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 March 31, 2022

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	**85-1170950**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1415 Ranch Road 620 South, Suite 201 Lakeway, Texas	**78734**
(Address of principal executive offices)	**(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	Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

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 May 10, 2022, the registrant had 23,344,567 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.

PART I. FINANCIAL INFORMATION

Anebulo Pharmaceuticals, Inc.
Condensed Balance Sheets
(unaudited)

	March 31, 2022	June 30, 2021
Assets		
Current assets:		
Cash	$ 16,547,727	$ 19,985,645
Prepaid expenses and other current assets	700,740	1,667,846
Total assets	$ 17,248,467	$ 21,653,491
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 83,277	$ 110,048
Accrued expenses	2,500	131,585
Total liabilities	85,777	241,633
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value; 40,000,000 shares authorized; 23,344,567 shares issued and outstanding at March 31, 2022 and June 30, 2021	23,345	23,345
Additional paid-in capital	60,286,306	60,032,597
Accumulated deficit	(43,146,961)	(38,644,084)
Total stockholders' equity	17,162,690	21,411,858
Total liabilities and stockholders' equity	$ 17,248,467	$ 21,653,491

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

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2022	**2021**	**2022**	**2021**
Research and development	$ 915,363	$ 273,038	$ 1,843,397	$ 463,306
General and administrative	964,281	279,093	2,662,293	665,742
Total operating expenses	1,879,644	552,131	4,505,690	1,129,048
Loss from operations	(1,879,644)	(552,131)	(4,505,690)	(1,129,048)
Other income (expenses), net	3,153	(3,701)	2,813	(11,767)
Net loss	$ (1,876,491)	$ (555,832)	$ (4,502,877)	$ (1,140,815)
Deemed dividends	-	(8,208,393)	-	(8,208,393)
Net loss attributable to common stockholders	$ (1,876,491)	$ (8,764,225)	$ (4,502,877)	$ (9,349,208)
Weighted average common shares outstanding, basic and diluted	23,344,567	12,982,500	23,344,567	12,656,310
Net loss per share, basic and diluted	$ (0.08)	$ (0.68)	$ (0.19)	$ (0.74)

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

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

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance at June 30, 2020	2,047,500	$ 2,975,752	12,000,000	$ 12,000	$ -	$ (183,137)	$ (171,137)
Issuance of restricted common stock	-	-	982,500	983	(983)	-	-
Stock-based compensation expense	-	-	-	-	16,408	-	16,408
Net loss	-	-	-	-	-	(256,379)	(256,379)
Balance at September 30, 2020	2,047,500	2,975,752	12,982,500	$ 12,983	$ 15,425	$ (439,516)	$ (411,108)
Stock-based compensation expense	-	-	-	-	20,694	-	20,694
Net loss	-	-	-	-	-	(328,604)	(328,604)
Balance at December 31, 2020	2,047,500	2,975,752	12,982,500	$ 12,983	$ 36,119	$ (768,120)	$ (719,018)
Deemed dividends	-	-	-	-	-	$ (8,208,393)	$ (8,208,393)
Stock-based compensation expense	-	-	-	-	47,407	-	47,407
Net loss	-	-	-	-	-	(555,832)	(555,832)
Balance at March 31, 2021	2,047,500	2,975,752	$ 12,982,500	$ 12,983	$ 83,526	$ (9,532,345)	$ (9,435,836)
Balance at June 30, 2021	-	-	23,344,567	23,345	60,032,597	(38,644,084)	$ 21,411,858
Stock-based compensation expense	-	-	-	-	34,173	-	34,173
Net loss	-	-	-	-	-	(1,553,395)	(1,553,395)
Balance at September 30, 2021	-	-	23,344,567	23,345	60,066,770	(40,197,479)	19,892,636
Stock-based compensation expense	-	-	-	-	94,282	-	94,282
Net loss	-	-	-	-	-	(1,072,991)	(1,072,991)
Balance at December 31, 2021	-	-	23,344,567	23,345	60,161,052	(41,270,470)	18,913,927
Stock-based compensation expense	-	-	-	-	125,254	-	125,254
Net loss	-	-	-	-	-	(1,876,491)	(1,876,491)
Balance at March 31, 2022	-	$ -	23,344,567	$ 23,345	$ 60,286,306	$ (43,146,961)	$ 17,162,690

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

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

	Nine Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (4,502,877)	$ (1,140,815)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	253,709	84,509
Changes in operating assets and liabilities:		
Receivable – related party	-	3,500
Prepaid expenses and other current assets	967,106	(591,662)
Accounts payable	(26,771)	82,027
Accrued expenses	(129,085)	188,560
Net cash used in operating activities	(3,437,918)	(1,373,881)
Cash flows from financing activities:		
Proceeds from issuance of Series A preferred milestone warrants	-	2,250,000
Repayment of promissory notes, related party	-	(201,286)
Deferred offering costs	-	(392,730)
Net cash provided by financing activities	-	1,655,984
Net (decrease) increase in cash	(3,437,918)	282,103
Cash, beginning of period	19,985,645	3,024,980
Cash, end of the period	$ 16,547,727	$ 3,307,083
Supplemental cash flow information:		
Cash paid for interest	$ -	$ 13,053
Supplemental Disclosure of Noncash Investing and Financing Activities:		
Deemed dividends	$ -	$ 8,208,393
Fair value of warrants issued to investors	$ -	$ 10,458,393

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

Anebulo Pharmaceuticals, Inc.
Notes to Condensed Financial Statements
(unaudited)

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 biotechnology company focused on developing and commercializing new treatments for patients suffering from Acute Cannabis Intoxication (ACI) and addiction. The Company's principal operations are located in Lakeway, Texas.

Stock split and Initial Public Offering

On April 23, 2021, the Company effected a six-for-one stock split of its common stock prior to the completion of the Company's Initial Public Offering (IPO). All shares, stock options, warrants and per share information presented in the accompanying condensed financial statements and notes thereto have been adjusted to reflect the stock split on a retroactive basis for all periods presented. There was no change in the par value of the Company's common stock.

On May 11, 2021, the Company completed an IPO of 3,078,224 shares of its common stock, including the exercise by the underwriter of its option to purchase 78,224 additional shares of common stock, for aggregate gross proceeds of approximately $21,548,000 and its shares started trading on The Nasdaq Capital Market under the ticker symbol "ANEB." The Company received approximately $19,783,000 in net proceeds after deducting underwriting discounts and commissions and other offering expenses payable by the Company. Upon the closing of the IPO on May 11, 2021, a cashless exercise of warrants resulted in the issuance of 5,236,343 shares of Series A convertible preferred stock and all of the outstanding shares of Series A convertible preferred stock automatically converted into 7,283,843 shares of common stock.

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 $4,502,877 for the nine months ended March 31, 2022. As of March 31, 2022, the Company had an accumulated deficit of $43,146,961. The Company expects to continue to generate operating losses. As of May 11, 2022, the issuance date of the condensed financial statements for the three and nine months ended March 31, 2022, the Company expected that its cash and cash equivalents would be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance date of the condensed financial statements.

The Company may seek additional funding in order to reach its development and commercialization objectives. The Company may not be able to obtain funding on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any funding may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects.

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 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).

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, 2021 and the notes thereto, which are included in the Company's Annual Report on Form 10-K (File No. 001-40388).

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.

Reclassifications

Certain reclassifications have been made to prior period amounts to conform to the current period presentation.

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, 2021, and notes thereto, which are included in the Company's Annual Report on Form 10-K that was filed with the SEC on September 22, 2021. Since the date of those financial statements, there have been no material changes to significant accounting policies.

Note 3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	March 31, 2022	June 30, 2021
Prepaid research and development	$ 529,927	$ 544,435
Prepaid insurance	123,453	1,093,101
Prepaid other	47,360	30,310
Total prepaid expenses and other current assets	$ 700,740	$ 1,667,846

Note 4. Accrued Expenses

Accrued expenses consisted of the following:

	March 31, 2022	June 30, 2021
Accrued professional fees	$ 2,500	$ 9,923
Accrued research and development	-	121,662
Total accrued expenses	$ 2,500	$ 131,585

Note 5. License Agreement

In May 2020, the Company licensed certain intellectual property, know-how and clinical trial data from Vernalis Development Limited ("Vernalis"). 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, with 60 days' prior notice by the Company, or until such time as all royalties and other sums cease to be payable in accordance with the terms of the agreement. The Company is required to pay development milestone payments related to clinical trials and granting of marketing authorization ranging from $350,000 to $3,000,000, up to a total development milestone payment of $29,900,000, and sales milestone payments of $10,000,000 and $25,000,000, in the first year when cumulative annual net sales of licensed product exceeds $500,000,000 and $1,000,000,000, respectively. The Company is also required to pay single-digit royalties on product sales over the term of the contract.

As part of the 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 $1,350,000, whether or not the Company achieves those milestones. The Company has determined that no further milestone payments are considered probable as of March 31, 2022, and therefore no liability has been recorded.

Note 6. Stockholders' Equity (Deficit)

On April 23, 2021, the Company effected a six-for-one stock split of its common stock prior to the completion of the Company's IPO. All shares, stock options, warrants and per share information presented in the accompanying condensed financial statements and notes thereto have been adjusted to reflect the stock split on a retroactive basis for all periods presented. There was no change in the par value of the Company's common stock.

On May 11, 2021, the Company completed an IPO of 3,078,224 shares of its common stock, including the exercise by the underwriter of its option to purchase 78,224 additional shares of common stock, for aggregate gross proceeds of approximately $21,548,000 and its shares started trading on The Nasdaq Capital Market under the ticker symbol "ANEB." The Company received approximately $19,783,000 in net proceeds after deducting underwriting discounts and commissions and other offering expenses payable by the Company. Upon the closing of the IPO on May 11, 2021, a cashless exercise of warrants resulted in the issuance of 5,236,343 shares of Series A convertible preferred stock and all of the outstanding shares of Series A convertible preferred stock automatically converted into 7,283,843 shares of common stock.

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. As set forth in the Restated Certificate, the Company's authorized capital stock consists of 40,000,000 shares of common stock, par value $0.001 per share, and 2,000,000 sharesof preferred stock, par value $0.001 per share.

In September 2020, the Company awarded 982,500 shares of restricted common stock to its former Chief Executive Officer ("former CEO") under the 2020 Stock Incentive Plan ("2020 Stock Incentive Plan") at a grant date fair value of $0.11 per share. The restrictions were subject to the satisfaction of certain performance targets and vesting requirements pursuant to the award and employment agreement. The restricted common stock vested fully upon completion of the Company's IPO in May 2021. The restricted common stock has voting and dividend rights, and therefore all 982,500 shares have been considered issued and outstanding since their date of issuance.

Note 7. 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 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 years from the date of grant. As of March 31, 2022, the Company had 1,183,667 shares available for future issuance under the 2020 Stock Incentive Plan.

Stock Options

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 we make for the volatility of our common stock the expected term of the stock options, the risk-free interest rate for a period that approximates the expected term, and our 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.

The following table summarizes the range of key assumptions used to determine the fair value of stock options granted during the three and nine months ended March 31, 2022 and 2021.

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2022	2021	2022	2021
Risk-free interest rate	1.29% – 2.14%	0.27% – 0.64%	0.79% – 2.14%	0.27% – 0.64%
Expected term (in years)	4.50	2.8 – 3.54	3.0 – 4.50	2.8 – 3.54
Expected volatility	50.0%	49.6%	50.0%	49.6%
Expected dividend yield	–	–	–	–

The following table summarizes stock option activity for the nine months ended March 31, 2022:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at June 30, 2021	604,404	$ 2.18	4.7	$ 2,802,420
Granted	879,429	$ 6.16		
Exercised	-	$ -		
Forfeited	-	$ -		
Outstanding at March 31, 2022	1,483,833	$ 4.54	4.5	$ 3,765,907
Options exercisable at March 31, 2022	225,741	$ 2.54	4.0	$ 1,025,177

The weighted-average grant date fair value of options awarded during the nine months ended March 31, 2022 was approximately $3.07 per share. As of March 31, 2022, unrecognized stock-based compensation expense related to unvested stock options totaled approximately $2,820,786 which is expected to be recognized over a weighted average period of 3.1 years.

Restricted Stock

In September 2020, the Company awarded 982,500 shares of restricted common stock to its former CEO, at a grant date fair value of $0.11 per share. The restrictions are subject to the satisfaction of certain performance targets and vesting requirements pursuant to the award and employment agreement.

Upon the IPO in May 2021, the former CEO became entitled to the full vesting of his restricted stock.

Compensation Expense

The Company recorded stock-based compensation expenses for the following periods:

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2022	2021	2022	2021
Research and development	$ 245	$ 2,105	$ 12,233	$ 2,105
General and administrative	125,009	45,302	241,476	82,404
Total stock-based compensation expense	$ 125,254	$ 47,407	$ 253,709	$ 84,509

Note 8. 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:

	March 31,	
	2022	2021
Series A Convertible Preferred Stock, as converted	-	2,047,500
Stock options outstanding	1,483,833	604,404
Total	1,483,833	2,651,904

Note 9. Deemed Dividends

The Company received proceeds for the issuance of certain milestone warrants of $2,250,000 and the fair value of the warrants in excess of proceeds received of $8,208,393 was recorded as a deemed dividend, against accumulated deficit for the three and nine month periods ended March 31, 2021. The milestone warrants were later converted to Series A preferred stock (which was converted into common stock) upon IPO.

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 together with our condensed financial statements and related notes and other financial information appearing elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biotechnology company developing novel solutions for people suffering from ACI and substance addiction. Our lead product candidate, ANEB-001, is intended to reverse the negative effects of ACI within 1 hour of administration. The signs and symptoms of ACI range from profound sedation to anxiety and panic to psychosis with hallucinations. There is no approved medical treatment currently available to specifically alleviate the symptoms of ACI. If approved by the FDA, we believe ANEB-001 has the potential to be the first FDA approved treatment of its kind on the market for reversing the effects of THC, the principal psychoactive constituent of cannabis. Clinical trials completed to date have shown that ANEB-001 is rapidly absorbed, well tolerated and leads to weight loss, an effect that is consistent with central CB1 antagonism. The first patient has been dosed in a Phase 2 proof-of-concept clinical study investigating ANEB-001 as a potential treatment for acute cannabinoid intoxication. We continue to anticipate reporting initial topline results from Part A of this trial in the first half of calendar 2022.

ACI episodes have become a widespread health issue in the United States, particularly in the increasing number of states that have legalized cannabis for personal and recreational use. The ingestion of large quantities of THC is a major cause of ACI. Excessive ingestion of THC via edible products such as candies and brownies, and intoxication from synthetic cannabinoids (also known as "synthetics," "K2" or "spice"), are two leading 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. In recent years, hospital emergency rooms across the United States have seen a dramatic increase in patient visits with cannabis-related conditions. Before the legalization of cannabis, an estimated 450,000 patients visited hospital emergency rooms annually for cannabis-related conditions. In 2014, this number more than doubled to an estimated 1.1 million patients, according to data published in "Trends and Related Factors of Cannabis-Associated Emergency Department Visits in the United States: 2006-2014," Journal of Addiction Medicine (May/June 2019), which provided a national estimate analyzing data from NEDS, the largest database of U.S. hospital-owned emergency department visits. Based on our own analysis of the most recent NEDS data, we believe that the number of hospitalizations grew to 1.74 million patients in 2018 and was growing at an approximately 15% compounded annual growth rate between 2012 and 2018. We believe the number of cannabis-related hospitalizations and other health problems associated with ACIs such as depression, anxiety and mental disorders 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 ACI.

In May 2020, we entered into the royalty-bearing License Agreement with Vernalis to exploit its license compounds and licensed products to combat symptoms of ACI and substance addiction. We are currently developing our lead product candidate, ANEB-001 to quickly and effectively combat symptoms of ACI.

Our objective is to develop and commercialize new treatment options for patients suffering from ACI and addiction. Our lead product candidate is ANEB-001, a potent, small molecule cannabinoid receptor antagonist, to address the unmet medical need for a specific antidote for ACI. ANEB-001 is an orally bioavailable, rapidly absorbed treatment that we anticipate will reverse the symptoms of ACIs, in most cases within 1 hour of administration. Our proprietary position in the treatment of ACI is protected by one issued patent and rights to one patent application 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 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 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 12, 2021, the United States Patent and Trademark Office issued to the Company U.S. Patent No. 11,141,404, titled "Formulations and Methods For Treating Acute Cannabinoid Overdose." The issued patent describes the use of the Company's investigational drug ANEB-001 to treat acute cannabinoid overdose and is expected to provide patent protection through 2040. We began our Phase 2 proof-of-concept study for ANEB-001 in January 2022, and we expect initial topline results from the first cohort in the first half of calendar 2022.

On December 31, 2021, Daniel Schneeberger, M.D. advised the Company of his resignation as Chief Executive Officer "CEO" of the Company and from the Board of Directors, effective on February 1, 2022. On January 3, 2022, Simon Allen was appointed to be the Company's CEO and elected a member of the Board of Directors, both of which became effective on February 1, 2022.

Stock Split and Initial Public Offering

On April 23, 2021, we effected a six-for-one stock split of our common stock prior to the completion of our IPO. All shares, stock options, warrants and per share information presented in the accompanying condensed financial statements and notes thereto have been adjusted to reflect the stock split on a retroactive basis for all periods presented. There was no change in the par value of our common stock.

On May 11, 2021, the Company completed an IPO of 3,078,224 shares of its common stock, including the exercise by the underwriter of its option to purchase 78,224 additional shares of common stock, for aggregate gross proceeds of approximately $21,548,000 and its shares started trading on The Nasdaq Capital Market under the ticker symbol "ANEB." The Company received approximately $19,783,000 in net proceeds after deducting underwriting discounts and commissions and other offering expenses payable by the Company. Upon the closing of the IPO on May 11, 2021, a cashless exercise of warrants resulted in the issuance of 5,236,343 shares of Series A convertible preferred stock and all of the outstanding shares of Series A convertible preferred stock automatically converted into 7,283,843 shares of common stock.

Components of Results of Operations

Revenue

We have not generated any revenue since inception. If our development efforts for our current lead product candidate, ANEB-001, 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 ANEB-001. Our research and development expenses for the three and nine months ended March 31, 2022 and 2021 included research and development consulting expenses, clinical trials, and costs associated with development of our lead product candidate, ANEB-001.

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 ANEB-001 and conduct clinical trials with patients suffering from symptoms of ACI, 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 that we plan to hire;
- 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;
- manufacturing costs in connection with producing materials for use in conducting preclinical studies and clinical trials;
- 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 and nine months ended March 31, 2022 and 2021 consisted primarily of professional fees, stock-based compensation, insurance, personnel costs and rent.

Results of Operations

Comparison of the Three and Nine Months Ended March 31, 2022 and 2021

The following table summarizes our results of operations:

	Three Months Ended March 31,		Period to Period	Nine Months Ended March 31,		Period to Period
	2022	2021	Change	2022	2021	Change
Research and development	$ 915,363	$ 273,038	$ 642,325	$ 1,843,397	$ 463,306	$ 1,380,091
General and administrative	964,281	279,093	685,188	2,662,293	665,742	1,996,551
Total operating expenses	1,879,644	552,131	1,327,513	4,505,690	1,129,048	3,376,642
Loss from operations	(1,879,644)	(552,131)	(1,327,513)	(4,505,690)	(1,129,048)	(3,376,642)
Other income (expenses), net	3,153	(3,701)	6,854	2,813	(11,767)	14,580
Net loss	$ (1,876,491)	$ (555,832)	$ (1,320,659)	$ (4,502,877)	$ (1,140,815)	$ (3,362,062)

Research and Development Expenses

	Three Months Ended March 31,		Period to Period	Nine Months Ended March 31,		Period to Period
	2022	2021	Change	2022	2021	Change
Pre-clinical and clinical studies	$ 692,871	$ 245,615	$ 447,256	$ 1,083,954	$ 410,370	$ 673,584
Contract manufacturing	110,989	-	110,989	428,439	-	428,439
Compensation and related benefits	21,530	2,706	18,824	64,590	2,706	61,884
Stock compensation expense	245	2,105	(1,860)	12,233	2,105	10,128
Other research and development	89,728	22,612	67,116	254,181	48,125	206,056
Total research and development expenses	$ 915,363	$ 273,038	$ 642,325	$ 1,843,397	$ 463,306	$ 1,380,091

The overall increase was primarily attributable to an increase in activities related to pre-clinical and clinical studies, contract manufacturing, and direct third-party costs incurred under agreements with CROs and CMOs for ANEB-001. The increase in pre-clinical and clinical studies was related to Phase 1 and Phase 2 clinical studies for ANEB-001.

General and Administrative Expenses

General and administrative expenses consisted of the following:

	Three Months Ended March 31,		Period to Period	Nine Months Ended March 31,		Period to Period
	2022	2021	Change	2022	2021	Change
Compensation and related benefits	$ 209,835	$ 64,636	$ 145,199	$ 389,147	$ 72,214	$ 316,933
Professional and consultant fees	203,465	149,038	54,427	810,624	470,307	340,317
Stock compensation expense	125,009	45,302	79,707	241,476	82,404	159,072
Officers' insurance	334,695	-	334,695	997,208	-	997,208
Facilities, fees and other costs	91,277	20,117	71,160	223,838	40,817	183,021
Total general and administrative expenses	$ 964,281	$ 279,093	$ 685,188	$ 2,662,293	$ 665,742	$ 1,996,551

The overall increase was primarily attributable to an increase in directors' and officers' insurance, and compensation and related benefits for additional executives and finance employees to enable the Company to operate as a public company. In addition, there was an increase in professional and consultant fees, including legal and accounting fees, and facilities and other costs related to operating as a public company.

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 sold 3,078,224 shares of our common stock, including the exercise by the underwriter of its option to purchase 78,224 additional shares of common stock, at a public offering price of $7.00 per share. We received net proceeds from our IPO of approximately $19,783,000, after deducting underwriter discounts and offering expenses paid by us. As of March 31, 2022, we had cash of approximately $16,548,000. We anticipate that additional capital will be needed to commence and complete a Phase 3 study of our drug candidate ANEB-001. As and if necessary, we will seek to raise these additional funds through various potential sources, such as equity and debt financings or through corporate collaboration and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations, or, if such funds are available to us, that such additional financing will be sufficient to meet our needs.

Cash Flows

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

	Nine Months Ended March 31,	
	2022	**2021**
Net cash used in operating activities	$ (3,437,918)	$ (1,373,881)
Net cash provided by financing activities	-	1,655,984
Net (decrease) increase in cash	$ (3,437,918)	$ 282,103

During the nine months ended March 31, 2022, we used cash in operating activities of $3,437,918 primarily resulting from our net loss of $4,502,877, partially offset by the non-cash related stock-based compensation of $253,709, a decrease in prepaid expenses of $967,106, decrease in accrued expenses of $129,085, and decrease in accounts payable of $26,771. During the nine months ended March 31, 2021, we used cash in operating activities of $1,373,881, primarily resulting from our net loss of $1,140,815, and the change in prepaid expenses and other current assets of $591,622, partially offset by the non-cash related stock-based compensation of $84,509, the change in accounts payable of $82,027, and the change in accrued expenses of $188,560. The cash used in operating activities was offset by the cash generated from financing activities of $1,655,984, which was primarily comprised of proceeds from issuance of Series A preferred milestone warrants of $2,250,000, partially offset by the repayment of promissory notes of $201,286, and of the payment of offering costs of $392,730.

Funding Requirements

We expect that our cash at March 31, 2022 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 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.

Until such time, if ever, as we can generate substantial product revenue from sales of any of our current or future product candidates, we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaboration, license or development agreements. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. We have no current agreements or understandings with investors to provide such capital.

Contractual Obligations and Commitments

License Agreement with Vernalis Development Limited

On May 26, 2020, we entered into an exclusive License Agreement with 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 ANEB-001, 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 ANEB-001. In exchange for the exclusive license, we agreed to pay Vernalis a non-refundable signature fee of $150,000, total potential developmental milestone payments of up to $29,900,000, total potential sales milestone payments of up to $35,000,000, and low to mid-single digit royalties on net sales. Subsequently, in May 2021 as part of the IPO, we issued 192,857 shares of common stock to Vernalis in lieu of future milestone payments of $1,350,000.

Under the License Agreement, we purchased the API for ANEB-001 from Vernalis on an "as is" basis for $20,000. We have the sole discretion to carry out the development and commercialization of ANEB-001, 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 ANEB-001 in the United States and certain European countries and (ii) conduct a Phase 2 and human clinical trial within specified periods, which periods could be 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 700 square feet of leased space under a sublease with a related party. Our office lease is month-to-month, and currently we pay rent of approximately $1,200 per month. In October 2020, we entered into an agreement with a third-party contract manufacturing organization. The total cost for the manufacturing contracts is approximately $973,000. In March 2022, we entered into an agreement with another third-party contract manufacturing organization. The total cost for the manufacturing contracts is approximately $1,914,000 and is expected to be incurred in calendar 2022. In February 2021, we entered into an agreement with a third-party CRO to manage and conduct our Phase 2 clinical trial with the anticipation of completing the trial by the first half of calendar 2022. The total cost for the CRO agreement is approximately €2,235,144 or $2,503,361.

On October 12, 2021, the United States Patent and Trademark Office issued to the Company U.S. Patent No. 11,141,404, titled "Formulations and Methods For Treating Acute Cannabinoid Overdose." The issued patent describes the use of the Company's investigational drug ANEB-001 to treat acute cannabinoid overdose and is expected to provide patent protection through 2040. We began our Phase 2 proof-of-concept study for ANEB-001 in January 2022, and we expect initial topline results from the first cohort in the first half of calendar 2022.

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 Policies and Significant Judgments and 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, 2021, and notes thereto, which are included in the Company's Annual Report on Form 10-K that was filed with the SEC on September 22, 2021, 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

The 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 or at achievement of a performance requirement. The awards expire five years from the date of grant.

We estimate the fair value of each stock option grant using the Black-Scholes option pricing model, which uses inputs such as the fair value of our common stock, assumptions we make for the volatility of our common stock the expected term of the stock options, the risk-free interest rate for a period that approximates the expected term, and our expected dividend yield. The fair value of our common stock is used to determine the fair value of restricted stock.

Prior to our IPO, the fair value of our common stock was estimated on each grant date by our Board of Directors. In order to determine the fair value of our common stock, our Board of Directors considered, among other things, timely valuations of our common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately Held-Company Equity Securities Issued as Compensation.* Given the absence of a public trading market for our common stock prior to our IPO, our Board of Directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including (i) our business, financial condition and results of operations, including related industry trends affecting our operations; (ii) our forecasted operating performance and projected future cash flows; (iii) the illiquid nature of our common stock; (iv) the rights and privileges of our common stock; (v) market multiples of our most comparable public peers; and (vi) market conditions affecting our industry.

There are significant judgments and estimates inherent in these valuations. The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

After the closing of the IPO, our Board of Directors now determines the fair value of our shares of common stock underlying stock-based awards based on the closing price of our common stock as reported by Nasdaq on the date of grant.

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.

Financial Impact of COVID-19 Pandemic

While we cannot presently predict the scope and severity of any potential business shutdowns or disruptions, if we or any of our business partners, clinical trial sites, distributors and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. For example, if our development program for cannabinoid overdoses were to be delayed, it may have a material adverse effect on our business, results of operations and financial condition.

The pandemic's impact on the medical community and the global economy could have an adverse impact on future sales upon which we expect to derive royalties and milestones, which could lead to a decrease in our revenues, net income and assets.

Several measures have been and are currently being implemented by the United States and other governments to address the current COVID-19 pandemic and its economic impacts. At this time, it is impossible to predict the success of these measures and whether or not they will have unforeseen negative consequences for our business. In addition, our results of operations, financial position and cash flows may be adversely affected by federal or state laws, regulations, orders, or other governmental or regulatory actions addressing the current COVID-19 pandemic or the U.S. healthcare system, which, if adopted, could result in direct or indirect restrictions to our business, results of operations, financial condition and cash flow.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to disclose this item.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on that evaluation of our disclosure controls and procedures as of March 31, 2022, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level.

Management's Quarterly Report on Internal Control over Financial Reporting

This Quarterly Report on Form 10-Q does not include a report of management's assessment regarding internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

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 March 31, 2022 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

You should carefully consider the factors discussed under Item 1A of Part I to our Annual Report on Form 10-K for the fiscal year ended June 30, 2021 regarding the numerous and varied risks, known and unknown, that may prevent us from achieving our goals. If any of these risks occur, our business, financial condition or results of operation may be materially and adversely affected. In such case, the trading price of our common stock could decline, and investors could lose all or part of their investment. These risk factors may not identify all risks that we face, and our operations could also be affected by factors that are not presently known to us or that we currently consider to be immaterial to our operations.

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 March 31, 2022, we had an accumulated deficit of $43,146,961, which included $8,292,794 of operating losses incurred since inception. The likelihood of our future success must be considered in light of the expenses, difficulties, complications and delays often encountered in connection with the clinical trials that will be conducted and on the development of new solutions to common addictions. 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 the 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.

Special Note Regarding Forward-Looking Statements

This report contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this 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 report.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements include the following:

- We have not generated any revenue since our inception and expect to incur future losses and may never become profitable.
- We currently rely on a license from a third party, and in the future may rely on additional licenses from other third parties, in relation to our development of ANEB-001, and if we fail to comply with our obligations under our current or future intellectual property license agreements or otherwise experience disruptions to our business relationships with our current or any future licensors, we could lose intellectual property rights that are important to our business.
- We currently have no product revenue and will need to raise additional capital, which may be unavailable to us or may cause dilution or place significant restrictions on our ability to operate.
- We have less than one year of operating history as a publicly-traded company, and our inexperience could materially and adversely affect us and our stockholders.
- If we are unable to obtain and maintain patent protection for important aspects of ANEB-001, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products that are similar or identical to ours, and our ability to successfully commercialize our current or future product candidates may be adversely affected.
- We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.
- The expiration or loss of patent protection may adversely affect our future revenues and operating earnings.
- Delays in the completion of, or the termination of, a clinical trial for ANEB-001, our lead drug candidate, could adversely affect our business.
- If we are not able to obtain any required regulatory approvals for ANEB-001, we will not be able to commercialize our lead drug candidate and our ability to generate revenue will be limited.

- Even if we receive regulatory approval for ANEB-001, our lead drug candidate, we may not be able to successfully commercialize the product and the revenue that we generate from its sales, if any, may be limited.
- Even if we obtain marketing approval for ANEB-001, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expenses. Additionally, ANEB-001 could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with ANEB-001.
- ANEB-001, our lead drug candidate, may face competition sooner than expected.
- We will be completely dependent on third parties to manufacture ANEB-001, and our commercialization of ANEB-001 could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the U.S. Food and Drug Administration ("FDA") or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of ANEB-001 or fail to do so at acceptable quality levels or prices.
- Any termination or suspension of, or delays in the commencement or completion of, any necessary studies of ANEB-001, our lead drug candidate, for any indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.
- Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.
- Clinical trials for ANEB-001 have and may in the future be conducted outside the United States and not under an Investigational New Drug Application ("IND"), and where this is the case, the FDA may not accept data from such trials.
- Laws impacting the U.S. healthcare system are subject to a great deal of uncertainty, which may result in adverse consequences to our business.

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

The Company did not sell any unregistered securities during the period covered by this report.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description
3.1	Certificate of Incorporation of Anebulo Pharmaceuticals, Inc. (filed as Exhibit 3.1 to the Company's Registration Statement on Form S-1 filed with the SEC on April 1, 2021 and incorporated herein by reference).
3.2	By-laws of Anebulo Pharmaceuticals, Inc. (filed as Exhibit 3.2 to the Company's Registration Statement on Form S-1 filed with the SEC on April 1, 2021 and incorporated herein by reference).
3.3	Form of Second Amended and Restated Certificate of Incorporation of Anebulo Pharmaceuticals, Inc. (filed as Exhibit 3.3 to the Company's Registration Statement on Form S-1/A filed with the SEC on April 26, 2021 and incorporated herein by reference).
3.4	Form of Amended and Restated By-laws of Anebulo Pharmaceuticals, Inc. (filed as Exhibit 3.4 to the Company's Registration Statement on Form S-1/A filed with the SEC on April 26, 2021 and incorporated herein by reference).
4.1	Specimen Stock Certificate for Common Stock (filed as Exhibit 4.1 to the Company's Registration Statement on Form S-1 filed with the SEC on April 1, 2021 and incorporated herein by reference).
4.2	Warrant to Purchase Shares of Preferred Stock, dated as of March 8, 2021, between Anebulo Pharmaceuticals, Inc. and Aron English (filed as Exhibit 4.2 to the Company's Registration Statement on Form S-1 filed with the SEC on April 1, 2021 and incorporated herein by reference).
4.3	Warrant to Purchase Shares of Preferred Stock, dated as of March 8, 2021, between Anebulo Pharmaceuticals, Inc. and 22NW, LP (filed as Exhibit 4.3 to the Company's Registration Statement on Form S-1 filed with the SEC on April 1, 2021 and incorporated herein by reference).
10.1	10.1 Employment Agreement, effective as of February 1, 2022, between Anebulo Pharmaceuticals, Inc. and Simon Allen (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on January 5, 2022 and incorporated herein by reference).
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.

* Filed herewith.

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: May 11, 2022

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

Date: May 11, 2022

By: */s/ Rex Merchant*
Rex Merchant
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, Simon Allen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2022 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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

(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: May 11, 2022

By: */s/ Simon Allen*
Simon Allen
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, Rex Merchant, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2022 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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

(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: May 11, 2022

By: */s/ Rex Merchant*
Rex Merchant
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 March 31, 2022, 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 March 31, 2022 (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: May 11, 2022

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

Date: May 11, 2022

By */s/ Rex Merchant*
Rex Merchant
Chief Financial Officer
(*Principal Financial and Accounting Officer*)