UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2021
or

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

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.)**
1415 Ranch Road 620 South, Suite 201 **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	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 [X]

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 [X] 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	[X]	Smaller reporting company	[X]
		Emerging growth company	[X]

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 [X]

The number of shares of the registrant's common stock, par value $0.001 per share, outstanding as of June 16, 2021 was 23,344,567 shares.

Anebulo Pharmaceuticals, Inc.
Table of Contents

In this report, unless otherwise stated or as the context otherwise requires, references to "Anebulo Pharmaceuticals," "Anebulo," "the 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 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 following this offering, which may be unavailable to us or may cause dilution or place significant restrictions on our ability to operate.
- We have no 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 expense. 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 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 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.
- Our stock price may be volatile and your investment could decline in value.
- We will incur significantly increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance efforts.

These risks are not exhaustive. Additional factors could harm our business and financial performance, such as risks associated with the ongoing COVID-19 global pandemic.

Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. Given these uncertainties, 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. We qualify all of the forward-looking statements in this report by these cautionary statements.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Anebulo Pharmaceuticals, Inc.
Balance Sheets

	March 31, 2021 (unaudited)	June 30, 2020 (audited)
Assets		
Current assets:		
Cash and cash equivalents	$ 3,307,083	$ 3,024,980
Receivable - related party	-	3,500
Prepaid expenses and other current assets	591,662	-
Total current assets	3,898,745	3,028,480
Deferred offering costs	392,730	-
Total assets	$ 4,291,475	$ 3,028,480
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 82,027	$ -
Accrued expenses	211,139	22,579
Promissory notes - related party	-	201,286
Total current liabilities	293,166	223,865
Warrant liability	10,458,393	-
Total Liabilities	10,751,559	223,865
Commitments and contingencies		
Series A convertible preferred stock, $0.0001 par value; 8,943,906 shares authorized; 2,047,500 shares issued and outstanding at March 31, 2021 and June 30, 2020	2,975,752	2,975,752
Stockholders' deficit:		
Common stock, $0.001 par value; 22,800,000 shares authorized; 12,982,500 and 12,000,000 shares issued and outstanding at March 31, 2021 and June 30, 2020, respectively	12,983	12,000
Additional paid-in capital	83,526	-
Accumulated deficit	(9,532,345)	(183,137)
Total stockholders' deficit	(9,435,836)	(171,137)
Total liabilities, convertible preferred stock, and stockholders' deficit	$ 4,291,475	$ 3,028,480

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

Anebulo Pharmaceuticals, Inc.
Statements of Operations
(Unaudited)

	Three months ended March 31, 2021	Nine months ended March 31, 2021
Operating expenses:		
Research and development	$ 273,038	$ 463,306
General and administrative	279,093	665,742
Total operating expenses	552,131	1,129,048
Other expense:		
Interest expense	3,701	11,767
Loss from operations before taxes	(555,832)	(1,140,815)
Income tax expense	-	-
Net loss	$ (555,832)	$ (1,140,815)
Deemed dividend	(8,208,393)	(8,208,393)
Net loss attributable to common stockholders	$ (8,764,225)	$ (9,349,208)
Weighted average common shares outstanding, basic and diluted	12,982,500	12,656,310
Net loss per share, basic and diluted	$ (0.68)	$ (0.74)

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

Anebulo Pharmaceuticals, Inc.
Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
For the Three and Nine Months Ended March 31, 2021
(unaudited)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	2,047,500	$ 2,975,752	12,982,500	$ 12,983	$ 36,119	$ (768,120)	$ (719,018)
Deemed dividend	-	-	-	-	-	(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, unaudited	2,047,500	$ 2,975,752	12,982,500	$ 12,983	$ 83,526	$ (9,532,345)	$ (9,435,836)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at June 30, 2020 (audited)	2,047,500	$ 2,975,752	12,000,000	$ 12,000	$ -	$ (183,137)	$ (171,137)
Issuance of restricted common stock	-	-	982,500	983	(983)	-	-
Deemed dividend	-	-	-	-	-	(8,208,393)	(8,208,393)
Stock-based compensation expense	-	-	-	-	84,509	-	84,509
Net loss	-	-	-	-	-	(1,140,815)	(1,140,815)
Balance at March 31, 2021, unaudited	2,047,500	$ 2,975,752	12,982,500	$ 12,983	$ 83,526	$ (9,532,345)	$ (9,435,836)

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

Anebulo Pharmaceuticals, Inc.
Statement of Cash Flows

	Nine months ended March 31, 2021
	(unaudited)
Cash flows from operating activities:	
Net loss	$ (1,140,815)
Adjustments to reconcile net loss to net cash used in operating activities:	
Stock-based compensation	84,509
Changes in operating assets and liabilities:	
Receivable - related party	3,500
Prepaid expenses and other current assets	(591,662)
Deferred offering costs	(392,730)
Accounts payable	82,027
Accrued expenses	188,560
Net cash used in operating activities	(1,766,611)
Cash flows from financing activities:	
Proceeds from issuance of Series A preferred milestone warrants	2,250,000
Repayment of promissory notes, related parted	(201,286)
Net cash provided by financing activities	2,048,714
Net decrease in cash, cash equivalents and restricted cash	282,103
Cash and cash equivalents, beginning of period	3,024,980
Cash and cash equivalents, end of the period	$ 3,307,083
Supplemental cash flow information:	
Cash paid for interest	$ 13,053
Supplemental disclosure of noncash investing and financing activities:	
Fair value of warrants issued to investors	$ 10,458,393
Deemed dividend	$ 8,208,393

The accompanying notes are an integral part of these unaudited interim consolidated financial statements.

Anebulo Pharmaceuticals, Inc.
Notes to Unaudited Interim Financial Statements

1. Organization and Description of Business

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 cannabinoid overdose and addiction. The Company's principal operations are located in Lakeway, Texas.

The accompanying interim unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position, results of operations and cash flows for the period presented. The accompanying interim unaudited financial statements should be read in conjunction with the audited financial statements and notes thereto as of June 30, 2020 and for the period from April 23, 2020 (inception) to June 30, 2020.

From inception, the Company has devoted substantially all of its efforts to raising capital and acquiring licensing rights to its drug product. The Company has determined that it has one operating and reporting segment. The Company has one lead product candidate, ANEB-001, under development, which was licensed from Vernalis (R&D) Ltd in May 2020 ("License Agreement"), as described in Note 8.

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 initial public offering ("IPO"). As set forth in the Restated Certificate, the Company's authorized capital stock now consists of 40,000,000 shares of common stock, par value $0.001 per share, and 2,000,000 shares of preferred stock, par value $0.001 per share.

2. Liquidity and Going Concern

Through March 31, 2021, the Company has raised $3,200,000 of funding through the sales of its Series A Convertible Preferred Stock ("Series A Preferred") and the issuance of two promissory notes. As of March 31, 2021, the Company had an accumulated deficit of $9,532,345 and cash and cash equivalents of $3,307,083. The Company's ability to continue as a going concern is highly contingent on the ability to raise additional capital for ongoing research and development and clinical trials as the Company expects to continue incurring losses for the foreseeable future.

On May 11, 2021, the Company closed on an IPO of 3,000,000 shares of its common stock at an offering price of $7.00 per share for gross proceeds of approximately $21,000,000.

The Company believes that its existing cash and cash equivalents, plus the net proceeds from the IPO, will enable the Company to meet its operational liquidity needs and fund its planned investing activities for at least the next 12 months from the date of issuance of these unaudited financial statements.

3. Basis of Presentation and Summary of Significant Accounting Policies

Basis of presentation

The accompanying unaudited interim financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. 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").

In the opinion of management, the accompanying unaudited interim financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of March 31, 2021 and its results of operations for the three and nine months ended March 31, 2021, cash flows for the nine months ended March 31, 2021, and convertible preferred stock and stockholders' deficit for the three and nine months ended March 31, 2021. Operating results for the three and nine months ended March 31, 2021 are not necessarily indicative of the results that may be expected for the full year ending June 30, 2021. The unaudited interim financial statements, presented herein, do not contain the required disclosures under GAAP for annual financial statements. The accompanying unaudited interim financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended June 30, 2020 included in the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission ("SEC") on March 23, 2020 and amended on May 6, 2021.

Recapitalization

On April 23, 2021, the Company approved a 6-for-1 forward stock split to be consummated prior to the completion of the Company's IPO. All information in the accompanying financial statements and notes thereto regarding share amounts of Series A preferred stock and common stock and price per share of the Series A preferred stock and common stock reflect the application of the stock split. On May 4, 2021, the Company filed a certificate of amendment to amend its certificate of incorporation to increase the number of authorized common stock and amend the number of authorized preferred stock to 2,000,000 shares following the IPO.

Use of estimates and assumptions

The preparation of the unaudited interim financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the unaudited interim financial statements, including as a result of the ongoing COVID-19 pandemic, actual results may materially vary from these estimates. Estimates and assumptions are periodically reviewed, and the effects of revisions are reflected in the unaudited interim consolidated financial statements in the period they are determined to be necessary.

Risk and Uncertainties

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. Periodically, the Company may maintain deposits in financial institutions in excess of government insured limits. Management believes that the Company is not exposed to significant credit risk as the Company's deposits are held at financial institutions that management believes to be of high credit quality, and the Company has not experienced any losses on these deposits.

The Company operates in an industry that is subject to intense competition, government regulations and rapid technological change. Operations are subject to significant risk and uncertainties including financial, operational, technological, regulatory, and other risks, including potential risk of business failure.

In March 2020, the World Health Organization declared the global novel coronavirus disease 2019 (COVID-19) outbreak a pandemic. As of March 31, 2021, the Company's operations have not been significantly impacted by the COVID-19 outbreak. However, the Company cannot at this time predict the specific extent, duration, or full impact that the COVID-19 outbreak will have on its financial condition and operations, including ongoing and planned clinical trials.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents.

Fair Value of Financial Instruments

Fair value is defined as the price received to sell an investment in a timely transaction or pay to transfer a liability in a timely transaction with an independent buyer in the principal market, or in the absence of a principal market, the most advantageous market for the investment or liability. A framework is used for measuring fair value utilizing a three-tier hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

The three levels of the fair value hierarchy are as follows:

***Level* 1**—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
***Level* 2**—Quoted prices in markets that are not considered to be active or financial instrument valuations for which all significant inputs are observable, either directly or indirectly; and
***Level* 3**—Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

Financial instruments are categorized in their entirety based on the lowest level of input that is significant to the fair value measurement. The assessment of the significance of a particular input to the fair value measurement requires judgment and considers factors specific to the investment. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3.

Warrant Liability

The Company accounts for the Series A warrants ("Warrants") in accordance with the guidance contained in ASC 815-40, under which the Warrants do not meet the criteria for equity treatment and must be recorded as a liability. Accordingly, the Company classifies the Warrants as a liability at their fair value and adjusts the warrant liability to fair value at each reporting period. The change in fair value is recognized in the statement of operations. The Company utilizes the Black-Scholes option pricing model to value the warrant liability at each reporting period and records changes in value to other income (expense). Upon the exercise of the warrants, the warrant liability is marked to fair value at the conversion date and then reclassified to equity.

Convertible Preferred Stock

The Company has classified its Series A Preferred securities as temporary equity in the accompanying balance sheets due to certain change in control events that are outside of the Company's control, including sale or transfer of control of the Company, as holders of the Series A Preferred could cause redemption of the shares in these situations.

Deferred Offering Costs

In conjunction with the IPO of the Company's common stock, costs incurred related to the IPO are capitalized as deferred equity issuance costs in other non-current assets until the IPO is completed or the potential IPO is abandoned. If the Company completes an IPO, these costs will be offset against proceeds received; or if the IPO does not occur, they will be expensed. Offering costs include direct and incremental costs related to the offering such as legal fees and related costs associated with the proposed IPO. As of March 31, 2021, the Company recorded deferred IPO offering costs of approximately $393,000.

Research and Development Costs

Research and development costs are charged to expense as incurred. Payments for these activities will be based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the interim unaudited financial statements as prepaid or accrued research and development. Research and development activities may consist of salaries and benefits, contract services, materials and supplies, stock-based compensation expense, depreciation of equipment, and other outside expenses.

Anebulo Pharmaceuticals, Inc.
Notes to Unaudited Interim Financial Statements

Stock-Based Compensation

The Company recognizes stock-based compensation expense related to stock options granted to employees and non-employees based on the estimated fair value of the awards on the date of grant. The Company estimates the grant date fair value, and the resulting stock-based compensation expense, for stock options that only have service vesting requirements or performance-based vesting requirements without market conditions using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards with service vesting requirements is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. Determining the appropriate amount to expense for performance-based awards based on the achievement of stated goals requires judgment. The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are made as appropriate. The cumulative impact of any revisions is reflected in the period of change. If any applicable financial performance goals are not met, no compensation cost is recognized, and any previously recognized compensation cost is reversed.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions, which determine the fair value of stock-based awards. These assumptions include:

Expected term - Our expected term represents the period that the stock-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term). For stock-based awards granted to non-employees, the expected term represents the contractual term of the award.

Common stock price - The Board of directors estimates the fair value of common stock. Given the absence of a public trading market for its common stock, and in accordance with the American Institute of Certified Public Accountants' Practice Guide, Valuation of Privately Held-Company Equity Securities Issued as Compensation, the board of directors exercises reasonable judgment and considers a number of objective and subjective factors to determine its best estimate of the fair value of the common stock, as further described below under "Common stock valuations."

Expected volatility - The Company is a privately held company and did not have any trading history for its common stock and the expected volatility was estimated using weighted-average measures of implied volatility and the historical volatility of its peer group of companies for a period equal to the expected life of the stock options. The peer group of publicly traded biopharmaceutical companies was chosen based on their similar size, stage in the life cycle or area of specialty.

Risk-free interest rate - The risk-free interest rate is based on the rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of the stock

options.

Expected dividend - The Company has never paid, and does not anticipate paying, cash dividends on its common stock. Therefore, the expected dividend yield was assumed to be zero.

In addition to the Black-Scholes assumptions, The Company adopted ASU 2016-09 in June 2020 and as a result, the Company has made an entity-wide accounting policy election to account for pre-vesting award forfeitures when they occur.

Leases

In February 2016, the FASB issued ASU No. 2016-02, "*Leases*" ("ASC 842") to enhance the transparency and comparability of financial reporting related to leasing arrangements. Under this new lease standard, most leases are required to be recognized on the balance sheet as right-of-use assets and lease liabilities. Disclosure requirements have been enhanced with the objective of enabling financial statement users to assess the amount, timing, and uncertainty of cash flows arising from leases. Prior to January 1, 2019, U.S. GAAP did not require lessees to recognize assets and liabilities related to operating leases on the balance sheet. The new standard establishes a right-of-use ("ROU") model that requires a lessee to recognize a ROU asset and corresponding lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement as well as the reduction of the right-of-use asset.

This ASU is effective for non-public reporting companies for interim and annual periods beginning after December 15, 2021, with early adoption permitted, and must be adopted using a modified retrospective approach. The Company has adopted the standard effective April 23, 2020 (inception). The Company has elected to apply (i) the practical expedient which allows the Company to not separate lease and non-lease components, for new leases entered into after adoption and (ii) the short-term lease exemption for all leases with an original term of less than 12 months, for purposes of applying the recognition and measurements requirements in the new standard.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on specific facts and circumstances, the existence of an identified asset(s), if any, and the Company's control over the use of the identified asset(s), if applicable. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of future lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company will utilize the incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term on an amount equal to the lease payments in a similar economic environment.

Operating leases are recognized on the balance sheet as ROU lease assets, lease liabilities current and lease liabilities non-current. Fixed rents are included in the calculation of the lease balances while variable costs paid for certain operating and pass-through costs are excluded. Lease expense is recognized over the expected term on a straight-line basis.

In August 2020, the Company entered into a one-year sub-lease for office space in Lakeway, Texas, from a related party and recorded rent expense of $3,609 and $9,021 for the three and nine months ended March 31, 2021, respectively. Remaining payments due under the lease total $5,413.

Loss Per Share

The Company's Series A Preferred securities participate on a one-for-one basis with common stock in the distribution of dividends, if and when declared by the Board of Directors.

Since the Company has reported a net loss for the three and nine months ended March 31, 2021, therefore, no income was allocated to the Company's Series A Preferred securities. Basic and diluted net loss per share are the same because the impact of Series A Preferred would be anti-dilutive and has been excluded from the computation of diluted weighted-average shares outstanding.

Recently issued and adopted accounting pronouncements

The Company considers the applicability and impact of all ASUs. ASUs not discussed below were assessed and determined to be either not applicable or are expected to have minimal impact on the financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, which simplifies the accounting for income taxes by removing certain exceptions to the general principles in the existing guidance for income taxes and making other minor improvements. The amendments are effective for annual reporting periods beginning after December 15, 2020 with early adoption permitted. The Company is currently evaluating the impact of adopting this new accounting guidance.

On July 1, 2020, the Company adopted ASU No. 2018-07, Improvements to Nonemployee Share-Based Payment Accounting Compensation, issued by the FASB in June 2018. The amendments in this ASU expanded the scope of Compensation—Stock Compensation ("Topic 718") to include share-based payment transactions for acquiring goods and services from nonemployees. The amendments specified that Topic 718 applied to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The Company applied the new guidance to share-based payments entered into after July 1, 2020 and the adoption of this standard did not have a material impact on the Company's financial statements.

4. Fair Value Measurements

The following tables present the financial instruments carried at fair value on a recurring basis as of March 31, 2021 and June 30, 2020, respectively, in accordance with the FASB ASC 820 hierarchy (in thousands):

	Fair Value Measurements at March 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets				
Cash and cash equivalents	$ 3,307,083	$ —	$ —	$ 3,307,083

Liabilities				
Warrant liability	$ —	—	$ 10,458,393	$ 10,458,393

	Fair Value Measurements at June 30, 2020			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets				
Cash and cash equivalents	$ 3,024,980	$ —	$ —	$ 3,024,980

The Company's financial assets and liabilities which are measured at fair value on a recurring basis were comprised of cash and cash equivalents, based on Level 1 inputs, and a warrant liability, based on Level 3 inputs.

The Company estimates the fair value of the warrant liability using the Black-Scholes option-pricing model upon issuance and at each balance sheet date. Any subsequent changes in the fair value of the warrant liability will be recorded in current period earnings as other expense/income. The Company received proceeds for the issuance of series A preferred warrants of $2,250,000 and the excess fair value of $8,208,393 was recorded as a deemed dividend, against accumulated deficit for the period ended March 31, 2021. The change in the fair value of the warrant liability between March 8, 2021 and March 31, 2021 was de minimis. Therefore, no loss was recorded in other expense for the three and nine months ended March 31, 2021.

The assumptions used to determine the fair value of the warrant liability as of March 31, 2021 were as follows:

Dividend yield	0.00%
Expected volatility	49.6%
Risk-free rate	0.35%
Expected term (years)	2.94

There were no assets or liabilities measured at fair value on a nonrecurring basis at March 31, 2021 and June 30, 2020. There were no transfers between Level 1 and Level 2 of the fair value hierarchy during the periods ended March 31, 2021 and June 30, 2020. As of March 31, 2021 and June 30, 2020, the Company did not have any Level 2 assets or liabilities.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets at March 31, 2021 consisted of the following:

Research and development	$ 561,468
Franchise tax refund receivable	23,070
Other	7,125
	$ 591,662

There were no prepaid expenses or other current assets as of June 30, 2020.

6. Accrued Expenses

Accrued expenses consisted of the following:

	March 31, 2021	**June 30, 2020**
Research and development	$ 148,132	$ -
Legal expenses	63,007	22,579
	$ 211,139	$ 22,579

7. Promissory Notes

On May 28, 2020 and June 18, 2020, the Company issued promissory notes ("2020 Notes") for $175,000 and $25,000, respectively, to a related party investor. The annual interest rate on the 2020 Notes is a fixed rate of 8.0%.

On March 22, 2021, total principal and accrued interest of $200,000 and $13,057, respectively, for the promissory notes issued on May 28, 2020 and June 18, 2020, respectively, were paid in full to the related party investor of the Company.

For the three and nine months ended March 31, 2021, the Company recorded interest expense of $3,701 and $11,767, respectively.

8. License Agreement

In May 2020, the Company licensed certain intellectual property, know-how and clinical trial data from Vernalis Development Limited ("Vernalis"). The Company is required to make cash payments upon reaching certain development milestones ("Development Milestones") related to clinical trials, granting of marketing authorization and sales milestones. The Company is also required to pay single-digit royalties on product sales over the term of the contract. During the nine months ended March 31, 2021, the Company did not reach any of the Development Milestones and therefore did not record any additional license expense under this agreement.

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 to be made by the Company of $1,350,000, whether or not the Company achieves those milestones.

9. Series A Convertible Preferred Stock

In June 2020, the Company authorized the sale and issuance of up to 8,943,906 shares of Series A Preferred. The Series A Preferred financing was structured so that 2,047,500 shares would be issued at the first closing to one investor ("Initial Investor") at $1.4652 per share ("First Closing") and up to 6,896,406 shares at $1.685 per share could be issued upon the exercise of certain warrants ("Milestone Warrants") upon achieving the following development milestones ("Development Milestones): (a) the earlier of (x)

filing by the Company with the FDA of an IND, or (y) the making of an analogous regulatory filing in any foreign jurisdictions; and (b) arrangement by the Company of active pharmaceutical ingredient in amounts sufficient to facilitate the consummation of any trial to be effected pursuant to a filing.

Upon certification by the Board of Directors, the Company has the obligation to issue and the Initial Investor plus one designated additional investor ("Additional Investor") have the right and obligation to purchase Milestone Warrants to purchase 766,266 and 6,130,140 shares of Series A Preferred, respectively and as amended. The Milestone Warrants will have a purchase price of $0.32626 per share of the additional 6,896,406 shares of Series A Preferred for total proceeds of $2,250,000 and the right to purchase the additional 6,896,406 shares of Series A Preferred at $1.685 per share. The term of the Milestone Warrants will be three years from the date of issuance.

On June 18, 2020, the Company issued 2,047,500 shares of Series A Preferred for gross cash proceeds of $3,000,000. Issuance costs paid in cash totaled $24,248.

On March 8, 2021, the requisite development milestones were achieved, and therefore the Milestone Warrants were purchased for $2,250,000 in cash. (SeeNote 4)

The Company determined the obligation of the Company, the rights and obligations of the initial Series A Preferred shareholder and the one designated additional investor to purchase Milestone Warrants does not meet the definition of a freestanding financial instrument as it is not separable from the Series A Preferred issued in June 2020.

As of March 31, 2021, the rights and preferences of the Series A Preferred are as follows:

Conversion - Each share of Series A Preferred may be converted at any time, at the option of the holder, into shares of common stock, subject to the applicable conversion rate as determined by dividing the original issue price by the conversion price. The initial conversion price for the Series A Preferred issued at the First Closing is $1.4652, however, it may be adjusted for certain dilutive events. The initial conversion price for the Series A Preferred issued upon the exercise of the Milestone Warrants will be $1.685, however, it may be adjusted for certain dilutive events. The Series A Preferred automatically converts into shares of common stock at a 1:1 conversion ratio at the earlier of the closing of a public offering of the Company's securities at any price per share or at the election of the holders of at least a majority of the then-outstanding shares of Series A Preferred.

If the Initial Investor or any of its affiliates that may have received a portion of the shares from the Initial Closing, fails to purchase the designated Milestone Warrant upon the achievement of the development milestones, then all of shares from the Initial Closing still held by the Initial Investor and any of its affiliates will automatically convert into shares of Common Stock at a 1:1 conversion.

Dividends - Series A Preferred shareholders shall first receive, or simultaneously receive, a dividend if declared on any other class or series of capital stock.

Voting Rights - Preferred Stock and common stockholders vote together as one class on an as converted basis. Common stock voting rights on certain matters are subject to the powers, preferences, and rights of the Preferred Stock. Holders are entitled to vote on all matters and shall have the number of votes equal to the number of shares of common stock into which the shares of Preferred Stock held by such holder are then convertible. Certain actions such as mergers, acquisition, liquidation, dissolution, wind up of business, and deemed liquidation events, must be approved by the holders of at least a majority of the then-outstanding shares of Series A Preferred.

Liquidation Preference - Upon liquidation, dissolution, or winding up of business, the Preferred Stockholders are entitled to receive a liquidation preference in priority to holders of common stock equal to the original Series A Preferred issue price plus any accrued but unpaid dividends if that amount is greater than what it would have received had their shares been converted to common stock. If assets available for distribution are insufficient to satisfy the liquidation payment to holders in full, assets available for distribution will be allocated among holders based on their pro rata shareholdings. When holders are satisfied in full, any excess assets available for distribution will be allocated ratably among common stockholders based on their pro rata shareholdings. The liquidation preference as of March 31, 2021 is $3,000,000.

Redemption – Other than as described in Note 3, the Series A Preferred is not redeemable.

Upon the closing of the IPO on May 11, 2021, all outstanding shares of the Company's convertible preferred stock were automatically converted into shares of common stock and all outstanding shares of the Company's Series A milestone warrants were converted on a net exercised basis into shares of common stock, resulting in a total of 7,283,843 shares of common stock being issued to former holders of the Company's convertible preferred stock and Series A milestone warrants.

10. Common Stock

The Company authorized the sale and issuance of up to 22,800,000 shares of common stock. One related party investor owns 12,000,000 shares of common stock outstanding as of March 31, 2021. As of June 30, 2020, the related party investor owed the Company $3,500, for the purchase of these shares, which was paid in September 2020.

In September 2020, the Company awarded 982,500 shares of restricted common stock to its Chief Executive Officer ("CEO") under the 2020 Stock Incentive Plan ("2020 Stock Plan") at a grant date fair value of $0.1083 per share. The restrictions are subject to the satisfaction of certain performance targets and vesting requirements pursuant to the award and employment agreement. The restricted common stock has voting and dividend rights, and therefore all 982,500 shares of restricted common stock are considered issued and outstanding as of March 31, 2021.

As of March 31, 2021, the Company had reserved 1,650,000 shares of common stock for the 2020 Stock Plan, 2,047,500 shares of common stock for the conversion of Series A Preferred, and 6,896,406 shares of common stock for the conversions of Series A Preferred from the exercise of future Milestone Warrants.

On May 11, 2021, the Company closed its IPO of 3,000,000 shares of its common stock at an offering price of $7.00 per share for gross proceeds of approximately $21,000,000. Furthermore, the series A Preferred warrants will be remeasured and reclassified to equity, upon automatic cashless exercise of the warrants and conversion of the underlying Series A preferred stock to common stock. The change in fair value will be recorded in other income (expense) in the statement of operations.

As of March 31, 2021, the rights of the common stockholders are as follows:

Voting Rights - The holders of the common stock are entitled to one vote for each share of common stock. The voting, dividend, and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights, powers, and preferences of the holders of the Series A Preferred.

Dividends - The Corporation shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Corporation (other than dividends on shares of Common Stock payable in shares of Common Stock) unless the holders of the Series A Preferred Stock then outstanding shall first receive, or simultaneously receive,

a dividend on each outstanding share of Series A Preferred stock then outstanding.

Liquidation Preference - In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, after the payment or provision for payment of all debts and liabilities of the Company and all preferential amounts to which the holders of Preferred Stock are entitled with respect to the distribution of assets in liquidation, the holders of common stock shall be entitled to share ratably in the remaining assets of the Company available for distribution.

11. Stock Incentive Plan

In June 2020, the Board of Directors adopted the 2020 Stock 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. 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 or ten years from the date of grant.

12. Stock-Based Compensation

In September 2020, the Company awarded 982,500 shares of restricted common stock to its CEO, at a grant date fair value of $0.1083 per share. The restrictions are subject to the satisfaction of certain performance targets and vesting requirements pursuant to the award and employment agreement.

In the event of a change in control of our company, the CEO will be entitled to the vesting of 50% of any stock-based awards granted but not yet vested prior to the change in control event not less than six months after the change in control event, provided the CEO remains employed by our company. If the change in control event is an initial public offering, the CEO will be entitled to the full vesting of any stock-based awards. Subsequently, the Company closed its IPO in May 2021, which resulted in a change of control. Therefore, the CEO will be entitled to the full vesting of any stock-based awards.

In March 2021, the Company issued non-qualified stock option awards under the 2020 Stock Plan of 604,404 shares of the Company's common stock to its Board of Directors and consultants of the Company. These awards are subject to the satisfaction of certain performance targets and vesting requirements pursuant to the award.

Stock Options

Value of Stock Options

The Company has valued awards herein using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, the Company estimates its expected stock volatility based on historical volatility of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for the time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table provides the assumptions used in determining the fair value of option awards as of March 31, 2021:

	2021
Expected volatility	49.6% - 50.9%
Risk-free interest rate	0.13% - 0.64%
Expected dividend yield	0%
Expected term (in years)	2.5 – 3.6

Changes in awards granted under the 2020 Stock Plan as of March 31, 2021 are as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2020	982,500	$ 0.1083	0.96	$ 2,038,688
Granted	604,404	$ 2.1833		
Exercised	-	$ -		
Forfeited	-	$ -		
Outstanding at March 31, 2021	1,586,904	$ 0.8986	2.6	$ 2,038,688
Options exercisable at March 31, 2021	383,418	$ 0.1895	1.7	$ 764,467

For the three months ended March 31, 2021, 301,554 shares vested and the Company recorded stock-based compensation expense of $45,302 in general and administrative expenses and $2,105 in research and development expenses. For the nine months ended March 31, 2021, 383,418 shares vested and the Company recorded stock-based compensation expense of $82,404 in general and administrative expenses and $2,105 in research and development expenses.

As of March 31, 2021, there are 63,096 shares available to be granted under the 2020 Stock Plan.

As of March 31, 2021, unrecognized stock-based compensation expense associated with the restricted common stock and non-qualified stock options totaled $501,700.

13. Subsequent Events

The Company has completed an evaluation of all subsequent events through June 21, 2021, the date these financial statements were available to be issued. The Company has concluded that no subsequent events have occurred that require disclosure except in Notes 1, 2, 3, 8, 9, and 10.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read this section in conjunction with our unaudited interim consolidated financial statements and related notes included in Part I. Item 1.

Forward-Looking Statements

This discussion contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements are identified by words 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. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause a difference result and include, but are not limited to, those discussed under the caption "Risk Factors" in this report. See "Special Note Regarding Forward-Looking Statements." Forward-looking statements are based on our management's current beliefs and assumptions and based on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments.

Overview

We are a clinical-stage biotechnology company developing novel solutions for people suffering from cannabinoid overdose and substance addiction. Our lead product candidate, ANEB-001, is intended to reverse the negative effects of cannabinoid overdose within 1 hour of administration. The signs and symptoms of cannabinoid overdose 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 cannabinoid overdose. 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. We intend to launch a Phase 2 proof-of-concept trial for ANEB-001 in the fourth calendar quarter of 2021.

Cannabinoid overdoses 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 cannabinoid overdose. Excessive ingestion of THC via edible products such as candies and brownies, and overdoses of 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 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 The Nationwide Emergency Department Sample (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 cannabinoid overdoses 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 cannabinoid overdose.

In May 2020, we entered into a royalty-bearing license agreement with Vernalis R&D Limited ("License Agreement") to exploit its license compounds and licensed products to combat symptoms of cannabinoid overdose and substance addiction. We are currently developing our lead product candidate, ANEB-001 to quickly, and effectively, combat symptoms of cannabinoid overdose.

Our objective is to develop and commercialize new treatment options for patients suffering from cannabinoid overdose 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 cannabinoid overdose. ANEB-001 is an orally bioavailable, rapidly absorbed treatment that we anticipate will reverse the symptoms of cannabinoid overdoses, in most cases within 1 hour of administration. Our proprietary position in the treatment of cannabinoid overdose is protected by rights to two patent applications covering various methods of use of the compound and delivery systems. We anticipate starting a Phase 2 proof-of-concept trial for ANEB-001 in the fourth quarter of 2021.

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. We have 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 May 6, 2021, we completed the initial public offering ("IPO") of our common stock, in which we sold 3,000,000 shares. The shares began trading on the Nasdaq Global Market on May 7, 2021. The shares were sold at an IPO price of $7.00 per share for gross proceeds of approximately $21,000,000. Upon the closing of the IPO, all outstanding shares of our convertible preferred stock were automatically converted into shares of common stock and all outstanding shares of Series A milestone warrants were converted on a net exercise basis into shares of common stock, resulting in a total of 7,283,843 shares of common stock being issued to former holders of our convertible preferred stock, and Series A milestone warrants.

We have not generated any revenue from product sales since inception. We expect to continue incurring significant research and development expenses related to ANEB-001. We have incurred operating losses since inception and expect to continue to incur significant operating losses and negative cash flows from operations for the foreseeable future. For the nine months ended March 31, 2021 and as of March 31, 2021, we recorded a net loss of $1,140,815 and an accumulated deficit of $9,532,345, respectively.

As of March 31, 2021, our cash and cash equivalents were $3,307,083. In March 2021, we raised $2,250,000 in gross proceeds from the sale of our series A preferred milestone warrants.

Financial Operations Overview

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 may never succeed in obtaining regulatory approval for any of our product candidates.

Research and Development Expenses

Our research and development expenses for the three and nine months ended March 31, 2021 included research and development consulting expenses 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. Following the closing of this offering, 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 cannabinoid overdose, as well as continue to expand our product-candidate pipeline. We anticipate research and development expenses will 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, or CROs, and contract manufacturing organizations, or 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; and therefore, 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. Product candidates in early stages of clinical development, generally have high development costs, primarily due to multiple clinical trials, API, drug product and clinical materials manufacturing, milestone payments, IND process and clinical trial planning. 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.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of any product candidates that we develop from our programs. We are also unable to predict when, if ever, material net cash inflows will commence from sales of product candidates we develop, if at all. This is due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- the duration, costs and timing of clinical trials of our current and future indication expansion programs and new product candidates;
- successful completion of preclinical studies and clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- acceptance of INDs for our planned clinical trial or future clinical trials;
- successful enrollment and completion of clinical trials;
- successful data from our clinical program or future clinical programs that supports an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt of regulatory and marketing approvals from applicable regulatory authorities;
- receipt and maintenance of marketing approvals from applicable regulatory authorities;
- establishing agreements with third-party manufacturers for clinical supply for our clinical program or future clinical programs and commercial manufacturing, if our product candidate is approved;

- entry into collaborations to further the development of our product candidates;
- obtaining, maintaining, protecting, expanding and enforcing patent and trade secret protection or regulatory exclusivity for our product candidates; and
- successfully launching commercial sales of our product candidates if and when approved.

A change in the outcome of any of these variables with respect to the development of any of our programs or any product candidate we develop would significantly change the costs, timing and viability associated with the development of such program or product candidate.

General and Administrative Expenses

General and administrative expenses for the three and nine months ended March 31, 2021 consisted primarily of professional fees, stock-based compensation, personnel costs and rent.

We anticipate that our general and administrative expenses will increase in the future to support our continued development efforts, ongoing and future potential research and development activities, and increased costs of operating as a public company. These increased costs will likely include additional personnel, outside consultants, lawyers, and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company, including services associated with maintaining compliance with the requirements of Nasdaq and the SEC, insurance, and investor relations costs. If any of our current or future indication expansion programs or new product candidates obtains U.S. regulatory approval, we expect that we would incur significantly increased expenses associated with building a sales and marketing team.

Results of Operations

Three months ended March 31, 2021

The following table sets forth our results of operations for the three months ended March 31, 2021. As such, the results for the three months ended March 31, 2021 may not provide a complete assessment of our financial performance and future periods.

	Three months ended March 31, 2021
Operating expenses:	
Research and development	$ 273,038
General and administrative	279,093
Total operating expenses	552,131
Other expense:	
Interest expense	3,701
Loss from operations before taxes	(555,832)
Income tax expense	-
Net loss	$ (555,832)
Deemed dividend	$ (8,208,393)
Net loss attributable to common shareholders	$ (8,764,225)

Research and Development Expenses

Research and development expenses for the three months ended March 31, 2021 consisted of the following:

	Three months ended March 31, 2021
Pre-clinical and clinical studies	$ 268,227
Compensation and related benefits	2,706
Stock compensation expense	2,105
Total research and development expenses	$ 273,038

General and Administrative Expenses

General and administrative expenses for the three months ended March 31, 2021 consisted of the following:

	Three months ended March 31, 2021
Compensation and related benefits	$ 64,636
Professional and consultant fees	149,038
Stock compensation expense	45,302
Facilities, fees and other related costs	20,117
Total general and administrative expenses	$ 279,093

Interest Expense

Interest expense of $3,701 for the three months ended March 31, 2021 was related to two promissory notes issued to a related party.

Income Taxes

For interim periods, we estimate the annual effective income tax rate and apply the estimated rate to the year-to-date income or loss before income taxes. The effective income tax rate for the three months ended March 31, 2021 was 0.0%. Currently, we have recorded a full valuation allowance against our net deferred tax assets, primarily related to federal net operating losses and research and development credits.

Deemed Dividend

Deemed dividend of $8,208,393 for the three months ended March 31, 2021 recorded against accumulated deficit and was related to the recording of the series A preferred warrant liability at fair value.

Nine months ended March 31, 2021

The following table sets forth our results of operations for the nine months ended March 31, 2021. As such, the results for the nine months ended March 31, 2021 may not provide a complete assessment of our financial performance and future periods.

	Nine months ended March 31, 2021
Operating expenses:	
Research and development	$ 463,306
General and administrative	665,742
Total operating expenses	1,129,048
Other expense:	
Interest expense	11,767
Loss from operations before taxes	(1,140,815)
Income tax expense	-
Net loss	$ (1,140,815)
Deemed dividend	$ (8,208,393)
Net loss attributable to common stockholders	$ (9,349,208)

Research and Development Expenses

Research and development expenses for the nine months ended March 31, 2021 consisted primarily of the following:

	Nine months ended March 31, 2021
Pre-clinical and clinical studies	$ 458,494
Compensation and related benefits	2,706
Stock compensation expense	2,105
Total research and development expenses	$ 463,305

General and Administrative Expenses

General and administrative expenses for the nine months ended March 31, 2021 consisted primarily of the following:

	Nine months ended March 31, 2021
Compensation and related benefits	$ 72,214
Professional and consultant fees	470,307
Stock compensation expense	82,404
Facilities, fees and other related costs	40,817
Total general and administrative expenses	$ 665,742

Interest Expense

Interest expense of $11,767 for the nine months ended March 31, 2021 was related to the two promissory notes issued to a related party and paid in full on March 22, 2021.

Income Taxes

For interim periods, we estimate the annual effective income tax rate and apply the estimated rate to the year-to-date income or loss before income taxes. The effective income tax rate for the nine months ended March 31, 2021 was 0.0%. Currently, we have recorded a full valuation allowance against our net deferred tax assets, primarily related to federal net operating losses and research and development credits.

Deemed Dividend

Deemed dividend of $8,208,393 for the nine months ended March 31, 2021 recorded against accumulated deficit and was related to the recording of the series A preferred warrant liability at fair value.

Liquidity and Capital Resources

Overview

To date, we have financed our operations primarily with proceeds from sales of our series A convertible preferred stock and issuance of two promissory notes to a related party. From our inception through June 30, 2020, we received gross proceeds of $3,200,000. As of March 31, 2021 and June 30, 2020, we had cash and cash equivalents of $3,307,083 and $3,024,980 and an accumulated deficit of $9,532,345 and $183,137, respectively. Additionally, on March 15, 2021, we received proceeds from the issuance of milestone warrants of $2,250,000, pursuant to the Securities Purchase Agreement.

On May 11, 2021, we completed our IPO and received gross proceeds from the issuance of common stock of $21,000,000.

We intend to use the net proceeds of our IPO to make expenditures to fund proprietary research and development of our ANEB-001 product and to support preclinical testing and clinical trials necessary for regulatory filings. A portion of the net proceeds from the IPO may be used for the acquisition or licensing of complementary technologies, products or businesses. The net proceeds of the IPO will also be available for working capital and other general corporate purposes, including enhancing our corporate infrastructure and systems to assist in creating a more robust means of tracking data, automating back-office functions and improving our financial reporting system. We will need additional funding to complete the clinical development of, seek regulatory approval for and commercially launch ANEB-001 and other pipeline development products.

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.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves or potentially discontinue operations. With our cash on hand and the funds received from our IPO in May 2021, we will have adequate cash resources to fund operations for at least the next twelve (12) months from the date of issuance of these financial statements.

Financing Transactions

On May 28, 2020 and June 18, 2020, we executed two promissory notes payable to Dr. Lawler in the aggregate principal amount of $200,000, reflecting cash advances by the lender to us in May and June 2020. The indebtedness is unsecured and bears interest at the rate of 8.0% per year. All accrued and unpaid interest and principal on the promissory note issued on May 28, 2020 is due and payable on demand by the holder on or after the date on which we consummate an equity financing (or series of equity financings having materially similar terms and conditions) pursuant to which we sell and issue shares of preferred stock for total aggregate gross proceeds of at least $2,500,000.

On March 22, 2021, all accrued and unpaid interest and principal on the promissory notes issued on May 28, 2020 and June 18, 2020 were paid in full.

On June 18, 2020, we received gross proceeds of $3,000,000 from a private placement of our series A preferred stock (the "Private Placement"), convertible into 2,047,500 shares of our common stock, pursuant to the terms of a securities purchase agreement (the "Securities Purchase Agreement") with 22NW, LP, an institutional accredited investor affiliated with Aron R. English, who became a director of our company at such time. The series A preferred stock is convertible into shares of common stock automatically upon the closing of our IPO. The conversion price of the series A preferred stock is $1.4652 per share. The conversion price is subject to adjustment if, at any time prior to conversion of the shares, we issue in a financing additional shares of common stock or other equity or equity-linked securities at a purchase, conversion or exercise price less than $1.4652 per share. In any such case, we have agreed to issue additional shares of series A preferred stock to the investors so that the effective purchase price per share in the Private Placement is reduced by a weighted-average anti-dilution percentage that takes into account both the lower per share purchase, conversion or exercise price and the number of such additional shares issued at the lower price. No adjustment will be made, however, in respect of shares of common stock or stock options issued to employees, directors or consultants, or in connection with acquisitions of other corporations or strategic collaborations approved by our board of directors.

On March 8, 2021, the requisite development milestones were achieved, and therefore the Milestone Warrants were earned and warrants to purchase Series A preferred stock were issued for $2,250,000 in cash. The warrants are exercisable for cash into up to an additional 6,896,406 shares of series A preferred stock at an exercise price of $1.685 per share or on a "net-exercise" basis into such lesser number of shares of series A preferred stock by surrendering a portion of the underlying warrant shares, based on the positive difference between the stated warrant exercise price and the IPO price per share from the IPO, to pay the exercise price.

On May 11, 2021, we completed the IPO of our common stock, in which we sold 3,000,000 shares. The shares began trading on the Nasdaq Global Market on May 7, 2021. The shares were sold at an IPO price of $7.00 per share for gross proceeds of approximately $21,000,000. Upon the closing of the IPO, all outstanding shares of our convertible preferred stock were automatically converted into shares of common stock and all outstanding shares of Series A underlying the milestone warrants were converted on a net exercise basis into shares of common stock, resulting in a total of 7,283,843 shares of common stock being issued to former holders of our convertible preferred stock, and Series A milestone warrants.

Cash Flows

The following table sets forth a summary of our cash flows for the nine months ended March 31, 2021:

	Nine months ended March 31, 2021
Net cash used in operating activities	$ (1,766,611)
Net cash provided by financing activities	2,048,714
Net increase in cash and cash equivalents	$ 282,103

Operating Activities

During the nine months ended March 31, 2021, our operating activities used $1,766,611 in cash, which was more than the net loss of $1,140,815, primarily due to increases in prepaid expenses and deferred costs associated with our IPO. These charges were partially offset by increases in accounts payable, and accrued expenses, and a decrease in a related party receivable.

Financing Activities

During the nine months ended March 31, 2021, cash provided by financing activities was $2,048,714. This was primarily due to proceeds received from the issuance of Series A preferred milestone warrants of $2,250,000 offset by the extinguishment of the related party promissory notes of $201,286.

Outlook

Based on the net proceeds from our IPO in May 2021, our research and development plans and our timing expectations related to the development of our clinical programs, we expect that the net proceeds from the IPO will enable us to fund our operating expenses, clinical development, milestone payments and capital expenditure requirements for at least the next twelve (12) months from the issuance of these financial statements. However, we have based this estimate on assumptions that may prove to be incorrect, and we could use our capital resources sooner than we expect.

Contractual Obligations and Commitments

License Agreement with Vernalis

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. In May 2021, we issued 192,857 shares of common stock to Vernalis in lieu of future milestone payments by us of $1,350,000, whether or not we achieve those milestones.

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.

Promissory Notes

On May 28, 2020 and June 18, 2020, we executed two promissory notes payable to Dr. Lawler in the aggregate principal amount of $200,000, reflecting cash advances by the lender to us in May and June 2020.

On March 22, 2021, all accrued and unpaid interest and principal on the promissory notes issued on May 28, 2020 and June 18, 2020 has been paid in full.

Office Lease, Manufacturing Contract and CRO Contract

In August 2020, we signed a one-year lease subleasing office space from a related party. The annualized lease obligation is approximately $14,000. 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. Subsequently in February 2021, we entered into an agreement with a third-party contract research organization ("CRO") to manage and conduct our Phase 2 clinical trial in the fourth calendar quarter of 2021 with the anticipation of completing the trial by the first calendar quarter of 2022. The total cost for the CRO agreement is approximately €1,450,758 or $1,760,000.

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.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of March 31, 2021.

Contractual Obligations and Commitments

Not applicable.

Critical Accounting Policies and Significant Judgments and Estimates

The Critical Accounting Policies and Significant Judgments and Estimates included in our Registration Statement on Form S-1, filed with the Securities and Exchange Commission, or SEC, on March 23, 2020, as amended May 6, 2021, have not materially changed.

JOBS Act Accounting Election

The JOBS Act, 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 irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act refers to controls and procedures 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. Because there are inherent limitations in all control systems, a control system, no matter how well conceived and operated, can provide only reasonable, as opposed to absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, as of the end of the period covered by this report.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(d) and 15d-15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting during our third fiscal quarter ended March 31, 2021. We have not experienced any material impact to our internal control over financial reporting despite the fact that our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness.

Part II. Other Information

Item 1. Legal Proceedings

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. Other than as described below, our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which would have a material adverse effect on our results of operations, financial condition or cash flows.

Item 1A. Risk Factors

Risks Related to our Business, Financial Condition and Capital Requirements

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, 2021, we have an accumulated deficit of $9,532,345. 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, but are not limited to, 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 for the foreseeable 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.

The future success of our business cannot be determined at this time, and we do not anticipate generating revenue from product sales for the foreseeable future. In addition, we have no experience in commercializing drug products on our own and face a number of challenges with respect to 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 cannabinoid overdoses and treating patients experiencing overdose symptoms may reduce the demand for our product, if it develops;
- changes in the market for reversing cannabinoid overdoses and treating patients experiencing overdose 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 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 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 are, and expect to continue to be, reliant upon third-party licensors for certain patent and other intellectual property rights that are important or necessary to the development of our product candidates, including ANEB-001. On May 26, 2020, we entered into the License Agreement with Vernalis, pursuant to which Vernalis granted to us an exclusive license to develop and commercialize our ANEB-001 product candidate. Under the License Agreement, we have the sole discretion to carry out the development and commercialization of ANEB-001, including obtaining regulatory approvals. We retain the sole right over certain patent rights (including patent applications) and know-how controlled by us that are necessary or reasonably useful to developing and commercializing the licensed product during the term of the License Agreement. The License Agreement imposes, and we expect that any future license agreement will impose, specified diligence, milestone payment, royalty, commercialization, development and other obligations on us and require us to meet development timelines, or to exercise diligent or commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the license.

Furthermore, our licensors have, or may have in the future, the right to terminate a license if we materially breach the agreement and fail to cure such breach within a specified period or in the event we undergo certain bankruptcy events. In spite of our best efforts, our current or any future licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements. If our license agreements are terminated, we may lose our rights to develop and commercialize product candidates and technology, lose patent protection, experience significant delays in the development and commercialization of our product candidates and technology, and incur liability for damages. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, our competitors or other third parties could have the freedom to seek regulatory approval of, and to market, products and technologies identical or competitive to ours and we may be required to cease our development and commercialization of certain of our product candidates and technology. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with any product candidates we may develop and our technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Our License Agreement with Vernalis continues for an indefinite term and terminates, among other ways, under the following circumstances: (i) on its terms when royalties and other sums cease to be payable thereunder; (ii) by us at any time by providing 60 days' prior notice; or (iii) upon an event of default, such as a material breach or insolvency of the other party. Upon termination, all rights and licenses granted by Vernalis will revert immediately to Vernalis; all outstanding sums as of the termination date will be immediately due and payable to Vernalis; and we will return or destroy, at Vernalis's request, any regulatory or other materials provided by Vernalis pursuant to the License Agreement.

Disputes may also arise between us and Vernalis or future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- whether, and the extent to which, our products, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensor(s); and
- the priority of invention of patented technology.

If we do not prevail in such disputes, we may lose any or all of our rights under such license agreements, experience significant delays in the development and commercialization of our products and technologies, or incur liability for damages, any of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, we may seek to obtain additional licenses from our licensor(s) and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensor(s), including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with our products.

In addition, the agreements under which we currently and in the future license intellectual property or technology from third parties are complex and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement,

either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize any affected products or services, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Absent the license agreements, we may infringe patents subject to those agreements, and if the license agreements are terminated, we may be subject to litigation by the licensor. Litigation could result in substantial costs to us and distract our management. If we do not prevail, we may be required to pay damages, including treble damages, attorneys' fees, costs and expenses and royalties or be enjoined from selling ANEB-001, which could adversely affect our ability to offer products or services, our ability to continue operations and our business, financial condition, results of operations and prospects.

We currently have no product revenue and will need to raise additional capital following the IPO in May 2021, which may be unavailable to us or may cause dilution or place significant restrictions on our ability to operate.

For the foreseeable future, we may be unable to generate sufficient revenue or cash flow to fund our operations. We will need to seek additional equity or debt financing 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.

We do not have any other 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. 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 product or future candidates and other business. This may materially adversely affect our operations and financial condition as well as our ability to achieve business objectives and maintain competitiveness. Our inability to fund our business could thus lead to the loss of your investment.

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 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.

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

We have no operating history as a publicly-traded company, and our inexperience could materially and adversely affect us and our stockholders.

We have no operating history as a publicly-traded company. Our board of directors and management team will have overall responsibility for our management. As a publicly-traded company, we will be required to develop and implement substantial control systems, policies and procedures in order to satisfy our periodic SEC reporting and Nasdaq obligations. We cannot assure you that management's past experience will be sufficient to successfully develop and implement these systems, policies and procedures and to operate our company. Failure to do so could jeopardize our status as a public company, and the loss of such status may materially and adversely affect us and our stockholders.

Risks Related to our Intellectual Property

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.

Our commercial success will depend, in part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to ANEB-001, our product candidate. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to aspects of our product candidate that are important to our business. Given that the development of our product candidates is at an early stage, our intellectual property portfolio with respect to certain aspects of our product candidates is also at an early stage. For example, we have filed or intend to file patent applications related to aspects of ANEB-001, our product candidate; however, there can be no assurance that any such patent applications will issue as granted patents around the world. The requirements for patentability differ in certain countries, and certain countries have heightened requirements for patentability. Further, in some cases, we have only filed provisional patent applications on certain aspects of our technology and product candidate, and provisional patent applications are not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non-provisional patent application within this timeline could cause us to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications.

Further, any changes we make to our product candidates to cause them to have what we view as more advantageous properties may not be covered by our existing patent applications, and we may be required to file new applications and/or seek other forms of protection for any such altered product candidates. There can be no assurance that we would be able to secure patent protection that would adequately cover any such altered product candidates. There can also be no assurance that any such patent applications will be issued as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection related to aspects of our product candidates could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Even if we obtain issued or granted patents with respect to our product candidates, we cannot be certain that such patents will not later be found to be invalid and/or unenforceable. Currently, we do not have patents on our core intellectual property.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we may enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, distribution partners, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our potential patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued, and even if issued, the patents may not meaningfully protect our current or future product candidates, effectively prevent competitors and third parties from commercializing competitive products or otherwise provide us with any competitive advantage. Our competitors or other third parties may

be able to circumvent our patents by developing similar or alternative products in a non-infringing manner.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Patent applications we own currently or that in the future issue as patents may not be issued in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents to which we have rights may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office (the "USPTO") or post-issuance become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding, or litigation could reduce the scope of, or invalidate or render unenforceable, such patent rights, allow third parties to commercialize our product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as post-grant review at the USPTO or oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates and other technologies. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

If we are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. Termination of these licenses or reduction or elimination of our rights under these licenses may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these licenses, including our rights to important intellectual property or technology. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products.

In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Some of our patents and patent applications may in the future be co-owned with third parties. In addition, future collaborators or licensors may co-own their patents and patent applications with other third parties with whom we do not have a direct relationship. Our rights to certain of these patents and patent applications may be dependent, in part, on inter-institutional or other operating agreements between the joint owners of such patents and patent applications, who are not parties to our license agreements. If our future collaborators or licensors do not have exclusive control of the grant of licenses under any such third-party co-owners' interest in such patents or patent applications or we are otherwise unable to secure such exclusive rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology to the extent such products and technology are not also covered by our intellectual property. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

We cannot be certain that our potential patent rights will be effective in protecting ANEB-001 and related technologies. Failure to protect such assets may have a material adverse effect on our business, operations, financial condition and prospects.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration, and specifics of any FDA marketing approval of ANEB-001 and related technologies we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act). The Hatch-Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. However, we may not be granted an extension in the United States and/or foreign countries and territories because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and growth prospects could be materially harmed.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patent rights on important aspects of ANEB-001 in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may develop their own products and may also export infringing products to territories where we may have patent protection, but enforcement is not as strong as that in the United States. These products may compete with ANEB-001, and our patent or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patent rights or marketing of competing products in violation of our proprietary rights generally. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our current or future product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our current or future product candidates in all of our expected significant foreign markets.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the

enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our future collaborators or licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States or other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On or after March 16, 2013, under the Leahy-Smith America Invents Act (the America Invents Act) enacted on September 16, 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third-party that files a patent application in the USPTO on or after March 16, 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third-party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to ANEB-001 or (ii) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biopharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

The expiration or loss of patent protection may adversely affect our future revenues and operating earnings.

Patent protection is important in the development and eventual commercialization of our product candidate. Patents covering our product candidate normally provide market exclusivity, which is important in order for our product candidate to become profitable. Even if we are successful in obtaining a patent, patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection, we may be open to competition from generic versions of such compositions, methods and devices. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar to ours.

Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

Delays in the completion of, or the termination of, a clinical trial for ANEB-001, our lead drug candidate, could adversely affect our business.

Clinical trials are very expensive, time-consuming, unpredictable and difficult to design and implement. The results of clinical trials may be unfavorable, they may continue for several years, and they may take significantly longer to complete and involve significantly more costs than expected. Delays in the commencement or completion of clinical testing could significantly affect product development costs and plans with respect to our drug candidate. The commencement and completion of clinical trials can be delayed and experience difficulties for a number of reasons, including delays and difficulties caused by circumstances over which we may have no control. For instance, approvals of the scope, design or trial site may not be obtained from the FDA and other required bodies in a timely manner or at all, agreements with acceptable terms may not be reached in a timely manner or at all with contract research organizations, to conduct the trials, a sufficient number of subjects may not be recruited and enrolled in the trials, and third-party manufacturers of the materials for use in the trials may encounter delays and problems in the manufacturing process, including failure to produce materials in sufficient quantities or of an acceptable quality to complete the trials. Clinical trial delays could shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

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.

Our drug candidate is a treatment in development for cannabinoid overdose. We must successfully complete clinical trials for our drug candidate before we can apply for marketing approval. Even if we complete our clinical trials, it does not assure marketing approval. Our clinical trials may be unsuccessful, which would materially harm our business. Even if our initial clinical trials are successful, we are required to conduct additional clinical trials to establish our drug candidate's safety and efficacy, before a New Drug Application ("NDA") or Biologics License Application ("BLA"), or their foreign equivalents can be filed with the FDA or comparable foreign regulatory authorities for marketing approval of our drug candidate.

Success in early phases of preclinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidate. The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market our drug in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. In the United States, the FDA generally requires the completion of clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are eventually approved for commercialization. If our development efforts for our drug candidate, including regulatory approval, are not successful for its planned indications, or if adequate demand for our drug candidate is not generated, our business will be materially adversely affected.

Our success depends on the receipt of regulatory approval and the issuance of such regulatory approvals is uncertain and subject to a number of risks, including the following:

- the results of toxicology studies may not support the filing of an Investigational New Drug Application ("IND") for our drug candidate or the FDA may require additional toxicology studies;

- the FDA or comparable foreign regulatory authorities or Institutional Review Boards ("IRB") may disagree with the design or implementation of our clinical trials;
- it may be difficult to run clinical trials involving the administration of THC to subjects because THC is a controlled substance and is illegal in certain jurisdictions;

- we may not be able to provide acceptable evidence of our drug candidate's safety and efficacy;
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA or other regulatory agencies for marketing approval;
- the dosing of our drug candidate in a particular clinical trial may not be at an optimal level;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our drug candidate;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA, BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Failure to obtain regulatory approval for our drug candidate for the foregoing, or any other reasons, will prevent us from commercializing our drug candidate, and our ability to generate revenue will be materially impaired. We cannot guarantee that regulators will agree with our assessment of the results of the clinical trials we intend to conduct in the future or that such trials will be successful. The FDA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or preclinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of our drug candidate.

We have not submitted an NDA or received regulatory approval to market our drug candidate in any jurisdiction. We have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third party contract research organizations, with expertise in this area to assist us in this process. Securing regulatory approvals to market a product requires the submission of preclinical, clinical, and/or pharmacokinetic data, information about product manufacturing processes and inspection of facilities and supporting information to the appropriate regulatory authorities for each therapeutic indication to establish a drug candidate's safety and efficacy for each indication. Our drug candidate may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the drug candidate involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application.

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.

If approved for marketing, the commercial success of ANEB-001 will depend upon the product's acceptance by the medical community, including physicians, patients and healthcare payors. The degree of market acceptance for our drug candidate will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience, dosing burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our drug candidate, and the target patient population to try new therapies;
- efficacy of our drug candidate compared to competing products;
- the introduction of any new products that may in the future become available targeting indications for which our drug candidate may be approved;
- new procedures or therapies that may reduce the incidences of any of the indications in which our drug candidate may show utility;

- pricing and cost-effectiveness;
- the inclusion or omission of our drug candidate in applicable therapeutic and vaccine guidelines;
- the effectiveness of our own or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in approved labeling from regulatory authorities;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement or government pricing approvals.

If our drug candidate is approved, but does not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our drug candidates may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our drug candidate successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our drug candidate not commercially viable. For example, regulatory authorities may approve our drug candidate for fewer or more limited indications than we request, may not approve the price we intend to charge for our drug candidate, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve our drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals or require risk management plans or a Risk Evaluation and Mitigation Strategy ("REMS") to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also require a REMS for an approved product when new safety information emerges. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our drug candidate. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our drug candidate.

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 expense. 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.

Even if we obtain regulatory approval for ANEB-001 for an indication, the FDA or foreign equivalent may still impose significant restrictions on their indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time-consuming post-approval studies and post-market surveillance to monitor safety and efficacy. Our drug candidate will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, as well as continued compliance with current Good Clinical Practices ("GCP") regulations, for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practice ("CGMP") requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

The FDA has the authority to require a REMS as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and/or enrollment in a registry.

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

If we or a regulatory agency discovers previously unknown problems with our product, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions:

- restrictions on the manufacturing or marketing of the product (including complete withdrawal or recall of the product);
- warning letters or holds on post-approval clinical trials;
- FDA's refusal to approve pending NDA's or supplements to approved NDA's;
- suspension or revocation of product license approvals;
- product seizures or detentions;
- FDA's refusal to allow imports or exports of products; or
- civil penalties, criminal penalties or injunctions.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our drug candidate and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

ANEB-001, our lead drug candidate, may face competition sooner than expected.

Our success will depend in part on our ability to obtain and maintain patent protection for important aspects of ANEB-001 and technologies and to prevent third parties from infringing upon our proprietary rights. We must also operate without infringing upon patents and proprietary rights of others, including by obtaining appropriate licenses to patents or other proprietary rights held by third parties, if necessary. However, the applications we have filed or may file in the future may never yield patents that protect our inventions and intellectual property assets. Failure to obtain patents that sufficiently cover our formulations and technologies would limit our protection against compounding pharmacies, outsourcing facilities, generic drug manufacturers, pharmaceutical companies and other parties who may seek to copy our products, produce products substantially similar to ours or use technologies substantially similar to those we own.

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 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.

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the API in ANEB-001 for use in our clinical trials or for commercial product, if any. In addition, we do not have the capability to encapsulate our drug candidate as a finished drug product for commercial distribution. As a result, we will be obligated to rely on contract manufacturers, if and when our drug candidate is approved for commercialization. We have not entered into an agreement with any contract manufacturers for commercial supply and may not be able to engage a contract manufacturer for commercial supply of our drug candidate on favorable terms to us, or at all.

The facilities used by our contract manufacturers to manufacture our drug candidate must be approved by the FDA or comparable foreign regulatory authorities pursuant to inspections that will be conducted after we submit an NDA or BLA to the FDA or their equivalents to other relevant regulatory authorities. We will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with CGMP regulations for manufacture of both active drug substances and finished drug products. These CGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our drug candidates. If our contract manufacturers do not successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our drug candidate or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidate, if approved.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with CGMP regulations and similar regulatory requirements. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market our drug candidate, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we will not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market any of our drug candidate.

If, for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our API or finished products or should cease doing business with us, we could experience significant interruptions in the supply of our drug candidate or may not be able to create a supply of our drug candidate at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of our drug

candidate might be negatively affected. Our inability to coordinate the efforts of our third-party manufacturing partners, or the lack of capacity available at our third party manufacturing partners, could impair our ability to supply our drug candidate at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of our drug candidate if we decided to transfer the manufacturing of our drug candidate to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential product. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of our drug candidate, increase our cost of goods sold and result in lost sales.

We cannot guarantee that our future manufacturing and supply partners will be able to reduce the costs of commercial scale manufacturing of our drug candidate over time. If the commercial-scale manufacturing costs of our drug candidate are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities.

We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

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.

The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to:

- the FDA or a comparable foreign regulatory authority failing to grant permission to proceed and placing the clinical study on hold;
- subjects for clinical testing failing to enroll or remain in our trials at the rate we expect;
- a facility manufacturing our drug candidate being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of CGMP requirements or other applicable requirements, or contamination of our drug candidate in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- subjects choosing an alternative treatment for the indications for which we are developing our drug candidate, or participating in competing clinical studies;
- subjects experiencing severe or unexpected drug-related adverse effects;
- reports from clinical testing on similar technologies and products raising safety and/or efficacy concerns;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or employing methods consistent with the clinical trial protocol, CGMP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical study sites by the FDA, comparable foreign regulatory authorities, or IRB's finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from using some or all of the data in support of our marketing applications with the FDA;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications with the FDA;
- one or more IRB's refusing to approve, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different contract research organizations and trial sites;
- deviations of the clinical sites from trial protocols or dropping out of a trial;
- adding new clinical trial sites;
- the inability of the contract research organization to execute any clinical trials for any reason; and
- government or regulatory delays or "clinical holds" requiring suspension or termination of a trial.

Product development costs for our drug candidate will increase if we have delays in testing or approval or if we need to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA, comparable foreign regulatory authorities, and IRB's for reexamination, which may impact the costs, timing or successful completion of that study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, the IRB, or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies of our drug candidate, its commercial prospects may be materially harmed and our ability to generate product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our drug candidate. In addition, if one or more clinical studies are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our drug candidate could be significantly reduced.

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.

Clinical testing of our drug candidate is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical testing and early clinical trials may not be predictive of the results of later-stage clinical trials. We cannot assure you that the FDA or comparable foreign regulatory authorities will view the results as we do or that any future trials of our drug candidate will achieve positive results. Drugs in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical testing and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any future clinical trial results for our drug candidate may not be successful.

In addition, a number of factors could contribute to a lack of favorable safety and efficacy results for our drug candidate. For example, such trials could result in increased variability due to varying site characteristics, such as local standards of care and differences in evaluation period, and due to varying patient characteristics including demographic factors and health status.

Risks Related to Government Regulation of our Industry

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell future products and profitability. On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, "PPACA"), which includes a number of healthcare reform provisions and requires most U.S. citizens to have health insurance. The law, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, and establishes a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Substantial new provisions affecting compliance also have been added, which may require modification of business practices with healthcare practitioners.

In the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the development and success of our future product candidates, and we could be adversely affected by current and future healthcare reforms.

Clinical trials for ANEB-001 have and may in the future be conducted outside the United States and not under an IND, and where this is the case, the FDA may not accept data from such trials.

Although the FDA may accept data from clinical trials conducted outside the United States and not under an IND in support of research or marketing applications for our product candidates, this is subject to certain conditions set out in 21 C.F.R. § 312.120. For example, such foreign clinical trials should be conducted in accordance with GCP, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. The FDA must also be able to validate the data from the study through an onsite inspection if the agency deems it necessary. The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the U.S. and the foreign country.

Risks Related to Ownership of Our Common Stock and this Offering

Our stock price may be volatile and your investment could decline in value.

The market price of our common stock may fluctuate substantially as a result of many factors, some of which are beyond our control. These fluctuations could cause you to lose all or part of the value of your investment in our common stock. Factors that could cause fluctuations in the market price of our common stock include the following:

- quarterly variations in our results of operations;
- results of operations that vary from the expectations of securities analysts and investors;
- results of operations that vary from those of our competitors;
- changes in expectations as to our future financial performance, including financial estimates by securities analysts;
- publication of research reports about us or the pharmaceutical industry;
- announcements by us or our competitors of significant contracts, acquisitions or capital commitments;
- announcements by third parties of significant claims or proceedings against us;
- changes affecting the availability of financing in the wholesale and consumer lending markets;
- regulatory developments in the pharmaceutical industry;
- significant future sales of our common stock, and additions or departures of key personnel;
- the realization of any of the other risk factors presented in this prospectus; and
- general economic, market and currency factors and conditions unrelated to our performance.

In addition, the stock market in general has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to operating performance of individual companies. These broad market factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A class action suit against us could result in significant liabilities and, regardless of the outcome, could result in substantial costs and the diversion of our management's attention and resources.

We will incur significantly increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance efforts.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. For example, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the accounting and internal controls provisions of the Foreign Corrupt Practices Act of 1977, as amended, and will be required to comply with the applicable requirements of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), and the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the "Dodd-Frank Act"), as well as rules and regulations subsequently implemented by the SEC and Nasdaq, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel will need to devote a substantial amount of time and resources to complying with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. In particular, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act, which will increase when we are no longer an "emerging growth company," as defined by the JOBS Act. These new obligations will require substantial attention from our management team and could divert their attention away from the day-to-day management of our business. We will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and maintain an internal audit function. We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors and board committees or as executive officers, and more expensive for us to obtain director and officer liability insurance.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

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. (1)
3.2	By-laws of Anebulo Pharmaceuticals, Inc. (1)
3.3	Second Amended and Restated Certificate of Incorporation of Anebulo Pharmaceuticals, Inc. (2)
3.4	Amended and Restated By-laws of Anebulo Pharmaceuticals, Inc. (2)
4.1	Specimen Stock Certificate for Common Stock (1)
10.6†	Amendment No. 1 to Employment Agreement, dated January 22, 2021, between Daniel Schneeberger and Anebulo Pharmaceuticals, Inc. (1)
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
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.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

(1) Incorporated by reference to Registration Statement on Form S-1, filed with the U.S. Securities and Exchange Commission (the "SEC") on April 1, 2021.

(2) Incorporated by reference to Registration Statement on Form S-1/A, filed with the SEC on April 26, 2021.

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: June 21, 2021

By: */s/ Daniel Schneeberger*
Daniel Schneeberger, M.D.
Chief Executive Officer (*Principal Executive Officer*)

Date: June 21, 2021

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

Exhibit 31.1

CERTIFICATIONS

I, Daniel Schneeberger, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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. I am 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 my 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. I have disclosed, based on my 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: June 21, 2021

By: */s/ Daniel Schneeberger*

Daniel Schneeberger, M.D.
Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 31.2

CERTIFICATIONS

I, Rex Merchant, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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. I am 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 my 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. I have disclosed, based on my 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: June 21, 2021

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, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) The Report 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: June 21, 2021

By */s/ Daniel Schneeberger*
Daniel Schneeberger, M.D.
Chief Executive Officer
(*Principal Executive Officer*)

"This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and ExchangeCommission 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."

Exhibit 32.2

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, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) The Report 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: June 21, 2021

By */s/ Rex Merchant*
Rex Merchant
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."