UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended December 31, 2022

or

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

For the transition period from _____ to _____

Commission File No. 001-40388

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

Delaware **(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	The Nasdaq Stock Market LLC

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

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

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

Large accelerated filer	□	Accelerated filer	□
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. □

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

As of February 8, 2023, the registrant had 25,633,217 shares of common stock, par value $0.001 per share, outstanding.

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

RISK FACTORS SUMMARY

Below is a summary of material factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under "Risk Factors" in Part II, Item 1A of this Quarterly Report. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should carefully consider the risks and uncertainties described under "Risk Factors" in Part II, Item 1A of this Quarterly Report as part of your evaluation of an investment in our common stock.

- We have not generated any revenue since our inception and expect to incur future losses and may never become profitable.
- Our business is highly dependent on our lead product candidate, ANEB-001, and we must complete clinical testing before we can seek regulatory approval and begin commercialization of any of our product candidates.
- We depend substantially on intellectual property licensed from third parties, including Vernalis Development Limited, and termination of any of these licenses could result in the loss of significant rights, which would harm our business.
- We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product discovery and development programs or commercialization efforts.
- We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates or if the scope of the intellectual property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be adversely affected.
- We have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We are early in our development efforts and have only one product candidate in clinical development. If we are unable to successfully develop and commercialize our product candidate or experience significant delays in doing so, our business may be materially harmed.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and the inability to successfully and timely conduct clinical trials and obtain regulatory approval for our product candidates would substantially harm our business.
- The results of clinical trials are not necessarily predictive of future results. Our existing product candidate in clinical trials, and any other product candidate we advance into clinical trials, may not have favorable results in later clinical trials or receive regulatory approval.
- Any products we develop may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices or healthcare reform initiatives, thereby harming our business.

- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Our product candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval.
- We currently have no marketing and sales organization and we have no direct experience marketing pharmaceutical products. If we are unable to establish our own marketing and sales capabilities, or enter into agreements with third parties to market and sell our products after approval, we may not be able to generate product revenues.
- New drugs, which may be developed by others, could impair our ability to maintain and grow our business and remain competitive.
- We depend on third parties in connection with our preclinical testing and clinical trials, which may result in costs and delays that prevent us from obtaining regulatory approval or successfully commercializing ANEB-001 or future product candidates.
- 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.
- The trading price and volume of our common stock in the public markets has experienced, and may in the future experience, volatility due to a variety of factors, many of which are beyond our control.

PART I. FINANCIAL INFORMATION

Anebulo Pharmaceuticals, Inc.
Condensed Balance Sheets
(unaudited)

	December 31, 2022	June 30, 2022
Assets		
Current assets:		
Cash	$ 16,355,350	$ 14,548,471
Prepaid expenses	532,906	1,030,960
Total assets	$ 16,888,256	$ 15,579,431
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 346,554	$ 380,828
Accrued expenses	1,025,847	131,703
Total liabilities	1,372,401	512,531
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 2,000,000 shares authorized, no shares issued or outstanding at December 31, 2022 and June 30, 2022	-	-
Common stock, $0.001 par value; 40,000,000 shares authorized; 25,633,217 and 23,344,567 shares issued and outstanding at December 31, 2022 and June 30, 2022, respectively	25,634	23,345
Additional paid-in capital	67,398,711	60,513,258
Accumulated deficit	(51,908,490)	(45,469,703)
Total stockholders' equity	15,515,855	15,066,900
Total liabilities and stockholders' equity	$ 16,888,256	$ 15,579,431

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

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

	Three Months Ended December 31,		Six Months Ended December 31,	
	2022	**2021**	**2022**	**2021**
Research and development	$ 1,869,920	$ 212,936	$ 3,093,696	$ 928,034
General and administrative	1,943,202	858,186	3,331,473	1,698,012
Total operating expenses	3,813,122	1,071,122	6,425,169	2,626,046
Loss from operations	(3,813,122)	(1,071,122)	(6,425,169)	(2,626,046)
Other expenses, net	(13,830)	(1,869)	(13,618)	(340)
Net loss	$ (3,826,952)	$ (1,072,991)	$ (6,438,787)	$ (2,626,386)
Weighted average common shares outstanding, basic and diluted	25,633,217	23,344,567	24,524,856	23,344,567
Net loss per share, basic and diluted	$ (0.15)	$ (0.05)	$ (0.26)	$ (0.11)

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

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

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at June 30, 2021	23,344,567	$ 23,345	$ 60,032,597	$ (38,644,084)	$ 21,411,858
Stock-based compensation expense	-	-	34,173	-	34,173
Net loss	-	-	-	(1,553,395)	(1,553,395)
Balance at September 30, 2021	23,344,567	23,345	60,066,770	(40,197,479)	19,892,636
Stock-based compensation expense	-	-	94,282	-	94,282
Net loss	-	-	-	(1,072,991)	(1,072,991
Balance at December 31, 2021	23,344,567	$ 23,345	$ 60,161,052	$ (41,270,470)	$ 18,913,927
Balance at June 30, 2022	23,344,567	$ 23,345	$ 60,513,258	$ (45,469,703)	$ 15,066,900
Issuance of common stock, net of offering costs of $248,927	2,264,650	2,265	6,395,556	-	6,397,821
Common stock issued upon exercise of options	24,000	24	52,376	-	52,400
Stock-based compensation expense	-	-	211,900	-	211,900
Net loss	-	-	-	(2,611,835)	(2,611,835)
Balance at September 30, 2022	25,633,217	$ 25,634	$ 67,173,090	$ (48,081,538)	$ 19,117,186
Stock-based compensation expense	-	-	225,621	-	225,621
Net loss	-	-	-	(3,826,952)	(3,826,952)
Balance at December 31, 2022	25,633,217	$ 25,634	$ 67,398,711	$ (51,908,490)	$ 15,515,855

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

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

	Six Months Ended December 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (6,438,787)	(2,626,386)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	437,521	128,455
Changes in operating assets and liabilities:		
Prepaid expenses	498,054	712,965
Accounts payable	(34,274)	(67,104)
Accrued expenses	894,144	(124,585)
Net cash used in operating activities	(4,643,342)	(1,976,655)
Cash flows from financing activities:		
Proceeds from issuance of common stock	6,646,748	-
Payment of offering costs	(248,927)	-
Proceeds from issuance of common stock upon exercise of options	52,400	-
Net cash provided by financing activities	6,450,221	-
Net increase (decrease) in cash	1,806,879	(1,976,655)
Cash, beginning of period	14,548,471	19,985,645
Cash, end of the period	$ 16,355,350	18,008,990

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

Note 1. Nature of business and basis of presentation

Organization

Anebulo Pharmaceuticals, Inc. (the "Company") was founded on April 23, 2020, as a Delaware corporation. The Company is a clinical stage biotechnology company focused on developing and commercializing new treatments for patients suffering from Acute Cannabis Intoxication ("ACI") and addiction. The Company's principal operations are located in Lakeway, Texas.

Liquidity and capital resources

Since inception, the Company's activities have consisted primarily of performing research and development to advance its product candidates. The Company is still in the development phase and has not been marketing any developed products to date. Since inception, the Company has incurred losses, including a net loss of approximately $6.4 million for the six months ended December 31, 2022. As of December 31, 2022, the Company had an accumulated deficit of approximately $51.9 million. The Company expects to continue to generate operating losses. The Company expects that its cash will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance date of the financial statements. Until such time, if ever, as the Company can generate substantial product revenue from sales of any current or future product candidates, the Company expects to seek additional funding in order to reach its development and commercialization objectives through various potential sources, such as equity and debt financings or through collaboration, license and development agreements. The Company may not be able to obtain funding or enter into collaboration, license or development agreements on acceptable terms, or at all. The terms of any funding may be dilutive to or adversely affect the rights of the Company's stockholders. If the Company is unable to obtain funding on satisfactory terms, or at all, the Company could be forced to delay, scale back or eliminate the development of its current or future product candidates or other business.

Risks and uncertainties

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

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

Basis of presentation

The accompanying condensed financial statements and accompanying notes have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP").

The unaudited interim condensed financial statements of the Company included herein have been prepared, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been omitted from this report, as is permitted by such rules and regulations. Accordingly, these condensed financial statements should be read in conjunction with the financial statements as of and for the year ended June 30, 2022 and the notes thereto, which are included in the Company's Annual Report on Form 10-K (File No. 001-40388).

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

Note 2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited financial statements as of and for the year ended June 30, 2022, and notes thereto, which are included in the Company's Annual Report on Form 10-K that was filed with the SEC on September 9, 2022. Since the date of those financial statements, there have been no material changes to significant accounting policies.

Note 3. Prepaid Expenses

Prepaid expenses consisted of the following:

	December 31, 2022	June 30, 2022
Prepaid insurance	$ 313,332	$ 790,343
Prepaid research and development	219,574	210,865
Prepaid other	-	29,752
Total prepaid expenses	$ 532,906	$ 1,030,960

Note 4. Accrued Expenses

Accrued expenses consisted of the following:

	December 31, 2022	June 30, 2022
Accrued research and development	$ 699,990	$ 105,980
Accrued payroll related expenses	295,107	25,723
Accrued other	30,750	-
Total accrued expenses	$ 1,025,847	$ 131,703

Note 5. License Agreement

In May 2020, the Company licensed certain intellectual property, know-how and clinical trial data from Vernalis Development Limited ("Vernalis"). The initial consideration in exchange for the license was $150,000 and was recorded as research and development expense in a prior period. The license term shall continue unless and until terminated for cause or insolvency, with 60 days' prior notice by the Company, or until such time as all royalties and other sums cease to be payable in accordance with the terms of the agreement. The Company is required to pay development milestone payments related to clinical trials and granting of marketing authorization ranging from $350,000 to $3,000,000, up to a total development milestone payment of $29,900,000, and sales milestone payments of $10,000,000 and $25,000,000, in the first year when cumulative annual net sales of licensed product exceeds $500,000,000 and $1,000,000,000, respectively. The Company is also required to pay single-digit royalties on product sales over the term of the contract.

As part of the initial public offering ("IPO") in May 2021, the Company issued 192,857 shares of common stock to Vernalis in lieu of future milestone payments by the Company of $1,350,000, whether or not the Company achieves those milestones. The Company recorded the $1,350,000 payment as research and development expense in a prior period. The Company has determined that no further milestone payments are considered probable as of December 31, 2022 and therefore no liability has been recorded.

Note 6. Stockholders' Equity

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

On September 28, 2022, the Company completed a private placement financing of 2,264,650 units (collectively, the "Units"), with each Unit consisting of (i) one share of its common stock and (ii) a warrant to purchase one share of its common stock, for aggregate gross proceeds of approximately $6,647,000 (or $2.935 per Unit). The Company received approximately $6,398,000 in net proceeds after deducting offering costs of approximately $249,000. Each warrant has an exercise price of $4.215 per share, which is subject to customary adjustments in the event of any combination or split of the Company's common stock. The warrants expire on September 28, 2027.

Note 7. Stock-Based Compensation

In June 2020, the Board of Directors adopted the 2020 Stock Incentive Plan, which provided for the grant of qualified incentive stock options and nonqualified stock options or other awards to the Company's employees, officers, directors, advisors, and outside consultants for the purchase of up to 1,650,000 shares of the Company's common stock. On October 22, 2021, the Company's stockholders approved an increase of the total authorized shares to 3,650,000 shares. Other awards include restricted stock, restricted stock units, stock appreciation rights and other stock-based awards. Other stock-based awards are awards valued in whole or in part by reference to, or are otherwise based on, shares of common stock. Stock options generally vest over a four-year period, at achievement of a performance requirement, or upon change of control (as defined in the applicable plan). The awards expire in five to ten years from the date of grant. In September 2020, the Company awarded 982,500 shares of restricted common stock to its former Chief Executive Officer. As of December 31, 2022, the Company had 583,387 shares available for future issuance under the 2020 Stock Incentive Plan.

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

The following table summarizes the range of key assumptions used to determine the fair value of stock options granted during the three and six months ended December 30, 2022 and 2021.

	Three Months Ended December 31,		Six Months Ended December 31,	
	2022	2021	2022	2021
Risk-free interest rate	3.72% – 4.32%	–%	2.87% – 4.32%	0.79% – 1.1%
Expected term (in years)	4.5 – 6.25	–	4.5 – 6.25	3.0 – 4.5
Expected volatility	60.0%	–%	50.0 – 60.0%	50%
Expected dividend yield	–	–	–	–

The following table summarizes stock option activity for the six months ended December 31, 2022:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at June 30, 2022	1,911,459	$ 4.63	4.4	
Granted	172,654	$ 3.31		
Exercised	(24,000)	$ 2.18		
Forfeited	-	$ -		
Outstanding at December 31, 2022	2,060,113	$ 4.55	4.2	$ 137,362
Options exercisable at December 31, 2022	373,476	$ 2.86	3.2	75,625

The weighted-average grant date fair value of options awarded during the six months ended December 31, 2022 was approximately $1.86 per share. As of December 31, 2022, unrecognized stock-based compensation expense related to unvested stock options totaled approximately $2.9 million which is expected to be recognized over a weighted average period of 3.1 years.

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

	Three Months Ended December 31,		Six Months Ended December 31,	
	2022	2021	2022	2021
Research and development	$ -	$ 2,108	$ -	$ 11,988
General and administrative	225,621	92,174	437,521	116,467
Total stock-based compensation expense	$ 225,621	$ 94,282	$ 437,521	$ 128,455

Note 8. Net Loss Per Share Attributable to Common Stockholders

Based on the amounts outstanding at December 31, 2022 and 2021, the Company excluded the following potential shares of common stock from the computation of diluted net loss per share attributable to common stockholders for the three and six months ended December 31, 2022 and 2021, because including them would have had an anti-dilutive effect. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

	December 31,	
	2022	2021
Stock options outstanding	2,060,113	661,063
Warrants outstanding	2,264,650	-
Total	4,324,763	661,063

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes included in this Quarterly Report and the audited financial statements and notes thereto as of and for the year ended June 30, 2022 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended June 30, 2022 ("Annual Report"), which was filed with the SEC on September 9, 2022. The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item 1A, "Risk Factors" in this Quarterly Report. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biotechnology company developing novel solutions for people suffering from acute cannabinoid intoxication ("ACI") and substance addiction. Our lead product candidate, ANEB-001, is intended to rapidly reverse the negative effects of ACI within 1 hour of administration. The signs and symptoms of ACI range from profound sedation to anxiety and panic to psychosis with hallucinations. There is no approved medical treatment currently available to specifically alleviate the symptoms of ACI. If approved by the FDA, we believe ANEB-001 has the potential to be the first FDA approved treatment of its kind on the market for reversing the effects of THC, the principal psychoactive constituent of cannabis. Clinical trials completed to date have shown that ANEB-001 is rapidly absorbed, well tolerated and when administered to obese subjects leads to weight loss, an effect that is consistent with central CB1 antagonism. We initiated a Phase 2 proof-of-concept clinical trial in the Netherlands in December 2021. We received initial topline data from Part A of the study on June 29, 2022 and announced the results in a press release on July 5, 2022. We announced preliminary pharmacodynamic data from Part B of the study in a press release on January 9, 2023 and expect the final data from the study by the end of the first quarter of 2023. We anticipate discussing the final data from this Phase 2 clinical trial with the FDA at an End of Phase 2A meeting in the first half of 2023.

ACI episodes have become a widespread health issue in the United States, particularly in the increasing number of states that have legalized cannabis for medical and recreational use. The ingestion of large quantities of THC is a major cause of ACI. Excessive ingestion of THC via edible products such as candies and brownies, and intoxication from synthetic cannabinoids (also known as "synthetics," "K2" or "spice"), are two leading causes of THC-related emergency room visits. Synthetic cannabinoids are analogous to fentanyl for opioids insofar as they are more potent at the cannabinoid receptor than their natural product congener THC. In recent years, hospital emergency rooms across the United States have seen a dramatic increase in patient visits with cannabis-related conditions. Before the legalization of cannabis, an estimated 450,000 patients visited hospital emergency rooms annually for cannabis-related conditions. In 2014, this number more than doubled to an estimated 1.1 million patients, according to data published in "Trends and Related Factors of Cannabis-Associated Emergency Department Visits in the United States: 2006-2014," Journal of Addiction Medicine (May/June 2019), which provided a national estimate analyzing data from 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 over 1.7 million patients in 2019 and was growing at an approximately 15% compounded annual growth rate between 2012 and 2019. We believe the number of cannabis-related hospitalizations and other health problems associated with ACIs such as depression, anxiety and mental disorders will continue to increase substantially as more states pass laws legalizing cannabis for medical and recreational use. Given the consequences, there is an urgent need for a treatment to rapidly reverse the symptoms of ACI.

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

Our objective is to develop and commercialize new treatment options for patients suffering from ACI and substance addiction. Our lead product candidate is ANEB-001, a potent, small molecule cannabinoid receptor antagonist, to address the unmet medical need for a specific antidote for ACI. ANEB-001 is an orally bioavailable, rapidly absorbed treatment that we anticipate will reverse the symptoms of ACI, in most cases within 1 hour of administration. Our proprietary position in the treatment of ACI is protected by rights to patent applications covering various compositions and methods of use of the compound and delivery systems.

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

On October 12, 2021, the United States Patent and Trademark Office issued to the Company U.S. Patent No. 11,141,404, titled "Formulations and Methods For Treating Acute Cannabinoid Overdose." The issued patent describes the use of the Company's investigational drug ANEB-001 to treat acute cannabinoid overdose and is expected to provide patent protection through 2040.

On September 25, 2022, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional accredited investors (the "Purchasers"), pursuant to which we sold and issued to the Purchasers in a private placement financing an aggregate of 2,264,650 units (collectively, the "Units"), with each Unit consisting of (i) one share of our common stock and (ii) a warrant to purchase one share of our common stock, for an aggregate purchase price of approximately $6,647,000 (or $2.935 per Unit) (the "Private Placement"). The closing of the Private Placement occurred on September 28, 2022. The Company received approximately $6,398,000 in net proceeds from the Private Placement after deducting offering costs of approximately $249,000. Each warrant has an exercise price of $4.215 per share, which is subject to customary adjustments in the event of any combination or split of our common stock, and has a five-year term.

Components of Results of Operations

Revenue

We have not generated any revenue since inception. If our development efforts for our current lead product candidate, ANEB-001, or other additional product candidates that we may develop in the future, are successful and result in marketing approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates. We have incurred operating losses since inception and expect to continue to incur significant operating losses and negative cash flows from operations in the future.

Research and Development Expenses

We expect to continue incurring significant research and development costs related to ANEB-001. Our research and development expenses for the three and six months ended December 31, 2022 and 2021 included research and development consulting expenses, clinical trials, and costs associated with development of our lead product candidate, ANEB-001.

We anticipate that our research and development activities will account for a significant portion of our operating expenses and these costs are expensed as incurred. We expect to significantly increase our research and development efforts as we continue to develop ANEB-001 and conduct clinical trials with patients suffering from symptoms of ACI, as well as continue to expand our product-candidate pipeline. Research and development expenses include:

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

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

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

General and Administrative Expenses

General and administrative expenses for the three and six months ended December 31, 2022 and 2021 consisted primarily of professional fees, stock-based compensation, insurance, personnel costs and rent.

Results of Operations

Comparison of the Three and Six Months Ended December 31, 2022 and 2021

The following table summarizes our results of operations:

	Three Months Ended December 31,		Period to Period	Six Months Ended December 31,		Period to Period
	2022	2021	Change	2022	2021	Change
Research and development	$ 1,869,920	$ 212,936	$ 1,656,984	$ 3,093,696	$ 928,034	$ 2,165,662
General and administrative	1,943,202	858,186	1,085,016	3,331,473	1,698,012	1,633,461
Total operating expenses	3,813,122	1,071,122	2,742,000	6,425,169	2,626,046	3,799,123
Loss from operations	(3,813,122)	(1,071,122)	(2,742,000)	(6,425,169)	(2,626,046)	(3,799,123)
Other expenses, net	(13,830)	(1,869)	(11,961)	(13,618)	(340)	(13,278)
Net loss	$ (3,826,952)	$ (1,072,991)	$ (2,753,961)	$ (6,438,787)	$ (2,626,386)	$ (3,812,401)

Research and Development Expenses

Research and development expenses consisted of the following:

	Three Months Ended December 31,		Period to Period	Six Months Ended December 31,		Period to Period
	2022	2021	Change	2022	2021	Change
Pre-clinical and clinical studies	$ 759,979	$ 99,971	$ 660,008	$ 1,491,264	$ 391,084	$ 1,100,180
Contract manufacturing	653,066	66,500	586,566	839,233	317,450	521,783
Compensation and related benefits	-	21,530	(21,530)	44,681	43,060	1,621
Stock-based compensation expense	-	2,108	(2,108)	-	11,988	(11,988)
Other research and development	456,875	22,827	434,048	718,518	164,452	554,066
Total research and development expenses	$ 1,869,920	$ 212,936	$ 1,656,984	$ 3,093,696	$ 928,034	$ 2,165,662

The overall increase in research and development expenses was primarily attributable to an increase in activities related to pre-clinical and clinical studies, and direct third-party costs incurred under agreements with CROs for ANEB-001. The increase in pre-clinical and clinical studies was related to Phase 2 clinical studies for ANEB-001. During the fiscal year ended June 30, 2022, we began fully engaging with our CMOs to produce drug substance and drug product for our clinical trials, thus increasing our contract manufacturing expense.

General and Administrative Expenses

General and administrative expenses consisted of the following:

	Three Months Ended December 31,		Period to Period	Six Months Ended December 31,		Period to Period
	2022	2021	Change	2022	2021	Change
Compensation and related benefits	$ 602,341	$ 88,791	$ 513,550	$ 957,972	$ 179,312	$ 778,660
Professional and consultant fees	739,837	278,628	461,209	1,205,195	607,159	598,036
Stock-based compensation expense	225,621	92,174	133,447	437,521	116,467	321,054
Officers' insurance	235,000	334,695	(99,695)	476,877	662,513	(185,636)
Facilities, fees and other costs	140,403	63,898	76,505	253,908	132,561	121,347
Total general and administrative expenses	$ 1,943,202	$ 858,186	$ 1,085,016	$ 3,331,473	$ 1,698,012	$ 1,633,461

The overall increase in general and administrative expenses was primarily attributable to compensation and related benefits and stock-based compensation for additional executives and employees, professional and consultant fees, including legal and accounting fees, and facilities and other costs to support our continuous growth in operations. This was partially offset by a decrease in directors' and officers' insurance resulting from a decrease in the yearly premium amount.

Liquidity and Capital Resources

Overview

Since our inception in April 2020, we have incurred significant operating losses. We expect to incur significant expenses and operating losses in the future as we advance the clinical development of our programs. In May 2021, we completed our IPO in which we sold 3,078,224 shares of our common stock, including the exercise by the underwriter of its option to purchase 78,224 additional shares of common stock, at a public offering price of $7.00 per share. We received net proceeds from our IPO of approximately $19.8 million, after deducting underwriter discounts and offering expenses paid by us. On September 28, 2022, we closed the Private Placement, pursuant to which we sold an aggregate of 2,264,650 Units, with each Unit consisting of (i) one share of our common stock and (ii) a warrant to purchase one share of our common stock, for an aggregate purchase price of approximately $6.6 million (or $2.935 per Unit). The Company received approximately $6.4 million in net proceeds from the Private Placement after deducting offering costs of approximately $249,000. As of December 31, 2022, we had cash of approximately $16.4 million. As and if necessary, we will seek to raise additional funds through various potential sources, such as equity and debt financings or through collaboration, license and development agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations on acceptable terms or at all, or, if such funds are available to us, that such additional financing will be sufficient to meet our needs.

Cash Flows

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

	Six Months Ended December 31,	
	2022	**2021**
Net cash used in operating activities	$ (4,643,342)	$ (1,976,655)
Net cash provided by financing activities	6,450,221	-
Net increase (decrease) in cash	$ 1,806,879	$ (1,976,655)

During the six months ended December 31, 2022, we used cash in operating activities of approximately $4.6 million primarily resulting from our net loss of approximately $6.4 million partially offset by the non-cash related stock-based compensation of approximately $438,000, and a change in operating assets and liabilities of approximately $1.3 million. We received cash from financing activities of approximately $6.5 million primarily resulting from the issuance of common stock and warrants of approximately $6.6 million, net of offering costs of approximately $249,000. During the six months ended December 31, 2021, we used cash in operating activities of approximately $2.0 million, primarily resulting from our net loss of approximately $2.6 million, partially offset by the non-cash related stock-based compensation of approximately $128,000, and a change in operating assets and liabilities of approximately $521,000.

Funding and Material Cash Requirements

We expect that our cash at December 31, 2022 will enable us to fund our current and planned operating expenses and capital expenditures for at least the next 12 months from the filing of this report. We have based these estimates on assumptions that may prove to be imprecise, and we may exhaust our available capital resources sooner that we currently expect. Because of the numerous risks and uncertainties associated with the development of our programs, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates.

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

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

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

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

Contractual Obligations and Commitments

License Agreement with Vernalis Development Limited

On May 26, 2020, we entered into the License Agreement with Vernalis. Pursuant to the License Agreement, Vernalis granted us an exclusive worldwide royalty-bearing license to develop and commercialize a compound that we refer to as ANEB-001, as well as access to and a right of reference with respect to any regulatory materials under its control. The License Agreement allows us to sublicense the rights thereunder to any person with similar or greater financial resources and expertise without Vernalis' prior consent, provided the proposed sublicensee is not developing or commercializing a product that contains a CB1 antagonist or is for the same indication covered by the trials or market authorization for ANEB-001. In exchange for the exclusive license, we agreed to pay Vernalis a non-refundable signature fee of $150,000, total potential developmental milestone payments of up to $29,900,000, total potential sales milestone payments of up to $35,000,000, and low to mid-single digit royalties on net sales. Subsequently, in May 2021 as part of the IPO, we issued 192,857 shares of common stock to Vernalis in lieu of future milestone payments of $1,350,000.

Under the License Agreement, we purchased the API for ANEB-001 from Vernalis on an "as is" basis for $20,000. We have the sole discretion to carry out the development and commercialization of ANEB-001, including obtaining regulatory approvals, and we are responsible for all costs and expenses in connection therewith. We have access to certain regulatory materials, including study reports from clinical and non-clinical trials, under Vernalis' control. We agreed to use commercially reasonable efforts to (i) develop and commercialize ANEB-001 in the United States and certain European countries and (ii) conduct a Phase 2 and human clinical trial within specified periods, which periods could be extended for a nominal fee. We also agreed to provide Vernalis with periodic reports of our activities and notice of market authorization within specified timeframes.

Office Lease, Manufacturing Contract and CRO Contract

We manage our business operations from our principal executive office in Lakeway, Texas, in 700 square feet of leased space under a sublease with a related party. Our office lease is month-to-month, and currently we pay rent of approximately $1,300 per month.

In March 2022, we entered into a manufacturing agreement with a third-party CMO. The total cost for the manufacturing contract is approximately $1,923,000, which is expected to be fully incurred by the end of the first calendar quarter of 2023.

In February 2021, we entered into an agreement with a third-party CRO to manage and conduct our Phase 2 clinical trial for ANEB-001 in the Netherlands, which was initiated in December 2021. We received initial topline data from Part A of the study on June 29, 2022 and announced the results in a press release on July 5, 2022. The total cost for the CRO agreement is approximately €2,235,148, which is expected to be fully incurred by the end of the first calendar quarter of 2023.

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

Critical Accounting Policies and Significant Judgments and Estimates

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

While our significant accounting policies are disclosed in the audited financial statements as of and for the year ended June 30, 2022, and notes thereto, which are included in the Company's Annual Report on Form 10-K that was filed with the SEC on September 9, 2022, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our condensed financial statements.

Accrued Research and Development Expenses

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

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

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

Stock-Based Compensation Expense

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

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

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

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

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

JOBS Act Accounting Election

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of December 31, 2022, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2022, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

You should carefully consider the following risk factors, as well as the other information in this Quarterly Report, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report and those we may make from time to time. When evaluating our business, you should consider all of the factors described as well as the other information in our Annual Report, including our financial statements and the related notes, "Management's Discussion and Analysis of Financial Condition and Results of Operation" and Item 1A, "Risk Factors." We have marked with an asterisk (*) those risk factors that did not appear as risk factors in, or contain changes to the similarly titled risk factors included in, Item 1A of our Annual Report. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

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 December 31, 2022, we had an accumulated deficit of approximately $51.9 million, which includes a fair value adjustment for Milestone Warrants of approximately $26.6 million. The likelihood of our future success must be considered in light of the expenses, difficulties, complications and delays often encountered in connection with the clinical trials that will be conducted and on the development of new solutions to common addictions. These potential challenges include unanticipated clinical trial delays, poor data, changes in the regulatory and competitive landscape and additional costs and expenses that may exceed current budget estimates. In order to complete certain clinical trials and otherwise operate pursuant to our current business strategy, we anticipate that we will incur increased operating expenses. In addition, we expect to incur significant losses and experience negative cash flow in the future as we fund the operating losses and capital expenditures. We recognize that if we are unable to generate sufficient revenues or source funding, we will not be able to continue operations as currently contemplated, complete planned clinical trials and/or achieve profitability. Our failure to achieve or maintain profitability will also negatively impact the value of our shares. If we are unsuccessful in addressing these risks, then we may need to curtail our business activities.

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

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

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

We currently 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 an exclusive license agreement (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 in the future, which may be unavailable to us or may cause dilution or place significant restrictions on our ability to operate.*

We may be unable to generate sufficient revenue or cash flow to fund our operations. We expect that our cash at December 31, 2022, will enable us to fund our current and planned operating expenses and capital expenditures into the second quarter of calendar year 2024. We have based these estimates on assumptions that may prove to be incorrect, and we may exhaust our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of our programs, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidate. Until such time, if ever, as we can generate substantial product revenue from sales of any of our current or future product candidates, we will need to seek additional equity or debt financing or potential collaboration, license or development agreements to provide the capital required to maintain or expand our operations, continue the development of our product candidate, build our sales and marketing capabilities, promote brand identity, develop or acquire complementary technologies, products or businesses, or provide for our working capital requirements and other operating and general corporate purposes.

We currently do not have any arrangements or credit facilities as a source of funds, and we make no assurance that we will be able to raise sufficient additional capital in the future if needed on acceptable terms, or at all. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of our current or future product candidates and other business. This may materially adversely affect our operations and financial condition as well as our ability to achieve business objectives and maintain competitiveness.

If we raise additional capital by issuing equity securities and/or equity-linked securities, the percentage ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. 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 revenue streams or to grant licenses on terms that are not favorable to us.

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

We have limited operating history as a publicly-traded company, and our inexperience could materially and adversely affect us and our stockholders.

We became a public company in May 2021 and, therefore, we have limited operating history as a publicly traded company. Our board of directors and management team have overall responsibility for our management. As a publicly-traded company, we are 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.

Our current and future operations substantially depend on our Founder and Chief Executive Officer and our ability to hire other key personnel, the loss of any of whom could disrupt our business operations.

Our business depends and will continue to depend in substantial part on the continued service of Joseph F. Lawler, M.D., Ph.D., our founder and a director, and Simon Allen, our Chief Executive Officer and a director. The loss of the services of Dr. Lawler or Mr. Allen would significantly impede implementation and execution of our business strategy and may result in the failure to reach our goals. Further, the loss of either Dr. Lawler or Mr. Allen would be negatively perceived in the capital markets. We do not have "key-man" life insurance for our benefit on the lives of either Dr. Lawler or Mr. Allen.

Our future viability and ability to achieve sales and profits will also depend on our ability to attract, train, retain and motivate highly qualified personnel in the diverse areas required for continuing operations. There is a risk that we will be unable to attract, train, retain or motivate qualified personnel, both near term or in the future, and the failure to do so may severely damage our prospects.

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. On October 12, 2021, the United States Patent and Trademark Office issued to us U.S. Patent No. 11,141,404, titled "Formulations and Methods for Treating Acute Cannabinoid Overdose." The issued patent describes the use of our investigational drug ANEB-001 to treat ACI, and is expected to provide patent protection through at least 2040. We seek to protect our proprietary position by filing additional patent applications in the United States and abroad related to aspects of our product candidate that are important to our business and maintaining and protecting our existing patent filings. 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 additional 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 additional issued or granted patents with respect to our product candidates, we cannot be certain that such patents or any of our existing patents will not later be found to be invalid and/or unenforceable.

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 current and future 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 worldwide 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, our patents may be subject to post-grant challenge proceedings in the United States, such as post-grant or inter partes review at the USPTO or oppositions proceedings 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 post-grant or opposition 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 current and future 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 and marketing 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 (the "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 third parties 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 may not be 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 foreign patent offices 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.

Changes in European patent practice could also increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. No earlier than June 1, 2023, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court, or UPC. This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any patent litigation or revocation proceeding in Europe.

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. We obtained one patent in October 2021, which is expected to provide patent protection through 2040. Even if we are successful in obtaining further patents, 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 CROs 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.

We are relying on clinical trials performed by our licensor Vernalis, a third party, for a different indication, and the FDA or a foreign equivalent regulator may disagree with our ability to reference clinical data from third-party trials.*

As part of the preclinical characterization of ANEB-001, Vernalis demonstrated that oral administration of ANEB-001 reduced hypolocomotion in mice after 30 minutes, effectively reversing the actions of THC. In 2006 and 2007, two Phase 1 studies for the treatment of obesity were conducted by Vernalis for ANEB-001. The Vernalis clinical trials were not conducted or overseen by us. Nonetheless, we are relying on these studies performed by a third party for a different indication. The FDA or a foreign equivalent regulator may disagree with our ability to reference the clinical data generated by the third-party trials. Should this occur, we are likely to experience delays in our ability to receive regulatory approval and commercialize our product candidate.

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 ACI. 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 an NDA, or its 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 IND for our drug candidate or the FDA may require additional toxicology studies;
- the FDA or comparable foreign regulatory authorities or 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 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 our ongoing and future clinical trials 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 no experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third party CROs, 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.

Interim, topline and preliminary data from our preclinical studies or clinical trials may change as more data become available, and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our preclinical studies or clinical trials, which may be subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, topline and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary, interim or topline data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the approvability or commercialization of the particular drug candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine to be material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug candidate or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our drug candidates, our business, operating results, prospects or financial condition may be harmed.

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 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 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. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change.

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.

Any products we develop may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices or healthcare reform initiatives, thereby harming our business.

In the United States, commercial sales of any products subject to regulatory approval could be conditioned on whether third-party payors (such as government authorities, managed care providers, private health insurers and other organizations) are able to provide coverage and reimbursement in connection with the products.

Coverage and reimbursement of costs are areas of significant uncertainty for any products subject to regulatory approval. The process for determining coverage versus reimbursement may vary widely among third-party payors. Third-party payors may also impose additional requirements on and restrictions to coverage and reimbursement, which could influence the purchase of certain healthcare services and products.

Third-party payors may limit coverage to specific drugs on an approved list, or formulary, which could omit some FDA-approved drugs for a particular indication. Third-party payors may also place drugs at certain formulary levels that result in a lower reimbursement and higher cost-sharing obligation for patients. A third-party payor's decision to provide coverage for a product may not necessarily imply approval of an adequate reimbursement rate. In addition, the unavailability of third-party reimbursement may affect our ability to maintain price levels sufficient to realize an appropriate return on our investment in product development. Coverage by one third-party payor may not necessarily indicate or imply coverage or reimbursement by other third-party payors. Also, the level or scope of coverage and reimbursement may vary significantly among third-party payors. Further, commercial third-party payors often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement rates. In addition to scrutinizing the safety and efficacy of medical products and services, third-party payors have increasingly begun to examine and challenge the price, cost-effectiveness and necessity of certain products and services. Thus, to obtain and maintain coverage and reimbursement for any products approved for sale, the conducting of expensive pharmacoeconomic studies may be required to demonstrate the medical necessity and cost-effectiveness of such products. There is a chance that third-party payors may not consider our product medically necessary or cost-effective. If third-party payors make such a determination, they may not cover the product after approval as a benefit under their plans. If third-party payors do cover the product, the returns from sales of our product may not sufficiently yield a profit. Our inability to promptly obtain coverage, and adequate reimbursement for new therapeutics we develop and for which we obtain regulatory approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our financial condition.

Furthermore, federal and state governmental authorities have increasingly shown an interest in implementing cost containment programs to limit government-paid healthcare costs. Such cost containment programs include restrictions on coverage and reimbursement, price controls and requirements to substitute branded prescription drugs with generic products. The adoption and expansion of such restrictive policies and controls could impose limitations or exclusions from coverage for our product.

In the United States, we expect third-party payors and government authorities to increase emphasis on managed care and cost containment measures, which will impact the pricing and coverage for pharmaceutical products. Coverage policies and third-party reimbursement rates may change at any time. Even if we achieve favorable coverage and reimbursement status for an approved product, less favorable coverage policies and reimbursement rates could still be implemented in the future.

Current legislation may increase the difficulty and cost for us to commercialize ANEB-001 and affect the prices we may obtain and our current and future relationships with healthcare professionals, clinical investigators, consultants, patient organizations, customers, CROs and third-party payors.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which the Company obtains marketing approval. The Company's current and future arrangements with healthcare professionals, including HCPs, clinical investigators, CROs, third-party payors and customers may expose it to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which the Company markets, sells and distributes its products for which it obtains marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. Moreover, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA") provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal civil and criminal false claims, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws that require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, state laws that require biotechnology companies to report information on the pricing of certain drug products, state and local laws that require the registration of pharmaceutical sales representatives;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the Centers for Medicare & Medicaid Services ("CMS") information regarding payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, on "covered entities," including certain healthcare providers, health plans, healthcare clearinghouses, and their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as analogous state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;

- analogous state laws and regulations, such as, state anti-kickback and false claims laws potentially applicable to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of personal data (including personal health information) in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and state transparency laws that require the reporting of certain pricing information; among other state laws.

Efforts to ensure that the Company's current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. If the Company's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of the Company's operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if the Company is successful in defending against any such actions that may be brought against it, its business may be impaired.

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.

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 CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs 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 CROs 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 IRBs 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.

We may be exposed to product liability risks, and clinical and preclinical liability risks, which could place a substantial financial burden upon us should we be sued.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. We cannot be sure that claims will not be asserted against us. We cannot give assurances that we will be able to continue to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or that such insurance will provide adequate coverage against potential liabilities. A successful liability claim or series of claims brought against us, and any claims or losses in excess of any product liability insurance coverage that we may obtain, could have a material adverse effect on our business, financial condition and results of operations.

ANEB-001, our lead product candidate, may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require it to be taken off the market, require it to include safety warnings or otherwise limit sales of the product.

Unforeseen side effects from ANEB-001 could arise either during clinical development or, if approved, after the product has been marketed. This could cause regulatory approvals for, or market acceptance of, the product to be harder and more costly to obtain.

To date, no serious adverse events have been attributed to ANEB-001. However, development of ANEB-001 for weight loss was discontinued by Vernalis after a different CB1 antagonist showed significant side effects after prolonged administration (months or more). While we current expect ANEB-001 to be limited to a single dose to treat ACI, there may be unforeseen side effects from ANEB-001 for the treatment of ACI or other indications we may explore. The results of our current or future clinical trials may show that our product candidate causes undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities with restrictive label warnings. If our product candidate receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by the use of our product:

- regulatory authorities may withdraw their approval of the product, which would force us to remove the product from the market;

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication, or field alerts to physicians, pharmacies and others;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our potential future collaborators from achieving or maintaining market acceptance of the product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our product.

We currently have no marketing and sales organization and we have no direct experience marketing pharmaceutical products. If we are unable to establish our own marketing and sales capabilities, or enter into agreements with third parties to market and sell our products after approval, we may not be able to generate product revenues.

We do not have a sales organization for the marketing, sales and distribution of any pharmaceutical products. In order to commercialize ANEB-001, we must develop these capabilities on our own or make arrangements with third parties for the marketing, sales and distribution of our products, if approved. The establishment and development of a direct sales force will be expensive and time-consuming and could delay our product launch, and we cannot be certain that we would be able to successfully develop this capability. As a result, we may seek one or more partners to handle some or all of the sales, marketing and distribution of our products once approved. There also may be certain markets within the United States and elsewhere for our product candidates that receive approval for which we may seek a co-promotion arrangement. However, we may not be able to enter into arrangements with third parties to sell any of our products that may be approved on favorable terms, or at all. In the event, we are unable to develop our own marketing and sales force or collaborate with a third-party marketing and sales organization, we will not be able to commercialize our current or future product candidates following approval, which will negatively impact our ability to generate product revenues. Furthermore, whether we commercialize our product candidates following approval on our own or rely on a third party, our ability to generate revenue would be dependent on the effectiveness of the sales force. In addition, to the extent we rely on third parties to commercialize any product candidate that may be approved in the future, we would likely receive less revenues than if we commercialized such product candidates ourselves.

New drugs, which may be developed by others, could impair our ability to maintain and grow our business and remain competitive.

The pharmaceutical industry is subject to rapid and substantial technological change. Developments by others may render our technologies and product candidates non-competitive or obsolete. For example, Aelis Farma, which is developing a medication based on a pregnanolone derivative to treat cannabis use disorders, and Opiant Pharmaceuticals, Inc., which is developing a drinabant injection to treat acute cannabis overdose, could obtain regulatory approval before we are able to obtain regulatory approval for ANEB-001, which could materially harm our business prospects. We also may be unable to keep pace with technological developments and other market factors. Technological competition from medical device, pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us.

Risks Related to our Reliance on Third Parties

We depend on third parties in connection with our preclinical testing and clinical trials, which may result in costs and delays that prevent us from obtaining regulatory approval or successfully commercializing ANEB-001 or future product candidates.

We engage third parties to perform various aspects of our preclinical testing and clinical trials. We have entered into agreements with third parties, including Traxeus, Aptuit (Verona) SRL, Sterling Pharma Solutions, and Centre for Human Drug Research, which provide certain pharmaceutical research and development services to us. We depend on these third parties to perform these activities on a timely basis in accordance with the protocol, good laboratory practices, good clinical practices and other regulatory requirements. Our reliance on these third parties for preclinical and clinical development activities reduces our control over these activities. Accordingly, if these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, our preclinical testing and clinical trials may be extended, delayed, terminated or our data may be rejected by the FDA. If there are delays in testing or obtaining regulatory approvals as a result of a third party's failure to perform, our drug discovery and development costs will likely increase, and we may not be able to obtain regulatory approval for or successfully commercialize our current or future product candidates.

Third parties' abilities to adequately and timely manufacture and supply our current or future product candidates is dependent on the operation of their facilities which may be impacted by, among other things:

- availability, performance or contamination of raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier;
- capacity of their facilities;
- the performance of information technology systems;
- compliance with regulatory requirements;
- inclement weather and natural disasters;
- changes in forecasts of future demand for product components;
- timing and actual number of production runs for product components;
- potential facility contamination by microorganisms or viruses;
- updating of manufacturing specifications; and
- product quality success rates and yields.

If the efficient manufacture and supply of our current or future product candidates is interrupted, we may experience delayed shipments or supply constraints, which may materially impact our ongoing and future preclinical testing and clinical trials.

Any contract manufacturer must undergo a potentially lengthy FDA approval process, as well as other regulatory approval processes, and are subject to continued review by the FDA and other regulatory authorities. If we or our third-party service providers cease or interrupt production or if our third-party service providers fail to supply materials, products or services to us, we may experience delayed shipments, and supply constraints for our current or future product candidates.

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 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 the 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.

Our reliance on collaborations with third parties to develop and commercialize ANEB-001 is subject to inherent risks and may result in delays in product development and lost or reduced revenues, restricting our ability to commercialize ANEB-001 and adversely affecting our profitability.

Our ability to develop, obtain regulatory approval of, manufacture and commercialize ANEB-001 depends upon our ability to maintain existing, and enter into and maintain new, contractual and collaborative arrangements with others. We also engage, and intend in the future to continue to engage, contract manufacturers and clinical trial investigators.

In addition, although not a primary component of our current strategy, the identification of new compounds or product candidates for development may require us to enter into license or other collaborative agreements with others, including other pharmaceutical companies and research institutions. Such collaborative agreements for the acquisition of new compounds or product candidates would typically require us to pay license fees, make milestone payments and/or pay royalties. Furthermore, these agreements may result in our revenues being lower than if we developed such product candidates and in our loss of control over the development of such product candidates.

Contractors or collaborators may have the right to terminate their agreements with us or reduce their payments to us under those agreements on limited or no notice and for no reason or reasons outside of our control. For example, we may be unable to maintain our relationship with Vernalis on a commercially reasonable basis, if at all. If we are unable to retain Vernalis as a licensor on commercially acceptable terms, we may not be able to commercialize ANEB-001 and we may experience delays in or suspension of the marketing of ANEB-001. The same could apply to other product candidates we may develop or acquire in the future. Our dependence upon third parties to assist with the development and commercialization of our product candidates may adversely affect our ability to generate profits or acceptable profit margins and our ability to develop and deliver such product candidates on a timely and competitive basis.

If our current or future licensees exercise termination rights they may have, or if these license agreements terminate because of delays in obtaining regulatory approvals, or for other reasons, and we are not able to establish replacement or additional research and development collaborations or licensing arrangements, we may not be able to develop and/or commercialize our product candidates. Moreover, any future collaborations or license arrangements we may enter into may not be on terms favorable to us.

A further risk we face with the collaborations is that business combinations and changes in the collaborator or their business strategy may adversely affect their willingness or ability to complete their obligations to us. Our current or any future collaborations or license arrangements ultimately may not be successful. Our agreements with collaborators typically allow them discretion in electing whether to pursue various development, regulatory, commercialization and other activities. If any collaborator were to breach its agreement with us or otherwise fail to conduct collaborative activities in a timely or successful manner, the preclinical or clinical development or commercialization of the affected product candidate or research program would be delayed or terminated.

Other risks associated with our collaborative and contractual arrangements with others include the following:

- we may not have day-to-day control over the activities of our contractors or collaborators;
- our collaborators may fail to maintain, defend or enforce patents they own on compounds or technologies that are incorporated into the product candidates we develop with them;
- third parties may not fulfill their regulatory or other obligations; and
- we may not realize the contemplated or expected benefits from collaborative or other arrangements; and disagreements may arise regarding a breach of the arrangement, the interpretation of the agreement, ownership of proprietary rights, clinical results or regulatory approvals.

These factors could lead to delays in the development and/or commercialization of our current or future product candidates, or could result in us not being able to commercialize our product candidates, if approved. Further, disagreements with our contractors or collaborators could require or result in litigation or arbitration, which would be time-consuming and expensive. Our ultimate success may depend upon the success and performance on the part of these third parties. If we fail to maintain these relationships or establish new relationships as required, development and/or commercialization of our product candidates will be delayed or may never be realized.

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. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidate, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

On March 23, 2010, President Obama signed into law the ACA, which includes a number of healthcare reform provisions and requires most U.S. citizens to have health insurance. The ACA was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. 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. The ACA also revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the law imposed a significant annual fee on companies that manufacture or import branded prescription drug products.

There have been judicial, congressional, and executive branch efforts to repeal, modify or delay the implementation of the law. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creates a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA. We are continuing to monitor any changes to the ACA that, in turn, may potentially impact our business in the future.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the IRA, among other things, (1) directs the U.S. Department of Health and Human Services ("HHS") to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce or eliminate our profitability. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for the Company's product candidates, if approved, and accordingly, the financial operations.

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.

Our ongoing clinical trial for ANEB-001 is being conducted in the Netherlands and we may conduct future clinical trials outside of the United States. 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. If the FDA does not accept such foreign clinical data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our drug candidate not receiving marketing approval.

Risks Related to Ownership of Our Common Stock

The trading price and volume of our common stock in the public markets has experienced, and may in the future experience, volatility due to a variety of factors, many of which are beyond our control.*

The trading price and volume of our common stock on The Nasdaq Capital Market has experienced, and may in the future experience, volatility. 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 Annual Report; 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.

Future sales, or the perception of future sales, of a substantial number of our shares of common stock could depress the trading price of our common stock.

If we or our stockholders, particularly our officers, directors and large stockholders, sell a significant percentage of our outstanding common stock in the public market or if the market perceives that these sales could occur, the market price of shares of our common stock could decline. These sales may make it more difficult for us to sell equity or equity-linked securities in the future at a time and price that we deem appropriate, or to use equity as consideration for future acquisitions.

Our principal stockholders and management own a substantial majority of our stock and will be able to exert significant control over matters subject to stockholder approval.*

Certain of our executive officers, directors and large stockholders own a substantial majority of our outstanding capital stock. As a result of their share ownership, these stockholders have the ability to influence us through their ownership positions. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, can control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

Anti-takeover provisions in our charter documents could discourage, delay or prevent a change in control of our company and may affect the trading price of our common stock.*

Our corporate documents and Delaware corporate law contain provisions that may enable our board of directors to resist a change in control of our company even if a change in control were to be considered favorable by you and other stockholders. These provisions:

- authorize the issuance of "blank check" preferred stock that could be issued by our board of directors to help defend against a takeover attempt;
- provide that vacancies on our board of directors, including vacancies as a result of removal or enlargement of the board of directors, may be filled by directors then in office, even though less than a quorum;
- establish that our board of directors is divided into three classes, with each class serving three-year staggered terms;
- specify that special meetings of our stockholders can be called only by our board of directors, chief executive officer or the chairman of our board of directors;

- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;

- include a forum selection clause, which means certain litigation can only be brought in Delaware; and

- require supermajority stockholder voting to effect certain amendments to our certificate of incorporation and bylaws.

In addition, Delaware corporate law prohibits large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or consolidating with us except under certain circumstances. These provisions and other provisions under Delaware corporate law could discourage, delay or prevent a transaction involving a change in control of our company. These provisions could also discourage proxy contests and make it more difficult for our stockholders to elect directors of their choosing and cause us to take other corporate actions our stockholders desire.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, and federal district courts will be the sole and exclusive forum for Securities Act claims, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by our directors, officers or other employees to us or to our stockholders, (iii) any action asserting a claim against us or any director, officer or other employee arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court having personal jurisdiction over the indispensable parties named as defendants; provided that these provisions of our certificate of incorporation will not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction.

Our certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, unless we consent in writing to the selection of an alternative forum. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. The choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our current or former directors, officers, or other employees or stockholders, which may discourage such lawsuits against us and our current or former directors, officers, and other employees or stockholders. Alternatively, if a court were to find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition and results of operations.

We do not expect to pay any dividends on our common stock.

We currently expect to retain all future earnings, if any, for future operation, expansion and debt repayment and have no current plans to pay any cash dividends to holders of our common stock. Any decision to declare and pay dividends in the future will be made at the discretion of our board of directors and will depend on, among other things, our operating results, financial condition, cash requirements, contractual restrictions and other factors that our board of directors may deem relevant. In addition, we must comply with the covenants in our credit agreements to be able to pay cash dividends, and our ability to pay dividends generally may be further limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur. As a result, you may not receive any return on an investment in our common stock unless you sell our common stock for a price greater than that which you paid for it.

General Risk Factors

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal control over financial reporting in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. In connection with our IPO, we began the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), which will require annual management assessment of the effectiveness of our internal control over financial reporting. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and could have a material and adverse effect on our business, results of operations and financial condition.

We are incurring significantly increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance efforts.

As a public company, we are incurring significant legal, accounting and other expenses that we did not incur as a private company. For example, we are subject to the reporting requirements of 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, 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 are increasing 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 being 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.

Changes in accounting principles or guidance, or in their interpretations, could result in unfavorable accounting charges or effects, including changes to our previously filed financial statements, which could cause our stock price to decline.

We prepare our financial statements in accordance with accounting principles generally accepted in the United States of America. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting principles and guidance. A change in these principles or guidance, or in their interpretations, may have a significant negative effect on our reported results and retroactively affect previously reported results, which, in turn, could cause our stock price to decline.

We are an "emerging growth company" and our election to delay adoption of new or revised accounting standards applicable to public companies may result in our financial statements not being comparable to those of some other public companies. As a result of this and other reduced disclosure requirements applicable to emerging growth companies, our securities may be less attractive to investors.

As a company with less than $1.07 billion in annual revenue, we qualify as an "emerging growth company" under the JOBS Act. An emerging growth company may take advantage of specified reduced reporting requirements that are otherwise generally applicable to public companies. In particular, as an emerging growth company we:

- are not required to obtain an attestation and report from our auditors on our management's assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- are not required to provide a detailed narrative disclosure discussing our compensation principles, objectives and elements and analyzing how those elements fit with our principles and objectives (commonly referred to as "compensation discussion and analysis");
- are not required to obtain a non-binding advisory vote from our stockholders on executive compensation or golden parachute arrangements (commonly referred to as the "say-on-pay," "say-on-frequency" and "say-on-golden-parachute" votes);
- are exempt from certain executive compensation disclosure provisions requiring a pay-for-performance graph and CEO pay ratio disclosure;
- may present only two years of audited financial statements and only two years of related Management's Discussion & Analysis of Financial Condition and Results of Operations ("MD&A"); and
- are eligible to claim longer phase-in periods for the adoption of new or revised financial accounting standards under Section 107 of the JOBS Act.

We have and intend to continue to take advantage of all of these reduced reporting requirements and exemptions, including the longer phase-in periods for the adoption of new or revised financial accounting standards under Section 107 of the JOBS Act. Our election to use the phase-in periods may make it difficult to compare our financial statements to those of non-emerging growth companies and other emerging growth companies that have opted out of the phase-in periods under Section 107 of the JOBS Act.

Certain of these reduced reporting requirements and exemptions were already available to us due to the fact that we also qualify as a "smaller reporting company" under SEC rules. For instance, smaller reporting companies are not required to obtain an auditor attestation and report regarding management's assessment of internal control over financial reporting, are not required to provide a compensation discussion and analysis, are not required to provide a pay-for-performance graph or CEO pay ratio disclosure, and may present only two years of audited financial statements and related MD&A disclosure.

Under the JOBS Act, we may take advantage of the above-described reduced reporting requirements and exemptions for up to five years after our initial sale of common equity pursuant to a registration statement declared effective under the Securities Act, or such earlier time that we no longer meet the definition of an emerging growth company. In this regard, the JOBS Act provides that we would cease to be an "emerging growth company" if we have more than $1.07 billion in annual revenue, have more than $700 million in market value of our common stock held by non-affiliates, or issue more than $1 billion in principal amount of non-convertible debt over a three-year period. Under current SEC rules, however, we will continue to qualify as a "smaller reporting company" for so long as we have a public float (i.e., the market value of common equity held by non-affiliates) of less than $250 million as of the last business day of our most recently completed second fiscal quarter, or have annual revenue is less than $100.0 million during the most recently completed fiscal year and have a public float of less than $700 million as of the last business day of our most recently completed second fiscal quarter.

We cannot predict if investors will find our securities less attractive due to our reliance on these exemptions. If investors were to find our securities less attractive as a result of our election, we may have difficulty raising all of the proceeds we seek in this offering.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.*

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation enacted in 2017 informally titled the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act and the Inflation Reduction Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Our ability to use net operating loss carryforwards and certain other tax attributes to offset future taxable income or taxes may be limited.*

Under current law, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change in its equity ownership value over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We may have experienced an ownership change in the past and we may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they change their recommendations regarding our stock adversely, or if our actual results differ significantly from our guidance, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. If any of the analysts who may cover us change their recommendation regarding our stock adversely, or provide more favorable relative recommendations about our competitors, our stock price would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

In addition, from time to time, we may release earnings guidance or other forward-looking statements in our earnings releases, earnings conference calls or otherwise regarding our future performance that represent our management's estimates as of the date of release. Some or all of the assumptions of any future guidance that we furnish may not materialize or may vary significantly from actual future results. Any failure to meet guidance or analysts' expectations could have a material adverse effect on the trading price or volume of our stock.

Health epidemics or pandemics may adversely affect our business, financial condition and results of operations.*

Health epidemics or pandemics may negatively impact worldwide economic and commercial activity and financial markets. For example, Covid-19 has previously resulted in significant business and operational disruptions, including business closures, supply chain disruptions, travel restrictions, stay-at-home orders and limitations on the availability of workforces. Our Netherlands Trial was previously delayed due to Covid-19 and it is possible we may encounter similar delays or other disruptions associated with Covid-19 or other health epidemics or pandemics. If we or any of our business partners, clinical trial sites, suppliers and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions as a result of Covid-19 (including new variants) or other health epidemic or pandemic, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. For example, if our development of ANEB-001 were to be delayed, it may have a material adverse effect on our business, results of operations and financial condition. In addition, an epidemic's or pandemic's impact on the medical community and the global economy could have an adverse impact on future sales upon which we expect to derive royalties and milestones, which could lead to a decrease in our revenues, net income and assets. If the adverse effects of a health epidemic or pandemic continue for a prolonged period or result in sustained economic stress, higher inflation levels or recession, many of the other risks described in this "Risk Factors" section could be exacerbated, such as those relating to our reliance on a limited number of suppliers and our need to raise additional capital to fund our existing operations.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.*

The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

Inflation may adversely affect us by increasing our costs.

Recently, inflation has increased throughout the U.S. economy. Inflation can adversely affect us by increasing the costs of clinical trials and research, the development of our product candidates, administration and other costs of doing business. We may experience increases in the prices of labor and other costs of doing business. In an inflationary environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations, which may not be available in sufficient amounts or on reasonable terms, if at all, sooner than expected.

If our internal information technology systems or sensitive information, or those of our third-party CROs or other contractors or consultants, are or were compromised, we could experience adverse consequences from such compromise, including but not limited to, a material disruption of the development of our product candidates, regulatory investigations or actions, litigation, fines and penalties, reputational harm, loss of revenue or profits, and other adverse consequences.*

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we may process confidential, and sensitive information, including personal data (such as health-related data), intellectual property, and trade secrets (collectively, "sensitive information"). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive information with or from third parties.

Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats come from a variety of sources, including traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including, without limitation, nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely may be subject to a variety of evolving threats, including, but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our services. Additionally, our workforce works remotely at least part of the time which poses increased risks to our information technology systems and data as a result of utilizing network connections outside our premises. Future or past business transactions (such as acquisitions or integrations) could also expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to conduct our business operations. For example, a security incident could result in a material disruption and delay of the development of our product candidates. In addition, the loss of pre-clinical study data or future clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data.

We may expend significant resources or modify our business activities to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third-party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause interruptions in our operations and could result in a material disruption of our programs. For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds from our Initial Public Offering

On May 11, 2021, we closed our IPO in which we issued and sold 3,078,224 shares of our common stock, including the additional shares pursuant to the underwriters' exercise of their option to purchase additional shares, at a public offering price to the public of $7.00 per share, for aggregate gross proceeds of $21.5 million. All shares issued and sold in the initial public offering were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-254979), which was declared effective by the SEC on May 6, 2021. We received aggregate net proceeds from our IPO of approximately $19.8 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The Benchmark Company, LLC acted as the sole underwriter in our IPO. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any affiliates of ours.

Through December 31, 2022, we have used approximately $9,843,000 of the net proceeds from the IPO for research and development expenses for ANEB-001, working capital and other general corporate purposes, including costs and expenses associated with being a public company. We have not used any of the net proceeds from the offering to make payments, directly or indirectly, to any director or officer of ours, or any of their associates, to any person owning 10 percent or more of our common stock or to any affiliate of ours. There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on May 10, 2021.

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	Second Amended and Restated Certificate of Incorporation of Anebulo Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K, filed with the SEC on September 9, 2022).
3.2	Certificate of Correction to Second Amended and Restated Certificate of Incorporation of Anebulo Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K, filed with the SEC on September 9, 2022).
3.3	Amended and Restated Bylaws of Anebulo Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on October 13, 2022).
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3.
4.2	Specimen Stock Certificate for Common Stock (filed as Exhibit 4.1 to the Company's Registration Statement on Form S-1 filed with the SEC on April 1, 2021 and incorporated herein by reference).
4.3	Investors' Rights Agreement, dated June 18, 2020, between Anebulo Pharmaceuticals, Inc. and 22NW, LP (filed as Exhibit 10.3 to the Company's Registration Statement on Form S-1 filed with the SEC on April 1, 2021 and incorporated herein by reference).
4.4	Securities Purchase Agreement, dated September 25, 2022, by and between Anebulo Pharmaceuticals, Inc. and the purchasers named therein (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 29, 2022).
4.5	Form of Common Stock Purchase Warrant, issued September 28, 2022 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed with the SEC on September 29, 2022).
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File – the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

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: February 10, 2023

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

Date: February 10, 2023

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

Exhibit 31.1

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

I, Simon Allen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended December 31, 2022 of Anebulo Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: February 10, 2023

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

Exhibit 31.2

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

I, Rex Merchant, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended December 31, 2022 of Anebulo Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: February 10, 2023

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 December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officers of the Company hereby certify, pursuant to 18 U.S.C. Section 1350, that to their knowledge:

(1) The Quarterly Report on Form 10-Q for the period ended December 31, 2022 (the "Report") of the Company fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 , as amended; 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: February 10, 2023

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

Date: February 10, 2023

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