Net cash used in operating activities	(1,689,989)	(2,726,825)
Net decrease in cash	(1,689,989)	(2,726,825)
Cash, beginning of period	3,094,200	11,247,403
Cash, end of the period	$ 1,404,211	8,520,578

The accompanying notes are an integral part of these condensed financial statements.

Note 1. Nature of business and basis of presentation

Organization

Anebulo Pharmaceuticals, Inc. (the "Company") was founded on April 23, 2020, as a Delaware corporation. The Company is a clinical stage pharmaceutical company focused on developing treatments for cannabis toxicity, such as unintentional cannabis poisoning, acute cannabinoid intoxication ("ACI"), and the broader landscape of acute cannabis-induced conditions. The Company's principal operations are located in Lakeway, Texas.

Liquidity and capital resources

Since inception, the Company's activities have consisted primarily of performing research and development to advance its product candidates. The Company is still in the development phase and has not been marketing any developed products to date. Since inception, the Company has incurred losses, including a net loss of approximately $2.2 million for the three-month period ended September 30, 2024. As of September 30, 2024, the Company had an accumulated deficit of $67.6 million. The Company expects to continue to generate operating losses. The Company expects that its cash and cash equivalents, along with available funding under the Loan and Security Agreement ("LSA"), will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance date of the financial statements.

Until such time, if ever, as the Company can generate substantial product revenue from sales of any current or future product candidates, the Company expects to seek additional funding in order to reach its development and commercialization objectives through various potential sources, such as equity and debt financings or through collaboration, license and development agreements. The Company may not be able to obtain funding or enter into collaboration, license or development agreements on acceptable terms, or at all. The terms of any funding may be dilutive to or adversely affect the rights of the Company's stockholders. If the Company is unable to obtain funding on satisfactory terms, or at all, the Company could be forced to delay, scale back or eliminate the development of its current or future product candidates or other business.

Risks and uncertainties

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include uncertainty regarding results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's current or future product candidates, uncertainty of market acceptance of the Company's product candidates, if approved, competition from substitute products and larger companies, securing and protecting proprietary technology, ability to establish strategic relationships and dependence on key individuals and sole source suppliers. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities and may not ultimately lead to a marketing approval and commercialization of a product.

The Company's product candidates require approvals from the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company was denied approval, approval was delayed or the Company was unable to maintain approval for any product candidate, it could have a materially adverse impact on the Company. Even if the Company's product development and regulatory efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales. The Company will need to generate significant revenue to achieve profitability, and it may never do so.

Basis of presentation

The accompanying condensed financial statements and accompanying notes have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The unaudited interim condensed financial statements of the Company included herein have been prepared, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been omitted from this report, as is permitted by such rules and regulations. Accordingly, these condensed financial statements should be read in conjunction with the financial statements as of and for the year ended June 30, 2024 and the notes thereto, which are included in the 2024 Form 10-K.

In the opinion of management, the information furnished reflects all adjustments, all of which are of a normal and recurring nature, necessary for a fair presentation of the results for the reported interim periods. The Company considers events or transactions that occur after the balance sheet date but before the condensed financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The results of operations for interim periods are not necessarily indicative of results to be expected for the full year or any other interim period.

Note 2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited financial statements as of and for the year ended June 30, 2024, and notes thereto, which are included in the Company's 2024 Form 10-K. Since the date of those financial statements, other than the Company's policy for accounting for research and development grants, there have been no material changes to significant accounting policies. Refer to Note 11 for further discussion.

Note 3. Prepaid Expenses

Prepaid expenses consisted of the following:

	September 30, 2024	June 30, 2024
Prepaid insurance	$ 155,507	$ 95,871
Prepaid research and development	118,893	274,879
Prepaid other	38,540	43,040
Total prepaid expenses	$ 312,940	$ 413,790

Note 4. Accrued Expenses

Accrued expenses consisted of the following:

	September 30, 2024	June 30, 2024
Accrued payroll related expenses	$ 32,843	$ 29,512
Accrued research and development	248,685	47,554
Accrued professional fees	35,555	27,091
Total accrued expenses	$ 317,083	$ 104,157

Note 5. Other Assets

Other assets include loan commitment fees. Total loan commitment fees of approximately $0.7 million are being amortized over three years, the term of the loan (see Note 10). The balance was $0.5 million and $0.6 million as of September 30, 2024 and June 30, 2024, respectively. For the three months ended September 30, 2024 and September 30, 2023, the Company recorded interest expense of $0.1 million and zero, respectively, related to the amortization of the loan commitment fees.

Note 6. License Agreement

In May 2020, the Company licensed certain intellectual property, know-how and clinical trial data from Vernalis Development Limited ("Vernalis") pursuant to the License Agreement. The initial consideration in exchange for the license was $150,000 and was recorded as research and development expense in the statement of operations for the period from April 23, 2020 (inception) to June 30, 2020. The license term shall continue unless and until terminated for cause or insolvency, upon sixty day written notice from the Company, or until such time as all royalties and other sums cease to be payable in accordance with the terms of the License Agreement. The Company is required to pay development milestone payments related to clinical trials and granting of marketing authorization ranging from $0.4 million to $3.0 million, up to a total development milestone payment of $29.9 million, and sales milestone payments of $10.0 million and $25.0 million, in the first year when cumulative annual net sales of licensed product exceeds $500.0 million and $1.0 billion, respectively. The Company is also required to pay single-digit royalties annual on net product sales over the term of the License Agreement.

As part of the initial public offering ("IPO") in May 2021, the Company issued 192,857 shares of common stock to Vernalis in lieu of future milestone payments by the Company of approximately $1.4 million, whether or not the Company achieves those milestones. The Company has determined that no further milestone payments are considered probable as of September 30, 2024, and therefore no liability has been recorded.

Note 7. Stockholders' Equity

On May 4, 2021, the Company filed an amended and restated certificate of incorporation (the "Restated Certificate") with the Secretary of State of the State of Delaware in connection with the closing of its IPO. On November 20, 2023, the Company filed a certificate of amendment to the Restated Certificate with the Secretary of State of the State of Delaware to increase the authorized number of shares of its common stock from 40,000,000 to 50,000,000 shares. As set forth in the Restated Certificate, as amended, the Company's authorized capital stock consists of 50,000,000 shares of common stock, par value $0.001 per share, and 2,000,000 shares of preferred stock, par value $0.001 per share.

On September 28, 2022, the Company completed a private placement financing of 2,264,650 units (collectively, the "Units"), with each Unit consisting of (i) one share of its common stock and (ii) a warrant to purchase one share of its common stock, for aggregate gross proceeds of approximately $6.6 million (or $2.935 per Unit). The Company received approximately $6.3 million in net proceeds after deducting financing fees of approximately $0.3 million. Each warrant has an exercise price of $4.215 per share, which is subject to customary adjustments in the event of any combination or split of the Company's common stock. The warrants expire on September 28, 2027.

On November 13, 2023, the Company issued 300,000 shares of common stock in conjunction with a Loan and Security Agreement – see Note 10.

Note 8. Stock-Based Compensation

In June 2020, the Board of Directors adopted the 2020 Stock Incentive Plan, which provided for the grant of qualified incentive stock options and nonqualified stock options or other awards to the Company's employees, officers, directors, advisors, and outside consultants for the purchase of up to 1,650,000 shares of the Company's common stock. On October 22, 2021, the Company's stockholders approved an increase of the total authorized shares available for issuance under the 2020 Stock Incentive Plan to 3,650,000 shares. Other awards include restricted stock, restricted stock units, stock appreciation rights and other stock-based awards. Other stock-based awards are awards valued in whole or in part by reference to, or are otherwise based on, shares of common stock. Stock options generally vest over a four-year period, at achievement of a performance requirement, or upon change of control (as defined in the applicable plan). The awards expire in five to ten years from the date of grant. As of September 30, 2024, the Company had 324,452 shares available for future issuance under the 2020 Stock Incentive Plan.

The Company grants non-qualified stock option awards under the 2020 Stock Incentive Plan to its Board of Directors, employees and consultants of the Company. These awards are subject to the satisfaction of certain performance targets and vesting requirements pursuant to the award.

The Company estimates the fair value of stock-based compensation utilizing the Black-Scholes option pricing model, which is dependent upon several variables, such as assumptions the Company makes for the volatility of its common stock the expected term of the stock options, the risk-free interest rate for a period that approximates the expected term, and the Company's expected dividend yield. Each of these inputs is subjective and generally requires significant judgement to determine. Stock-based compensation is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period, which is generally the vesting period of the respective award.

There were no options granted during the three months ended September 30, 2024. The following table summarizes the range of key assumptions used to determine the fair value of stock options granted during the three months ended September 30, 2024 and 2023.

	Three Months Ended September 30,	
	2024	2023
Risk-free interest rate	N/A	4.62%
Expected term (in years)	N/A	6.25
Expected volatility	N/A	60%
Expected dividend yield	N/A	0%

The following table summarizes stock option activity for the three months ended September 30, 2024:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at June 30, 2024	2,319,048	$ 3.00	6.0	
Granted	-	$ -		
Exercised	-	$ -		
Forfeited/cancelled	-	$ -		
Outstanding at September 30, 2024	2,319,048	$ 3.00	5.8	$ -
Options exercisable at September 30, 2024	903,994	$ 3.15	3.0	$ -

As of September 30, 2024, unrecognized stock-based compensation expense related to unvested stock options totaled approximately $2.1 million, which is expected to be recognized over a weighted average period of 2.3 years.

The Company recorded stock-based compensation expense of approximately $0.3 million and $0.2 million for the three months ended September 30, 2024 and 2023, respectively, all of which is included in general and administrative expenses.

Note 9. Net Loss Per Share Attributable to Common Stockholders

The following common stock equivalents were excluded from the calculation of net loss per share due to their anti-dilutive effect:

	September 30,	
	2024	**2023**
Stock options outstanding	2,319,048	2,054,893
Warrants outstanding	2,264,650	2,264,650
Total	4,583,698	4,319,543

Note 10. Loan and Security Agreement

On November 13, 2023, the Company entered into a Loan and Security Agreement ("LSA") with 22NW, LP ("22NW") and JFL Capital Management LLC ("JFL" and collectively with 22NW, the "Lenders") which will allow the Company to draw up to $10 million (the "Facility Amount") as needed to fund future operations until the third anniversary of the LSA (the "Maturity Date"). Pursuant to the LSA, if the Company elects to draw on the Facility Amount (an "Advance"), JFL has the right, but not the obligation to fund 50% of the Advance at the request of the Company. If JFL elects not to fund 50% of the Advance, then 22NW will fund 100% of the Advance. The outstanding balance will accrue interest at 0.25% per annum and no fee will be assessed on the unused balance. Upon the draw of at least $3 million in the aggregate, the LSA will be collateralized by substantially all of the Company's assets. All principal drawn and interest accrued under the LSA will be due and payable on the Maturity Date.

The Company issued 300,000 shares of common stock to 22NW upon the signing of the LSA. The Company will also issue 0.03 shares of common stock per dollar loaned in each Advance (rounded up or down to the nearest whole share) up to a maximum aggregate of 300,000 (the "Advance Shares"); provided that a minimum of 50,000 Advance Shares will be issued in connection with the first Advance. The Advance Shares shall be issued to the Lenders on a pro rata basis according to the portion of each Advance such Lender funds. There was no balance outstanding under the LSA as of September 30, 2024 or June 30, 2024, respectively.

Joseph F. Lawler, M.D., Ph.D., the Company's founder and a member of its Board of Directors, is the founder and Managing Member of JFL. Aron R. English, the President and Portfolio Manager of 22NW, and Nathaniel Calloway, the lead for 22NW, are each members of the Company's Board of Directors.

Note 11. Research and Development Grant

On July 16, 2024, the Company was awarded the first tranche of $0.9 million of a two-year cooperative grant of up to a total of approximately $1.9 million from the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health ("NIH"), to support the development of intravenous selonabant, for the potential use as an emergency treatment of acute cannabis-induced toxicities, including cannabis-induced CNS depression in children. The grant comes in the form of two tranches with the initial award of $0.9 million in the first year and subsequent funding of approximately $1 million subject to certain conditions and milestones prior to the second year, specifically that the Investigational New Drug Application to the FDA for a Phase 1 single ascending dose study of intravenous selonabant in healthy adults is permitted to proceed or that the FDA has not imposed a clinical hold that cannot be successfully addressed with available time and resources.

As the granting agency does not meet the definition of a customer under Topic 606, the Company accounts for qualifying grant receipts as other income within the Company's condensed statements of operations. The Company earns income for performing tasks under the grant agreement. Income is derived from the reimbursement of direct out-of-pocket expenses (including amounts to subrecipients), salaries and fringe benefits, and certain direct materials costs associated with grant activities.

At September 30, 2024, the Company recorded a grant receivable of $0.2 million, which relates to qualified expenses incurred in connection with grant activities which have not yet been billed back to the funding agency. The Company recorded $0.2 million of grant income for the three months ended September 30, 2024. Collection is deemed probable, and therefore no allowance for credit losses has been established. There were no receivable amounts at June 30, 2024, and no grant income was recognized during the three months ended September 30, 2023.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes included in this Quarterly Report and the audited financial statements and notes thereto as of and for the year ended June 30, 2024 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended June 30, 2024, which was filed with the Securities and Exchange Commission (the "SEC") on September 25, 2024 (the "2024 Form 10-K"). The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item 1A, "Risk Factors" in this Quarterly Report and in the 2024 Form 10-K. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage pharmaceutical company developing treatments for cannabis toxicity, such as unintentional cannabis poisoning, acute cannabinoid intoxication ("ACI"), and the broader landscape of acute cannabis-induced conditions. Our lead product candidate, selonabant (formerly ANEB-001), is intended to rapidly reverse the negative effects of cannabis toxicities and reduce time to recovery. Unintentional cannabis poisoning primarily occurs in children. Pediatric patients accidentally exposed to cannabis are at risk of serious and life-threatening outcomes including Central Nervous System ("CNS") depression, respiratory depression, seizures, and coma. ACI in adults is characterized by signs and symptoms that may include anxiety, panic attacks, agitation, psychosis, and tachycardia. There is no approved medical treatment currently available to specifically treat ACI or unintentional cannabis poisoning or ACI, and we are not aware of any competing products that are further along in the development process than selonabant in reversing the effects of cannabinoids like delta-9-tetrahydrocannabinol, better known as THC, the principal psychoactive constituent of cannabis.

Unintentional cannabis poisoning and ACI have become a widespread health issue in the United States, particularly in the increasing number of states that have legalized cannabis for medical and recreational use. Unintentional or excessive ingestion of THC via edible products such as candies and brownies, and intoxication from synthetic cannabinoids (also known as "synthetics," including "K2" or "spice"), are two potential causes of THC-related emergency room visits. Synthetic cannabinoids are analogous to fentanyl for opioids insofar as they are more potent at the cannabinoid receptor than their natural product congener THC.

Hospital emergency rooms across the United States have seen a dramatic increase in patient visits with cannabis-related conditions. In 2014, there were an estimated 1.1 million cannabis-related emergency department patient visits, according to data published in "Trends and Characteristics of Cannabis-Associated Emergency Department Visits in the United States, 2006-2018," Drug Alcohol Depend. 2022 Mar 1;232:109288. doi: 10.1016/j.drugalcdep.2022.109288. Epub 2022 Jan 10. PMID: 35033959; PMCID: PMC9885359) by Roehler DR, Hoots BE, Holland KM, Baldwin GT, and Vivolo-Kantor AM, which provided a national estimate analyzing data from The Nationwide Emergency Department Sample ("NEDS"), the largest database of U.S. hospital-owned emergency department visits. Based on our evaluation of a published analysis of the most recent NEDS data, we believe that the number of cannabis related emergency department visits grew to approximately 1.8 million patients in 2021. We believe the number of cannabis-related emergency department visits and health problems associated with unintentional cannabis poisoning and ACI will continue to increase substantially as more states pass laws legalizing cannabis for medical and recreational use. Given the consequences, there is an urgent need for a treatment to rapidly reverse the symptoms of unintentional cannabis poisoning and ACI.

Previous clinical trials completed by a third party have shown that oral selonabant is rapidly absorbed, well tolerated and, when repeatedly administered to obese subjects, leads to weight loss, an effect that is consistent with central antagonism of the cannabinoid receptor type-1 ("CB1"), the primary target of agonists like THC. In March 2021, our European clinical trial application ("CTA"), which is equivalent to an investigational new drug application in the United States, was accepted in the Netherlands to allow us to utilize oral selonabant in a randomized, double-blind, placebo-controlled Phase 2 human proof-of-concept clinical trial for potential use as a treatment for ACI (NCT05282797). The study (the "Netherlands Trial") was designed to evaluate the safety, tolerability, pharmacokinetics, and effectiveness of a single oral dose of selonabant in treating healthy adult subjects challenged with THC. On March 28, 2023, we announced complete results from Part A and Part B of the Netherlands Trial, in a total of 134 subjects. Dosing of an additional 20 subjects in an open-label extension of the study ("Part C") was initiated in July 2023 and the study was completed in August 2023. We met with the U.S. Food and Drug Administration (the "FDA") in July 2023 for a Type B meeting to discuss the Part A and B Phase 2 data and the potential path forward for Phase 3 development of oral selonabant for the treatment of adult ACI and received the minutes of the meeting in August 2023. The FDA indicated that a single well-controlled study of oral selonabant in ACI patients presenting to the emergency department combined with a larger THC challenge study in volunteers could potentially provide substantial evidence to support a new drug application. In addition, an observational study in patients presenting to emergency departments with ACI is currently ongoing. The study is designed to determine concentrations of cannabinoids and metabolites in plasma and gather information on signs and symptoms, patients' disposition and selected assessments, where possible. We believe the data generated from the Netherlands Trial provide support for our development pathway.

Rather than proceeding directly with the Phase 3 studies of oral selonabant in adults with ACI, we are prioritizing the advancement of a selonabant intravenous (IV) formulation as a potential treatment for pediatric patients with unintentional cannabis poisoning, which we believe offers the potential for a faster timeline to approval relative to the adult oral product. We are currently scaling up the intravenous formulation for initial clinical safety studies.

The recent decision by the United States Department of Justice to support the rescheduling of marijuana from a schedule I to a schedule III-controlled substance is a move that we believe will ultimately lead to increased use of cannabis-containing products among US households. This potentially includes edible products that are often the cause of unintentional cannabis poisoning in children. We have evaluated the potential advantages of prioritizing a near-term solution for children with more serious symptoms over progressing our plans for clinical studies to support an adult oral ACI treatment and have decided to focus current efforts on the pediatric indication at this time. Our decision to prioritize the development of an intravenous treatment for children is driven by multiple factors, including our recent development of a suitable IV selonabant formulation that enables its use in the pediatric population and our prior discussions with the FDA, which highlighted the need for an alternative formulation of selonabant for treating younger patients. There is increasing recognition among clinicians that this is a growing, unmet medical need in a vulnerable population where there are no approved treatments. Our belief is that the path to approval for an oral treatment for adult ACI may be facilitated by an initial approval for intravenous treatment of unintentional cannabis poisoning in the pediatric population. Furthermore, with this unprecedented change in cannabis regulation, Anebulo is uniquely positioned to become a provider of a rapid and clinically impactful solution for Emergency Departments to treat pediatric patients suffering from unintentional cannabis poisoning. Research has shown children are much more sensitive to the toxic effects of cannabis. Key factors such as an underdeveloped endocannabinoid system with more CB1 receptors in the brain than adults, and reduced ability to metabolize THC, contribute to a much greater risk to children. The risk is also evident in how cannabis effects this population; in contrast to adults who are exposed to acute cannabis toxicity, children are at risk of serious and life-threatening outcomes such as CNS depression, respiratory depression, seizures, and coma.

In May 2020, we entered into a royalty-bearing license agreement with Vernalis Development Limited ("Vernalis") to exploit its licensed compounds and licensed products to combat symptoms of ACI and substance addiction. We are currently developing our lead product candidate, selonabant to quickly, and effectively, combat symptoms of ACI.

Our lead product candidate is selonabant, a potent, small molecule cannabinoid receptor antagonist, to address the unmet medical need for a specific antidote for cannabis toxicity. Selonabant is orally bioavailable, rapidly absorbed, and has also been formulated for intravenous administration. We anticipate that both oral and IV selonabant treatments have the potential to reverse the symptoms of cannabis toxicity. Our proprietary position in the treatment of cannabis toxicity is protected by rights to two patent applications covering various methods of use of the compound and delivery systems.

We were incorporated in Delaware on April 23, 2020, and commenced operations in May 2020. Our operations to date have consisted of organizing and acquiring the license rights to Vernalis' licensed products, assembling an executive team, starting preparations for and conducting a Phase 2 proof-of-concept trial, including the synthesis of a new active pharmaceutical ingredient, the development and filing of a clinical trial protocol with regulatory agencies in Europe and raising capital. Prior to our initial public offering ("IPO"), we funded our operations through a private placement of our series A convertible preferred stock and issuance of two promissory notes to a related party.

On October 24, 2023, the United States Patent and Trademark Office issued us U.S. Patent No. 11,795,146 titled "Crystalline forms of a cannabinoid receptor type 1 (CB1) modulator and methods of use and preparation thereof." The issued patent describes crystalline forms of our investigational drug selonabant and methods of use to treat acute cannabinoid overdose and is expected to provide patent protection through 2042.

As more fully described in the Liquidity and Capital Resources section below, on November 13, 2023, we entered into a Loan and Security Agreement ("LSA") with 22NW, LP ("22NW") and JFL Capital Management LLC ("JFL") which will allow us to borrow up to $10 million as needed to fund future operations. The outstanding balance will accrue interest at 0.25% per annum and no fee will be assessed on the unused balance. The LSA will terminate and all outstanding principal drawn and interest accrued owed there under shall be due and payable on November 13, 2026 (the "Maturity Date"). As of September 30, 2024, there was no balance outstanding under the LSA.

On July 16, 2024, we were awarded the first tranche of $0.9 million of a two-year cooperative grant of up to a total of approximately $1.9 million from the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health ("NIH"), to support the development of intravenous selonabant, for the potential use as an emergency treatment of acute cannabis-induced toxicities, including cannabis-induced CNS depression in children. With the support of NIDA, Anebulo aims to complete IND-enabling activities and the scale up of its formulation of intravenous selonabant around calendar year end 2024 as it prepares for clinical studies and the Company expects to enroll the first healthy adult volunteer in the first half of calendar 2025. The grant comes in the form of two tranches with the initial award of $0.9 million in the first year and subsequent funding of approximately $1 million subject to certain conditions and milestones prior to the second year, specifically that the Investigational New Drug Application to the FDA for a Phase 1 single ascending dose study of intravenous selonabant in healthy adults is permitted to proceed or that the FDA has not imposed a clinical hold that cannot be successfully addressed with available time and resources.

Components of Results of Operations

Revenue

We have not generated any revenue since inception. If our development efforts for our current lead product candidate, selonabant, or other additional product candidates that we may develop in the future, are successful and result in marketing approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates. We have incurred operating losses since inception and expect to continue to incur significant operating losses and negative cash flows from operations in the future.

Research and Development Expenses

We expect to continue incurring significant research and development costs related to selonabant. Our research and development expenses for the three months ended September 30, 2024 and 2023 included research and development consulting expenses, clinical and nonclinical trials, and other costs, such as third-party and manufacturing costs, associated with development of our lead product candidate, selonabant.

We anticipate that our research and development activities will account for a significant portion of our operating expenses and these costs are expensed as incurred. We expect to significantly increase our research and development efforts as we continue to develop selonabant and conduct clinical trials with patients suffering from symptoms of cannabis toxicity, as well as continue to expand our product-candidate pipeline. Research and development expenses include:

- employee-related expenses, such as salaries, share-based compensation, benefits and travel expense for research and development personnel;
- direct third-party costs such as expenses incurred under agreements with contract research organizations ("CROs") and contract manufacturing organizations ("CMOs");
- costs associated with research and development activities of consultants;
- other third-party expenses directly attributable to the development of our product candidates; and
- amortization expense for future asset purchases used in research and development activities.

We currently have one lead product candidate; therefore, we do not track our internal research and development expenses on an indication-by-indication basis.

Research and development activities will continue to be central to our business model. We expect our research and development expenses to be significant over the next several years as we advance our current clinical development program and prepare to seek regulatory approval.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2024 and 2023 consisted primarily of professional fees, stock-based compensation, insurance, personnel costs and rent.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

The following table summarizes our results of operations:

	Three Months Ended September 30,		Period to Period
	2024	**2023**	**Change**
Research and development	$ 1,314,859	$ 1,270,220	$ 44,639
General and administrative	1,097,265	1,273,458	(176,193)
Total operating expenses	2,412,124	2,543,678	(131,554)
Loss from operations	(2,412,124)	(2,543,678)	131,554
Other (income) expenses:			
Interest expense	59,697	-	59,697
Interest income	(26,006)	(55,198)	29,192
Grant income	(245,362)	-	(245,362)
Other	283	(7,657)	7,940
Other income, net	(211,388)	(62,855)	(148,533)
Net loss	$ (2,200,736)	$ (2,480,823)	$ 280,087

Research and Development Expenses

Research and development expenses consisted of the following:

	Three Months Ended September 30,		Period to Period
	2024	2023	Change
Pre-clinical, nonclinical and clinical studies	$ 833,861	$ 841,133	$ (7,272)
Contract manufacturing	215,466	143,302	72,164
Other research and development	265,532	285,785	(20,253)
Total research and development expenses	$ 1,314,859	$ 1,270,220	$ 44,639

Research and development expenses during the three months ended September 30, 2024 were consistent with the comparable prior year period. We completed our Phase 2 proof of concept clinical trial for ACI during the first half of the fiscal year ended June 30, 2024. Rather than proceeding directly with the Phase 3 oral ACI studies in adults, we are prioritizing the advancement of a selonabant IV formulation as a potential treatment for pediatric patients with unintentional cannabis poisoning, which we believe offers the potential for a faster timeline to approval relative to the adult oral product. We expect our research and development expenses to increase as we continue to scale up the IV formulation and commence clinical safety studies.

General and Administrative Expenses

General and administrative expenses consisted of the following:

	Three Months Ended September 30,		Period to Period
	2024	2023	Change
Compensation and related benefits	$ 306,613	$ 264,710	$ 41,903
Professional and consultant fees	315,794	613,960	(298,166)
Stock-based compensation expense	286,920	210,797	76,123
Directors' and officers' insurance	117,158	117,525	(367)
Facilities, fees and other costs	70,780	66,466	4,314
Total general and administrative expenses	$ 1,097,265	$ 1,273,458	$ (176,193)

The overall decrease in general and administrative expenses was primarily attributable to a decrease in professional and consultant fees, including legal and investor relations fees, resulting from strategic cost reductions.

Interest Expense

Interest expense during the three months ended September 30, 2024 was $0.1 million, compared to zero during the three months ended September 30, 2023. Interest expense is due to the amortization of loan commitment fees in connection with the LSA, which was not entered into until November 2023, and therefore no expense was recorded during the three months ended September 30, 2023.

Interest Income

Interest income during the three months ended September 30, 2024 was approximately $26,000, compared to approximately $55,000 during the three months ended September 30, 2023. The decrease in interest income is due to an overall decrease in cash and cash equivalents as well as a decrease in interest rates.

Grant Income

During the three months ended September 30, 2024, we recognized grant income of $0.2 million in connection with our research and development grant with NIDA. Grant income is derived from the reimbursement of direct out-of-pocket expenses associated with grant activities. There was no grant income recognized during the three months ended September 30, 2023, as the NIDA grant was not executed until July 2024 and there were no other comparable grants.

Liquidity and Capital Resources

Overview

Since our inception in April 2020, we have incurred significant operating losses. We expect to incur significant expenses and operating losses in the future as we advance the clinical development of our programs. In May 2021, we completed our IPO in which we received net proceeds of approximately $19.8 million. On September 28, 2022, we closed a private placement offering, in which we received net proceeds of approximately $6.3 million. As of September 30, 2024, we had cash and cash equivalents of $1.4 million. As and if necessary, we will seek to raise additional funds through various potential sources, such as equity and debt financings or through collaboration, license and development agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations on acceptable terms or at all, or, if such funds are available to us, that such additional financing will be sufficient to meet our needs.

Loan and Security Agreement

On November 13, 2023, we entered into the LSA with 22NW and JFL (the "Lenders") which will allow us to draw up to $10 million (the "Facility Amount") as needed to fund future operations until the Maturity Date. Pursuant to the LSA, if we elect to draw on the Facility Amount (an "Advance"), JFL has the right, but not the obligation to fund 50% of the Advance at our request. If JFL elects not to fund 50% of the Advance, then 22NW is obligated to fund 100% of the Advance. The outstanding balance will accrue interest at 0.25% per annum and no fee will be assessed on the unused balance. Upon the draw of at least $3 million in the aggregate, the LSA will be collateralized by substantially all of our assets. All principal drawn and interest accrued under the LSA will be due and payable on the Maturity Date.

We issued 300,000 shares of common stock to 22NW upon the signing of the LSA. We will also issue 0.03 shares of common stock per dollar loaned in each Advance (rounded up or down to the nearest whole share) up to a maximum aggregate of 300,000 (the "Advance Shares"); provided that a minimum of 50,000 Advance Shares will be issued in connection with the first Advance. The Advance Shares shall be issued to the Lenders on a pro rata basis according to the portion of each Advance such Lender funds. As of September 30, 2024, there was no balance outstanding under the LSA.

Joseph F. Lawler, M.D., Ph.D., our founder and a member of our Board of Directors, is the founder and Managing Member of JFL. Aron R. English, the President and Portfolio Manager of 22NW, and Nathaniel Calloway, the lead for 22NW, are each members of our Board of Directors.

Cash Flows

The following table sets forth a summary of our cash flows:

	Three Months Ended September 30,	
	2024	**2023**
Net cash used in operating activities	(1,689,989)	(2,726,825)
Net decrease in cash	$ (1,689,989)	$ (2,726,825)

During the three months ended September 30, 2024, we used cash in operating activities of approximately $1.7 million primarily resulting from our net loss of $2.2 million, partially offset by non-cash related stock-based compensation and loan commitment amortization totaling approximately $0.3 million, and a change in operating assets and liabilities of approximately $0.2 million.

During the three months ended September 30, 2023, we used cash in operating activities of approximately $2.7 million primarily resulting from our net loss of $2.5 million, partially offset by non-cash related stock-based compensation of approximately $0.2 million, and a change in operating assets and liabilities of approximately $0.5 million.

Funding and Material Cash Requirements

We expect that our cash and cash equivalents at September 30, 2024, along with access to the Facility Amount under the LSA, will enable us to fund our current and planned operating expenses and capital expenditures for at least the next 12 months from the filing of this Quarterly Report. We have based these estimates on assumptions that may prove to be imprecise, and we may exhaust our available capital resources sooner that we currently expect. Because of the numerous risks and uncertainties associated with the development of our programs, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates.

Our present and future funding and cash requirements will depend on many factors, including, among other things:

- the progress, timing and completion of our ongoing and planned clinical trials and nonclinical studies;
- our ability to receive, and the timing of receipt of, future regulatory approvals for our product candidates and the costs related thereto;
- the scope, progress, results and costs of our ongoing and planned operations;
- the costs associated with expanding our operations and building our sales and marketing capabilities;
- our ability to establish strategic collaborations;
- the cost and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the revenue, if any, received from commercial sales of our products, if approved; and
- potential new product candidates we identify and attempt to develop.

Until such time, if ever, as we can generate substantial product revenue from sales of any of our current or future product candidates, to support our material cash requirements in the near-term (within one year) and long-term (beyond one year), we will need to seek additional equity or debt financing or potential collaboration, license or development agreements to provide the capital required to maintain or expand our operations, continue the development of our product candidate, build our sales and marketing capabilities, promote brand identity, develop or acquire complementary technologies, products or businesses, or provide for our working capital requirements and other operating and general corporate purposes. If we raise additional capital by issuing equity securities and/or equity-linked securities, the percentage ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. We may also issue equity securities and/or equity-linked securities that provide rights, preferences and privileges senior to those of our common stock. The LSA does, and any additional debt financing, if obtained, may, involve agreements that include liens on our assets and covenants limiting or restricting our ability to take specific actions such as incurring additional debt. Debt financing could also be required to be repaid regardless of our operating results. If we raise funds through collaborations, license or development agreements, we may be required to relinquish some rights to our current or future products or revenue streams or grant licenses on terms that are not favorable to us. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of our current or future product candidates and other business.

Contractual Obligations and Commitments

License Agreement with Vernalis Development Limited

On May 26, 2020, we entered into an exclusive license agreement (the "License Agreement") with Vernalis Development Limited, formerly Vernalis (R&D) Limited ("Vernalis"). Pursuant to the License Agreement, Vernalis granted us an exclusive worldwide royalty-bearing license to develop and commercialize a compound that we refer to as selonabant, as well as access to and a right of reference with respect to any regulatory materials under its control. The License Agreement allows us to sublicense the rights thereunder to any person with similar or greater financial resources and expertise without Vernalis' prior consent, provided the proposed sublicensee is not developing or commercializing a product that contains a CB1 antagonist or is for the same indication covered by the trials or market authorization for selonabant. In exchange for the exclusive license, we agreed to pay Vernalis a non-refundable signature fee of $0.2 million, total potential developmental milestone payments of up to $29.9 million (of which $0.4 million has been paid), total potential sales milestone payments of up to $35.0 million, and low to mid-single digit royalties on net sales.

We have the sole discretion to carry out the development and commercialization of selonabant, including obtaining regulatory approvals, and we are responsible for all costs and expenses in connection therewith. We have access to certain regulatory materials, including study reports from clinical and non-clinical trials, under Vernalis' control. We agreed to use commercially reasonable efforts to (i) develop and commercialize selonabant in the United States and certain European countries and (ii) conduct dose a patient as part of a Phase 2 and human clinical trial within two years of the commencement date of the License Agreement (which obligation we have met), and dose a patient as part of a Pivotal Trial (as such term is defined in the License Agreement) within four years of commencement of the License Agreement, which period was in accordance with the terms of the License Agreement extended for a nominal fee. We also agreed to provide Vernalis with periodic reports of our activities and notice of market authorization within specified timeframes.

Office Lease, Manufacturing Contract and CRO Contract

We manage our business operations from our principal executive office in Lakeway, Texas, in leased space under a sublease with a related party for approximately $400 per month.

We have a manufacturing agreement with a third-party CMO. The total cost for the current contract is approximately $3.0 million. The manufacturing aspect of this contract was substantially completed as of June 30, 2024. The stability study aspect of the contract is expected to be fully incurred during calendar 2026.

We enter into contracts in the normal course of business with clinical trial sites and clinical supply manufacturers and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and therefore, are cancellable contracts.

Critical Accounting Estimates

Our condensed financial statements are prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The preparation of our condensed financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our condensed financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are disclosed in the audited financial statements as of and for the year ended June 30, 2024, and notes thereto, which are included in our 2024 Form 10-K that was filed with the SEC on September 25, 2024, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our condensed financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our condensed financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed and some require advanced payments. We make estimates of our accrued expenses of each balance sheet date in our condensed financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with performing research services on our behalf and any clinical trials;
- investigative sites or other providers in connection with studies and any clinical trials;
- vendors in connection with the preparation of our NDA filing, market and patient awareness programs, market research and analysis and medical education; and
- vendors related to product manufacturing, development and distribution of clinical supplies.

We base our expenses for services rendered on our estimates of the services received and efforts expended pursuant to quotes, contracts and communicating with our vendors. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payments. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid or accrued expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period.

Stock-Based Compensation Expense

Our 2020 Stock Incentive Plan provides for the grant of qualified incentive stock options and nonqualified stock options or other awards to our employees, officers, directors, advisors, and outside consultants for the purchase of up to 3,650,000 shares of our common stock. Other awards include restricted stock, restricted stock units, stock appreciation rights and other stock-based awards. Other stock-based awards are awards valued in whole or in part by reference to, or are otherwise based on, shares of common stock. Stock options generally vest over a four-year period, at achievement of a performance requirement, or upon change of control (as defined in the applicable plan). The awards expire in five to ten years from the date of grant.

The fair value of stock options we grant is estimated using the Black Scholes option pricing model. This option pricing model based on certain subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free rate of interest, and (iv) expected dividends. The fair value of our common stock utilized in the model is determined based on the quoted closing market price of our common stock as reported by Nasdaq on the date of grant.

There were no significant changes to assumptions used to value options using the Black Scholes option pricing model during the three months ended September 30, 2024.

JOBS Act Accounting Election

The Jumpstart Our Business Startups ("JOBS") Act, enacted in April 2012, permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have and intend to continue to take advantage of all of the reduced reporting requirements and exemptions, including the longer phase-in periods for the adoption of new or revised financial accounting standards, for an emerging growth company under Section 107 of the JOBS Act. Our election to use the phase-in periods may make it difficult to compare our financial statements to those of non-emerging growth companies and other emerging growth companies that have opted out of the phase-in periods under Section 107 of the JOBS Act. See "Risk Factors" in our 2024 Form 10-K and our election to delay adoption of new or revised accounting standards applicable to public companies may result in our financial statements not being comparable to those of some other public companies. As a result of this and other reduced disclosure requirements applicable to emerging growth companies, our securities may be less attractive to investors.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required for smaller reporting companies.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of September 30, 2024, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2024, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may be a party to litigation or subject to claims incident to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. We are not currently a party to any material legal proceedings, and our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations or financial condition.

ITEM 1A. RISK FACTORS

We are subject to various risks that could have a material adverse impact on our financial position, results of operations or cash flows. Although it is not possible to predict or identify all such risks or uncertainties, they may include, but are not limited to, the factors discussed under "Risk Factors" in Part I, Item 1A of the Company's 2024 Form 10-K that was filed with the SEC on September 25, 2024. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also have a material adverse impact on our financial position, results of operations or cash flows. Except as set forth below, there have been no other material changes to our risk factors since our aforementioned Annual Report on Form 10-K.

We have not generated any revenue since our inception and expect to incur future losses and may never become profitable.

We have not generated any revenue. As of September 30, 2024, we have an accumulated deficit of $67.6 million, which includes a fair value adjustment of $26.6 million for warrants converted into Series A preferred stock on a cashless basis in connection with our IPO. The likelihood of our future success must be considered in light of the expenses, difficulties, complications and delays often encountered by companies in clinical development, including in connection with ongoing and future clinical trials and the emergence of competing products or therapies. These potential challenges include unanticipated clinical trial delays, poor data, changes in the regulatory and competitive landscape and additional costs and expenses that may exceed current budget estimates. In order to complete certain clinical trials and otherwise operate pursuant to our current business strategy, we anticipate that we will incur increased operating expenses. In addition, we expect to incur significant losses and experience negative cash flow in the future as we fund our operating losses and capital expenditures. We recognize that if we are unable to generate sufficient revenues or source funding, we will not be able to continue operations as currently contemplated, complete planned clinical trials and/or achieve profitability. Our failure to achieve or maintain profitability will also negatively impact the value of our shares. If we are unsuccessful in addressing these risks, then we may need to curtail our business activities.

The future success of our business cannot be determined at this time, and we do not anticipate generating revenue from product sales in the near term. In addition, we have no experience in obtaining regulatory approval for and commercializing drug products on our own and face a number of challenges with respect to development and commercialization efforts, including, among other challenges:

- having inadequate financial or other resources to complete the development of our product candidate;
- the inability to manufacture our product in commercial quantities, at an adequate quality, at an acceptable cost or in collaboration with third parties;
- experiencing delays or unplanned expenditures in product development, clinical testing or manufacturing;
- the inability to establish adequate sales, marketing and distribution channels;
- healthcare professionals may not adopt and patients may not accept our drug, if approved for marketing;
- we may not be aware of possible complications or other side effects from the use of our product since we have limited clinical experience with respect to the actual effects from use of our product;
- technological breakthroughs in reversing cannabis toxicity and treating patients experiencing intoxication symptoms may reduce the demand for our product, if it develops;
- changes in the market for reversing cannabis toxicity and treating patients experiencing intoxication symptoms, new alliances between existing market participants and the entrance of new market participants may interfere with our market penetration efforts;
- third-party payors may not agree to reimburse patients for any or all of the purchase price of our product, which may adversely affect patients' willingness to use our product;
- uncertainty as to market demand may result in inefficient pricing of our product;
- we may face third-party claims of intellectual property infringement;
- we may fail to obtain or maintain regulatory approvals for our product in our markets or may face adverse regulatory or legal actions relating to our product even if regulatory approval is obtained; and
- we are dependent upon the results of clinical studies relating to our product and the products of our competitors. If data from a clinical trial is unfavorable, we would be reluctant to advance the product for the indication for which it was being developed.

If we are unable to meet any one or more of these challenges successfully, our ability to effectively obtain regulatory approval for and commercialize our products could be limited, which in turn could have a material adverse effect on our business, financial condition and results of operations.

We currently have no product revenue and will need to raise additional capital in the future, which may be unavailable to us or may cause dilution or place significant restrictions on our ability to operate.

We may be unable to generate sufficient revenue or cash flow to fund our operations. We expect that our cash and cash equivalents at September 30, 2024, along with access to funding under the LSA, will enable us to fund our current and planned operating expenses and capital expenditures into the fourth quarter of calendar year 2025. We have based these estimates on assumptions that may prove to be incorrect, and we may exhaust our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of our programs, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidate. Until such time, if ever, as we can generate substantial product revenue from sales of any of our current or future product candidates, we will need to seek additional equity or debt financing or potential collaboration, license or development agreements to provide the capital required to maintain or expand our operations, continue the development of our product candidate, build our sales and marketing capabilities, promote brand identity, develop or acquire complementary technologies, products or businesses, or provide for our working capital requirements and other operating and general corporate purposes.

Other than the LSA, we currently do not have any arrangements or credit facilities as a source of funds, and we make no assurance that we will be able to raise sufficient additional capital in the future if needed on acceptable terms, or at all. Even if we draw down the entire $10 million available under the LSA, we will still require additional funding to fund our planned operations and capital expenditures. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of our current or future product candidates and other business, seek collaborations, or amend existing collaborations, for research and development programs at an earlier stage than otherwise would be desirable or for the development of programs that we otherwise would have sought to develop independently, or on terms that are less favorable than might otherwise be available, dispose of technology assets, or relinquish or license on unfavorable terms, our rights to technologies or any future product candidates that we otherwise would seek to develop or commercialize ourselves, pursue the sale of our company to a third party at a price that may result in a loss on investment for our stockholders, file for bankruptcy or cease operations altogether. This may materially adversely affect our operations and financial condition as well as our ability to achieve business objectives and maintain competitiveness.

If we raise additional capital by issuing equity securities and/or equity-linked securities, the percentage ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. In addition, the LSA requires that we issue 0.03 shares of common stock per dollar loaned under the LSA, which will result in dilution to shareholders. We may also issue equity securities and/or equity-linked securities that provide for rights, preferences and privileges senior to those of our common stock. Given our need for cash and that equity and equity-linked issuances are very common types of fundraising for companies like us, the risk of dilution is particularly significant for our stockholders.

The LSA includes, and future debt financing, if obtained, may involve agreements that include liens on our assets and covenants limiting or restricting our ability to take specific actions such as incurring additional debt. Debt financing, including the LSA, could also be required to be repaid regardless of our operating results.

If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our current or future products or revenue streams or to grant licenses on terms that are not favorable to us.

Any additional capital raising efforts may divert the attention of our management from day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

We did not sell any equity securities during the quarter ended September 30, 2024 in transactions that were not registered under the Securities Act.

Issuer Purchases of Equity Securities

None.

Repurchases

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

During the three months ended September 30, 2024, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

ITEM 6. EXHIBITS

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation of Anebulo Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K, filed with the SEC on September 9, 2022).
3.2	Certificate of Correction to Second Amended and Restated Certificate of Incorporation of Anebulo Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K, filed with the SEC on September 9, 2022).
3.3	Certificate of Amendment to the Second Amended and Restated Certificate of Incorporation of Anebulo Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on November 21, 2023).
3.4	Amended and Restated Bylaws of Anebulo Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on October 13, 2022).
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File – the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

† Compensatory plan or management contract.
# Certain of the schedules and attachments to this exhibit have been omitted pursuant to Regulation S-K, Item 601(a)(5). The Registrant hereby undertakes to provide further information regarding such omitted materials to the Securities and Exchange Commission upon request.

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 thereunto duly authorized.

ANEBULO PHARMACEUTICALS, INC.

Date: November 13, 2024

By: */s/ Richard Anthony Cunningham*
Richard Anthony Cunningham
Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2024

By: */s/ Daniel George*
Daniel George
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) OR 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Richard Anthony Cunningham, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2024 of Anebulo Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2024

By: */s/ Richard Anthony Cunningham*
Richard Anthony Cunningham
Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) OR 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Daniel George, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2024 of Anebulo Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2024

By: */s/ Daniel George*
Daniel George
Chief Financial Officer
(*Principal Financial and Accounting Officer*)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Anebulo Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officers of the Company hereby certify, pursuant to 18 U.S.C. Section 1350, that to their knowledge:

(1) The Quarterly Report on Form 10-Q for the period ended September 30, 2024 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2024

By */s/ Richard Anthony Cunningham*
Richard Anthony Cunningham
Chief Executive Officer
(*Principal Executive Officer*)

Date: November 13, 2024

By */s/ Daniel George*
Daniel George
Chief Financial Officer
(*Principal Financial and Accounting Officer*)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Anebulo Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.