UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2023

or

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

Commission File No. 001-40388

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

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ANEB	Nasdaq Stock Market LLC

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

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.1D-1(b). ☐

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the Registrant was $9,468,006 based on the closing price of the Registrant's common stock on the Nasdaq Capital Market on December 31, 2022. The calculation of the aggregate market value of voting and non-voting common stock excludes shares held by executive officers, directors and stockholders that the Registrant concluded were affiliates of the Registrant on such date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Registrant or that such person is controlled by or under common control with the Registrant.

The number of shares of the Registrant's common stock, par value $0.001 per share, outstanding as of September 14, 2023 was 25,633,217 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement (the "Proxy Statement") that will be filed for the 2023 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K. The Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Annual Report relates.

Anebulo Pharmaceuticals, Inc.
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In this Annual Report on Form 10-K (this "Annual Report"), unless otherwise stated or as the context otherwise requires, references to "Anebulo Pharmaceuticals," "Anebulo," "the Company," "we," "us," "our" and similar references refer to Anebulo Pharmaceuticals, Inc. The Anebulo logo, and other trademarks or service marks of Anebulo Pharmaceuticals, Inc. appearing in this Annual Report are the property of Anebulo Pharmaceuticals, Inc. This Annual Report also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this Annual 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 Annual Report contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (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 I, Item 1A, "Risk Factors" in this Annual Report. All statements other than statements of historical facts contained in this Annual 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 Annual 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 Annual 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;
- the timing and conduct of our clinical trials, including statements regarding the timing, progress and results of current and future nonclinical studies and clinical trials, and our research and development programs;
- the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of ANEB-001;
- our expectations regarding future growth;
- our ability to obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights;
- our ability to maintain our existing licensing arrangements and enter into and maintain other collaborations or licensing arrangements;
- our estimates regarding the commercial potential and market opportunity for our product candidates;
- the performance of our third-party suppliers and manufacturers;
- our ability to compete effectively with existing competitors and new market entrants;
- the impact on our business of economic or political events or trends; and
- the impact of governmental laws and regulations.

You should not place undue reliance on these forward-looking statements. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should carefully read this Annual Report, including the section titled "Risk Factors" and the documents that we reference in this Annual Report and have filed as exhibits to this Annual 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.

SUMMARY OF RISK FACTORS

Our business is subject to numerous risks and uncertainties of which you should be aware, including those described in the section entitled "Risk Factors." These risks include the following:

- 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 currently rely on a license from a third party, and in the future may rely on additional licenses from other third parties, in relation to our development of ANEB-001, and if we fail to comply with our obligations under our current or future intellectual property license agreements or otherwise experience disruptions to our business relationships with our current or any future licensors, we could lose intellectual property rights that are important to our business.
- We currently have no product revenue and will need to raise additional capital in the future, which may be unavailable to us or may cause dilution or place significant restrictions on our ability to operate.
- 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.
- If we are unable to obtain and maintain patent protection for important aspects of ANEB-001, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products that are similar or identical to ours, and our ability to successfully commercialize our current or future product candidates may be adversely affected.
- We 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 are relying on clinical trials performed by our licensor Vernalis Development Limited, formerly Vernalis (R&D) Limited ("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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.

The summary risk factors described above should be read together with the text of the full risk factors below, in the section entitled "Risk Factors" and the other information set forth in this Annual Report, including our financial statements and the related notes, as well as in other documents that we file with the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations and future growth prospects.

PART I

Item 1. Business.

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 and reduce time to recovery. The more severe 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 and we are not aware of any competing products that are further along in the development process than ANEB-001 in reversing the effects of delta-9-tetrahydrocannabinol, better known as THC, the primary psychoactive constituent of cannabis. Previous clinical trials conducted by a third party have shown that ANEB-001 is rapidly absorbed, well tolerated and when repeatedly administered to obese subjects led to weight loss, an effect that is consistent with central CB1 antagonism. In March 2021, our European clinical trial application ("CTA"), which is equivalent to an investigational new drug application in the United States, was accepted in the Netherlands to allow us to utilize ANEB-001 in a Phase 2 human proof-of-concept trial (the "Netherlands Trial") for potential use as a treatment for ACI. The study was designed to evaluate the safety, tolerability, pharmacokinetics, and effectiveness of a single dose of ANEB-001 in treating healthy subjects challenged with THC. We announced on January 3, 2022 that the first patient had been dosed in the Netherlands Trial. On May 11, 2022, we announced the dosing of all 60 subjects in Part A of the Netherlands Trial. On March 28, 2023, we announced complete results from Part A and Part B of the Netherlands Trial, in a total of 134 subjects. Dosing of an additional 20 subjects in an open-label extension of the study (Part C) was initiated in July 2023 and completed in August 2023. We met with the FDA in July 2023 for a Type B meeting to discuss the Part A and B Phase 2 data and the potential path forward for Phase 3 development of ANEB-001 and, received the minutes of the meeting in August 2023. The FDA indicated that a single well-controlled study of ANEB-001 in ACI patients presenting to the emergency department combined with a larger THC challenge study in volunteers could potentially provide substantial evidence to support a new drug application. In addition, an observational study in patients presenting to emergency departments with ACI is currently ongoing. The study will determine concentrations of cannabinoids and metabolites in plasma and gather information on signs and symptoms, patients' disposition and selected assessments, where possible. We believe the data generated from the Netherlands Trial provide support for our development pathway.

ACI has 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. 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 emergency department visits grew to 1.7 million patients in 2019 and was growing at an approximately 15% compounded annual growth rate between 2011 and 2019. We believe the number of cannabis-related emergency department visits, including other health problems associated with ACI such as depression, anxiety and mental disorders will continue to increase substantially as more states pass laws legalizing cannabis for medical or recreational use. Given the consequences, there is an urgent need for a treatment to rapidly reverse the symptoms of ACI.

Our Lead Product Candidate

Our objective is to develop and commercialize new treatments options for patients suffering from ACI and substance addiction. Our lead product candidate is ANEB-001, a potent, small molecule antagonist of cannabinoid binding receptor type-1 ("CB1"), the primary receptor involved in the psychotropic effects of cannabinoids, with the potential to address the unmet medical need for a therapy to treat ACI. ANEB-001 is an orally bioavailable, rapidly absorbed treatment that we anticipate will rapidly reverse the symptoms of ACI and reduce the time to recovery. Our proprietary position in the treatment of ACI is protected by one issued US patent and one allowed US patent and rights to six additional patent applications, two pending Patent Cooperation Treaty (PCT) applications and additional international patent applications, covering various methods of use of the compound, aspects of ANEB-001, and delivery systems. We began our Phase 2 trial in the Netherlands on December 2021 and announced complete data from Part A and Part B of the Netherlands Trial in March 2023. Dosing of an additional 20 subjects in an open-label extension of the study (Part C) was initiated in July 2023 and completed in August 2023. In July 2023, we met with the FDA for a Type B meeting to discuss the Part A and B Phase 2 data and the potential path forward for Phase 3 development of ANEB-001, and received the minutes of the meeting in August 2023. The FDA indicated that a single well-controlled study of ANEB-001 in ACI patients presenting to the emergency department combined with a larger THC challenge study in volunteers could potentially provide substantial evidence to support a new drug application. We are targeting to initiate Phase 3 registrational studies in the first half of calendar 2024.

Cannabinoids are a class of chemical compounds that are naturally occurring and are primarily found in cannabis plant extracts. The two major cannabinoids found in cannabis plant extracts include THC and CBD. These compounds bind themselves to CB1 and CB2 cannabinoid receptors, which are found throughout the body. Specifically, CB1 receptors are concentrated in the brain and central nervous system, while CB2 receptors are found mostly in peripheral organs and are associated with the immune system. When the chemical compounds bind themselves to these cannabinoid receptors, the process elicits certain physiological responses. Physiological responses to cannabinoids may vary among individuals. Some of the effects of cannabinoids have been shown to impact nervous system functions, immune responses, muscular motor functions, gastrointestinal maintenance, blood sugar management, and the integrity of ocular functions.

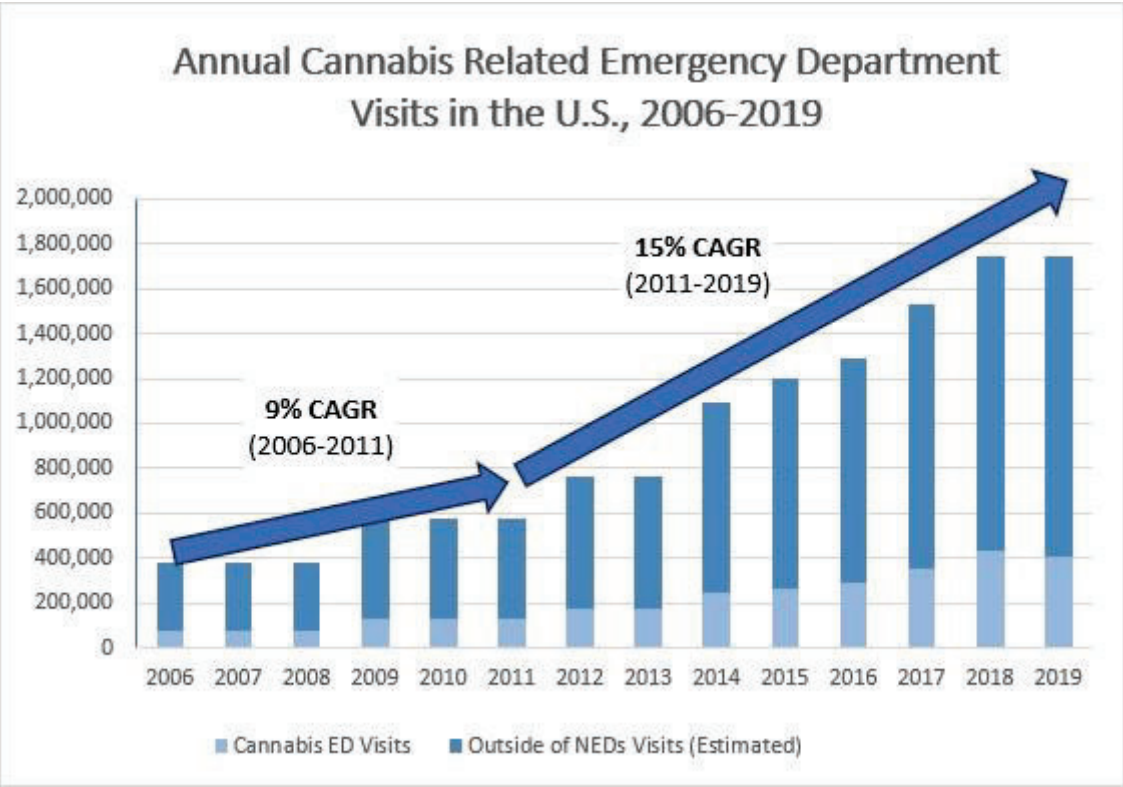
Individuals can use or consume cannabinoids in natural or unnatural formulations, orally or by inhalation, and intentionally and unintentionally, all of which can result in intoxication. Natural formulations include edibles and marijuana cigarettes; unnatural formulations include synthetics. Individuals consume cannabinoids orally by ingesting edibles or synthetics and by inhalation through smoking marijuana cigarettes or synthetics. Cannabinoids can also be ingested unintentionally through these same methods where, for example, children consume edibles by mistaking them for common consumer items like candy that would not otherwise contain THC. Symptoms of ACI produced by edibles and synthetics can include psychosis, panic and anxiety, feelings of paranoia, agitation, hallucinations, nausea, vomiting, cardiac arrhythmias, seizures and death. Many of these symptoms can require emergency medical attention and can take hours to days to resolve depending on the particular product and amount ingested. Currently, there is no specific treatment to reverse ACI and physicians have to rely on supportive care, including benzodiazepines, and wait for the body to metabolize the THC or synthetic cannabinoid.

We are relying on studies performed by a third party for a different indication, obesity, and the FDA or a foreign equivalent regulator may disagree with our ability to reference the clinical data generated by such third-party trials in connection with the indication for ACI and addiction. See "Risk Factors —Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization —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."

Our Market Opportunity

ACI has become a widespread health issue in the United States as an increasing number of states have legalized cannabis for medical or recreational use. As of June 30, 2023, cannabis was legal for recreational use in 23 states and the District of Columbia and for medical use in 38 states.

ACI frequently occurs due to the ingestion of edibles, which can contain relatively large amounts of THC, and consumption of synthetics. Symptoms of ACI produced by edibles and synthetics can include psychosis, panic and anxiety, feelings of paranoia, agitation, hallucinations, nausea, vomiting, cardiac arrhythmias, seizures and death. These symptoms can require emergency medical attention and can take hours to days to resolve. According to an article published in the Journal of Addiction Medicine that analyzed data from NEDS, an estimated 1.1 million emergency department visits were associated with cannabis in 2014. We have performed our own independent analysis of all currently available NEDS datasets and estimated that the number of cannabis-associated emergency department visits increased to 1.7 million patients in 2019. The number of cannabis-associated emergency department visits has grown at a 15% compounded annual growth rate from 2011 to 2019, which is when states first began legalizing recreational cannabis use.



Source for 2006-2014: Shen, J. J., Shan, G., Kim, P. C., Yoo, J. W., Dodge-Francis, C., & Lee, Y.-J. (2018). Trends and Related Factors of Cannabis-Associated Emergency Department Visits in the United States. Journal of Addiction Medicine, doi:10.1097/adm.0000000000000479, Source for 2015-2019: Company analysis of NEDS database.

We believe that both the number of cannabis-associated emergency department visits and the unmet medical need will continue to grow due to the increasing availability and consumption of edibles. In THC-containing edibles, the dose of THC can be as much as eight times more potent than a rolled marijuana cigarette. Edibles are frequently manufactured as common consumer products, such as brownies, cookies, candies and gummy snacks with brightly-colored packaging. THC concentrations in edibles peak after a delay of about two to four hours from ingestion. This time to peak concentration contrasts with smoking cannabis, which causes THC concentrations to peak in about three to 10 minutes from inhalation. Consumers possibly will approach edibles with the same serving size expectations as consumer products without THC. Moreover, children are particularly at risk for accidentally consuming edibles due to the edibles' brightly-colored packaging and formulation into candies and sweets. The confluence of these factors can be dangerous and increases the risk of ACI. Emergency department visits were 33 times more likely for edibles as compared with other routes of cannabis consumption, according to the recent article "Mental Health-related Emergency Department Visits Associated with Cannabis in Colorado," published in Academic Emergency Medicine (May 2018). Sales of edibles are rapidly growing, according to data collected by Statista, and are expected to continue growing into the future.

In November 2020, we sponsored a survey of U.S. physicians concerning patient emergency room visits for ACI within the past 12 months. Based on a survey of 27 emergency room physicians throughout the United States, the surveyed physicians saw on average 10.5 patients (a range of two to 45 patients) with cannabis intoxication per month. The survey asked these physicians to rank on a scale of 1 to 10 (i) the need for a cannabinoid antagonist to treat cannabis intoxication; (ii) the likelihood of their prescribing a cannabinoid antagonist that reverses cannabis intoxication within 30 minutes of administration; and (iii) the likelihood of such cannabinoid antagonist reducing the need for supportive medication to manage certain cannabis intoxication symptoms, such as agitation and acute psychosis. In response to these questions, the surveyed physicians ranked the need for a cannabinoid antagonist at an average of 7.52 out of 10, the likelihood of prescribing a cannabinoid antagonist that reverses cannabis intoxication within 30 minutes of administration at an average of 7.44 out of 10, and the likelihood of a specific cannabinoid antagonist reducing the need for supportive medication to manage certain ACI symptoms at an average of 7.48 out of 10. Although the survey pertained specifically to a cannabinoid antagonist that reverses cannabis intoxication within 30 minutes, we believe the survey results are indicative of likely prescribing behavior for any otherwise comparable product that takes effect rapidly even if not specifically within 30 minutes.

We believe that the market opportunity for our lead product candidate, ANEB-001, will continue to expand and accelerate if additional states pass laws to legalize recreational cannabis use. In Colorado, one of the first states to legalize recreational marijuana, the Colorado Department of Health and Environment reported that by 2018 marijuana use by adults one or more times during the past 30 days roughly doubled in the years following the state's legalization of cannabis. On April 1, 2022, the U.S. House of Representatives, for the second time, voted in favor of a bill to decriminalize marijuana at the federal level by removing cannabis from the list of controlled substances under the Controlled Substances Act. Although it is currently uncertain whether this bill will be subsequently approved by the U.S. Senate and signed into law by the President, in the event the use of cannabis is legalized in the United States at the federal level, we believe that the greater anticipated number of users will significantly increase the potential need for our lead candidate.

We believe that intoxication due to synthetic cannabinoids is an area with particularly high unmet medical need. Synthetics are among the fastest growing class of psychoactive drugs worldwide and can be as much as 85 times as potent as THC. This likely reflects the structural promiscuity of the CB1 receptor. In addition, the negative effects of an intoxication from synthetics can be longer lasting and more severe when compared with THC. These negative effects could include seizures and other dangerous outcomes. Compared with natural cannabis products, synthetics have lower shipping weights and can more readily evade traditional drug screening methods.

Our Growth Strategy

Our goal is to create a therapeutic to treat the underlying cause of ACI. As noted above, there are currently no FDA approved medical treatments on the market to specifically alleviate the negative neuropsychological effects of ACI. The absence and growing unmet need for such a treatment gives us the unique opportunity to create a novel solution and become a leader in the cannabinoid treatment space. To achieve our goal, our strategy will be guided by the following principles:

- **Develop and commercialize our ANEB-001 antagonist in the United States.** We commenced our Netherlands Trial in December 2021 and announced complete results from Part A and Part B of the Netherlands Trial in March 2023. Dosing of an additional 20 subjects in an open-label extension of the study (Part C) was initiated in July 2023 and completed in August 2023. In July 2023, we met with the FDA for a Type B meeting to discuss the Part A and B Phase 2 data and the potential path forward for Phase 3 development of ANEB-001, and received the minutes of the meeting in August 2023. The FDA indicated that a single well-controlled study of ANEB-001 in ACI patients presenting to the emergency department combined with a larger THC challenge study in volunteers could potentially provide substantial evidence to support a new drug application.

- **Explore strategic collaborations to commercialize ANEB-001.** Our plan is to widely commercialize ANEB-001, if approved. To accomplish this objective, we may partner with companies that possess a direct sales force and sales representatives.

- **Strive for capital efficiency in developing ANEB-001.** We aim to be capital efficient in our development of ANEB-001 by outsourcing our clinical research and data management. We anticipate this will lower our clinical development costs and improve our ability to efficiently commercialize ANEB-001 if it is approved by the FDA.

- **Introduce promising product candidate extensions.** We are in the initial stages of developing a non-oral formulation of ANEB-001.

- **Develop future product candidates to treat substance-related addiction.** We intend to leverage our expertise in the endocannabinoid system to develop additional product candidates for the treatment of substance addiction. CB1 antagonists have been shown to be promising in treating substance-related addiction. We believe that there is a large and growing unmet medical need for new treatment options because of the opioid epidemic.

Our Clinical Trials and Milestones

We are developing ANEB-001 as an acute treatment to quickly and effectively combat the symptoms of ACI. ANEB-001 was originally under development by Vernalis as a potential chronic treatment for obesity and other metabolic indications.

Preclinical Data

The initial preclinical characterization of ANEB-001 was performed at Vernalis' internal laboratory in the United Kingdom between 2003 and 2006. The compound was tested as a displacer in established radioligand binding assays for the CB1 receptor. ANEB-001 displaced the antagonist radioligand, [3H]-SR141716A from the human CB1 receptor with high affinity (0.55 nM) and was shown to be a competitive antagonist in cAMP assays. In vitro testing as a displacer in 90 binding assays and 19 enzyme and functional assays, showed that ANEB-001 had >1000x selectivity with the human CB1 receptor over all other tested receptors. Further, Vernalis demonstrated that oral administration of ANEB-001 reduced THC-induced hypolocomotion in mice after 30 minutes, effectively reversing the action of THC. C57 mice administered THC 3 mg/kg in 10 minutes pre-test exhibited reduced locomotor activity when placed in automated locomotor activity cages for 15 minutes. Providing it orally at a dose of 30 mg/kg 30 minutes pre-test significantly reversed the action of THC on the total activity time parameter ($p<0.01$ by one way ANOVA and Newman Keuls test, n=7 per group).

Historical Clinical Studies

In 2006 and 2007, two Phase 1 studies for the treatment of obesity were conducted by Vernalis for ANEB-001.

First Phase 1 trial

The Phase 1 study *(V24343-1Ob-01)* administered single (Part A) and multiple (Part B) ascending doses of ANEB-001 dosed daily for up to 14 days in otherwise healthy overweight and mildly obese subjects.

- Part A randomized 18 healthy volunteers to receive either a placebo (n=18) or two single oral doses of ANEB-001, with doses ranging from 1 mg to 200 mg. No severe adverse events were observed in either group in Part A. There was no difference between treatment groups in Part A in overall incidence, number of or severity of adverse events. Probable drug-related events in the treatment arm were nausea (22%), dizziness (11%), hiccups (8%), and decreased appetite (8%).

- Part B randomized 32 obese volunteers to receive either a placebo (eight obese volunteers) or four different doses of ANEB-001 for 14 days (24 obese volunteers). No severe adverse events were observed in either group in Part B, but an increased number of mild and moderate adverse events was observed in the obese volunteers who received the two higher dose arms (200/50 mg and 100 mg). The observed adverse events included nausea, vomiting, diarrhea, dizziness, hiccups, decreased appetite, hyperhidrosis and feeling hot. We believe these adverse events are "on-target," meaning they reflect CB1 antagonism, because these adverse events have also been observed with other CB1 antagonists.

Pharmacokinetic measurements in Part A of the Phase 1 study demonstrated that ANEB-001 was rapidly absorbed by the body following oral administration and achieved blood concentrations anticipated to be sufficient to block the CB1 cannabinoid receptor.

Vernalis also measured the impact of ANEB-001 on anxiety and depression in Part B of the Phase 1 study. Vernalis measured anxiety by using the Spielberger state score, a commonly used measure of trait and state anxiety. Vernalis found no significant impact on anxiety, except for the 200/50 mg arm (which represents a loading does of 200mg followed by a once daily ("OD") 50mg dose), which showed increased anxiety at all assessment times. The change was driven by a single subject and may be explained by somatic adverse events, which contributed to the Spielberger score. For depression, HAMD21 was used and small increases were noted in the 75/15 mg and 200/50 mg dose, which we believe were likely driven by somatic symptoms.

Summarizing the results from the Phase 1 study, ANEB-001 doses between 1 mg and 150 mg were found to be very well tolerated in both single and multiple doses with an adverse events profile similar to placebo. There was no observed effect on the cardiovascular system, ECGs, labs or physical exams and no significant effects on anxiety or depression scores.

With regard to pharmacodynamics, a marked reduction in test meal energy intake was seen even at the lowest dose level in Phase 1 Part B ($p<0.01$ on Day 14 for OD 100 mg, $p<0.05$ on Day 7 for OD 100 mg, not statistically significant for all other cohorts). Further, Vernalis observed statistically significant decreases in body weight ($p<0.001$ on Day 14 for OD 100 mg, $p<0.05$ for OD 50/5 mg and OD 200/50 mg, not significant for OD75/15 mg) indicating that ANEB-001 was able to cross the blood-brain barrier and antagonize central cannabinoid receptors. P-value is the probability that the difference between two data sets was due to chance. The smaller the p-value, the more likely the differences are not due to chance alone. In general, if the p-value is less than or equal to 0.05, the outcome is considered statistically significant. The FDA's evidentiary standard of efficacy generally relies on a p-value of less than or equal to 0.05.

Second Phase 1 trial

The second Phase 1 study conducted by Vernalis (V24343-1Ob-02) compared the pharmacokinetics of a single oral dose (1 to 200 mg) of ANEB-001 between fed and fasted states in eight subjects that were lean and in eight subjects that were overweight. There were no apparent differences in the tolerability of ANEB-001 between the subjects that were in fed and fasted states or between subjects that were lean and overweight. Total AUC (or area under the curve) was approximately 30% higher in subjects in the fed state compared to the subjects in the fasted state, with similar systemic exposure for the lean and overweight subjects.

The results of the historical Phase 1 studies demonstrate that ANEB-001 was well tolerated among healthy and obese subjects. There were no serious adverse events. The most commonly reported adverse event was gastrointestinal discomfort, which also occurred in subjects that were administered placebos. Based on the promising results of the historical Phase 1 studies, we believe ANEB-001 may offer the following clinical and product benefits:

- **Oral bioavailability.** ANEB-001 will be available as an oral treatment in the form of a pill, capsule or tablet.
- **Rapid onset of action.** ANEB-001 has shown CB1 antagonist effects in clinical studies – rapid reversal of signs and symptoms of ACI – in as little as 1 hour.
- **Low likelihood of drug-to-drug interactions.** Preclinical testing demonstrated that ANEB-001 did not inhibit the metabolic enzymes cytochromes 1A2, 2C9, 2C19, 2D6 and 3A4 at pharmacologically relevant concentrations.
- **Potential First-in-Class Treatment.** We are currently not aware of any competing products that are further along in the development process than ANEB-001 to specifically reverse the symptoms of ACI.
- **No serious adverse events.** A single dose of the drug is unlikely to produce adverse events associated with chronic dosing. The most commonly reported adverse effect in the previous Phase 1 studies was gastrointestinal discomfort, which also occurred in subjects who were administered a placebo.

Anebulo Clinical Studies

Phase 2 THC Challenge Study in Healthy Volunteers

We commenced the Netherlands Trial in December 2021 at the Center for Human Drug Research ("CHDR") in the Netherlands to evaluate the safety, tolerability, pharmacokinetics, and effectiveness of a single dose of ANEB-001 in treating healthy subjects challenged with delta-9-tetrahydrocannabinol, better known as THC, the primary psychoactive constituent of cannabis.

Part A of the study was a randomized, double-blind, placebo-controlled trial in 60 healthy adult occasional cannabis users randomized to three treatment arms of 20 subjects per arm. All subjects were challenged with a single oral dose of 10.5 mg THC and then treated with single oral doses of 50 mg ANEB-001, 100 mg ANEB-001, or placebo. Subjects were monitored for 24 hours to assess safety, tolerability, and pharmacokinetics, and repeatedly tested to determine potential effects on endpoints related to ACI symptoms. The tests also included a series of validated measures of subjective CNS symptoms using visual analog scale ("VAS") assessments, as well as objective measures of intoxication. Part B of the study was an adaptive design that included six cohorts of up to 15 healthy adults to examine different doses of THC and ANEB-001, and the impact of delayed dosing of ANEB-001 or placebo. Part B of the study was a randomized, double-blind, placebo-controlled phase. A total of 74 subjects participated in Part B. On March 28, 2023, we announced complete results from our Part A and Part B of the Netherlands Trial in a total of 134 subjects. Dosing of an additional 20 subjects in an open-label extension of the study (Part C) was initiated in July 2023 and completed in August 2023. Part C of the study was an open-label phase with 2 cohorts of 10 subjects. We believe the data generated from the Netherlands Trial provide support for our development pathway.

Data from Part A of the study previously showed positive protective effects of a single oral dose of 50 or 100 mg ANEB-001 when co-administered with an oral challenge dose of 10.5 mg THC. Subjects challenged with 10.5 mg THC and treated with placebo showed substantial CNS effects including feeling high, decreased alertness, increased body sway, and increased heart rate. Compared to placebo, treatment of subjects with ANEB-001 led to a significant, robust, and sustained reduction in the VAS feeling high score ($p < 0.0001$ at both dose levels) and improvement in the VAS alertness scale ($p < 0.01$). In addition, the proportion of subjects reporting feeling high on the VAS was significantly reduced by ANEB-001 ($p < 0.001$). Although THC-induced effects on body sway and heart rate in Part A of the study were small, there was also a trend towards statistical improvement of these parameters with ANEB-001 treatment compared to placebo. The 50 mg and 100 mg doses had similar results, suggesting that lower doses should be explored.

These data demonstrated a highly statistically significant reduction in key symptoms of ACI, with only 10% of subjects in the 50 mg ANEB-001 group and 30% in the 100 mg group reporting feeling high compared to 75% of subjects in the placebo group ($p < 0.001$). ANEB-001 was well tolerated in these healthy volunteers. Preliminary safety information showed all adverse events were mild and transient, except in the case of one subject in the 50 mg ANEB-001 group who experienced moderate nausea and vomiting.

Based on the encouraging data from Part A, we initiated Part B of the study at CHDR on July 26, 2022. In total, Parts A and B of the Phase 2 study enrolled 134 healthy subjects. In Part B of the study, subjects were challenged with substantially higher oral doses of THC (21, 30, or 40 mg) and treated with lower doses of ANEB-001 (10 or 30 mg) or a matching placebo. Delayed dosing of ANEB-001 was also examined by introducing a one-hour pause between the THC challenge and treatment with the ANEB-001 or placebo. The final cohort of the study included the administration of a high-fat meal prior to the THC challenge.

Based on the final data for Part B of the study, a single low oral dose of ANEB-001 (10 mg) administered 1 hour after a THC challenge rapidly and statistically significantly reversed key psychotropic effects of THC doses as high as 30 mg, including a reduction in the VAS for feeling high ($p=<0.0001$) and improvement in VAS alertness ($p=0.0042$) and reduced body sway ($p=0.0196$). In a pre-specified pooled analysis of data for the combined 21 mg or 30 mg THC dose levels, a single 10 mg of ANEB-001 administered one hour after THC achieved statistical significance on all primary outcomes, including a reduction in VAS feeling high ($p=<0.0001$), improvement in VAS alertness ($p=0.0024$), reduced body sway ($p=0.0014$), and reduction in heart rate ($p=0.0125$). ANEB-001 also reduced the time required for the THC effects to normalize back to baseline.

The Phase 2 study was conducted in the Netherlands by the CHDR. A total of 134 healthy subjects were enrolled. All subjects received oral THC challenge doses. In total, 91 subjects received single oral doses of ANEB-001. Pharmacodynamic outcomes were assessed by mixed-effect model repeated measures ("MMRM") analysis of covariance ("ANCOVA") through 8 hours post-ANEB-001 dosing. Safety was assessed by continuous observation for 24 hours and followed up at 7 to 14 days after treatment. ANEB-001 was well tolerated in this study and there were no serious adverse events. At the 30 mg THC dose, prior to dosing ANEB-001 or placebo, subjects developed mild to moderate THC-related symptoms including moderate euphoria, nausea, and/or vomiting, and mild bradyphrenia, dizziness, paresthesia, and/or feeling emotional. After delayed dosing of 10 mg ANEB-001 or placebo following a 21 mg or 30 mg THC challenge dose, the adverse events considered possibly or probably related to ANEB-001 were mild except for one case of moderate nausea/vomiting at THC doses of 21 mg and 30 mg; the incidence of dizziness and euphoria was greater in the placebo treated subjects. Administration of a high-fat meal delayed the absorption of THC resulting in blunted effects of a 30 mg THC dose on many of the outcomes. However, delayed dosing of 10 mg ANB-001 still significantly reduced VAS feeling high in fed subjects ($p=0.0030$).

Part C of the study was an open-label phase with two cohorts of 10 subjects each. Subjects in Cohort 7 received a single oral dose of 40 mg of THC together with a single oral dose of 10 mg of ANEB-001. Subjects in Cohort 8 received a single oral dose of 60 mg of THC together with a single oral dose of 20 mg of ANEB-001. In the earlier Part B of the study, a single oral dose of 40 mg THC without ANEB-001 was not well tolerated due to overt THC-related effects. However, the use of even higher THC challenge doses was considered acceptable by an independent institutional review board ("IRB") provided that all subjects would also receive ANEB-001. Part C of the study was therefore conducted as open-label without a placebo arm. Subjective and objective assessments performed during the open-label Part C of the study were similar to those used in Parts A and B, with the addition of several new outcome measures intended to explore further evidence of clinically meaningful effects. Based on preliminary safety observations, THC challenge doses of 40 mg and 60 mg were well-tolerated when dosed in combination with ANEB-001, and all treatment-related adverse events were mild and transient. Full safety, pharmacokinetic ("PK"), and pharmacodynamic data from the study, as well as results at higher doses of THC, are expected in fourth quarter of calendar 2023. In total, 183 subjects have been dosed with ANEB-001 in the Phase 1 and Phase 2 studies.

We have enrolled our first subject in our observational PK study in the United States . The purpose of the study is to gather data on ACI subjects in the emergency department setting. The PK data for THC and THC metabolites is expected to further support PK/PD modeling efforts and ANEB-001 development.

We believe the Phase 2 study provides support for our continuing discussions with the FDA and potential future discussions with comparable foreign regulatory authorities, and allows us to design and conduct more extensive clinical trials with the goal of generating additional clinical data that will ultimately enable us to file a marketing application with the FDA.

Vernalis License Agreement

On May 26, 2020, we entered into an exclusive license agreement (the "License Agreement") with Vernalis Development Limited, formerly Vernalis (R&D) Limited ("Vernalis"). Pursuant to the License Agreement, Vernalis granted us an exclusive worldwide royalty-bearing license to develop and commercialize a compound that we refer to as 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.

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.

With respect to intellectual property, both parties agreed to retain sole ownership over their respective intellectual property as of the date of the License Agreement. In addition, 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 ANEB-001 during the term of the License Agreement.

The License Agreement continues for an indefinite term unless and until it is terminated or until such time as all royalties and other sums cease to be payable thereunder. Our obligations to pay royalties commence upon the first commercial sale of our product and cease upon the later to occur of: (i) the tenth anniversary of the first commercial sale of our product, or (ii) the expiration date of the regulatory exclusivity of our product. We may terminate the License Agreement in its entirety at any time by providing 60 days' prior notice to Vernalis. Moreover, a party may terminate the License Agreement for cause (i) upon written notice when the other party commits a material breach not remedied within the specified timeframes and defaults on its obligations thereunder, or (ii) when the other party is insolvent as more particularly described therein. In the event of 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' request, any regulatory materials, information pertaining to ANEB-001, and any unused API purchased from Vernalis. If Vernalis terminates the License Agreement due to our material breach or insolvency, or if we terminate the License Agreement at will, both parties will negotiate in good faith to grant Vernalis a license to such intellectual property and regulatory materials needed to develop and commercialize ANEB-001 and provide appropriate compensation to us within six months of the termination date.

Competition

The clinical biotechnology industry is a competitive industry characterized by technological innovation and growth. Our competitors include other biotechnology and pharmaceutical companies, academic institutions, and public and private research institutions. These entities engage in efforts to research, discover and develop new medicines and treatments for substance use. These entities also seek patent protection and licensing revenues for their research results and may compete with us in recruiting skilled talent. Some of these entities are larger and better funded than us. Our management can make no assurances that we can effectively compete with these competitors. Potential current competitors include Aelis Farma, which is developing a medication based on a pregnenolone derivative to treat cannabis use disorders, and Indivior PLC, which is developing a drinabant injection to treat acute cannabis overdose.

Research and Development

We are making, and expect to continue to make, substantial expenditures to fund proprietary research and development of our ANEB-001 product candidate and to support preclinical testing and clinical trials necessary for regulatory filings. Our research and development team, including a third-party CRO, is continually undertaking efforts to advance research and development goals. During the fiscal years ended June 30, 2023 and June 30, 2022, we incurred research and development expenses of approximately $5,600,000 and $2,962,000, respectively.

Regulation

Government Regulation and Product Approval

We operate in an extensively regulated industry. Governmental authorities at all levels in the United States and in other countries regulate aspects of bringing therapeutics, drugs, and other biologics to market, including research, testing, safety, product approval, development, manufacture, efficacy, quality control, packaging, storage, record-keeping, promotion, labeling, advertising, marketing, distribution, sales, imports and exports of our products.

As a therapeutic product for human use, ANEB-001 will be subject to regulation in the United States by the FDA under the Federal Food, Drug and Cosmetic Act ("FDCA") and similar regulatory requirements in other countries. Regulatory requirements include, among other things, rigorous preclinical and clinical testing. The processes obtaining regulatory approval, commercializing our product and maintaining compliance with applicable statutes and regulations require the substantial expenditure of time and financial resources and play a significant role in our research and development, production, and marketing activities. Failure to comply with these regulatory processes and other requirements could delay our ability to receive regulatory approvals, adversely affect the commercialization of our product, and hinder our ability to receive royalties or revenues.

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations. Failure to comply with such regulations during and after the product development and approval process could result in administrative or judicial sanctions. Such sanctions include the FDA's refusal to approve pending applications, withdrawal of an approval, placement on a clinical hold, untitled or warning letters, product recalls, seizure of products, partial or complete suspension of production or distribution, injunctions, fines, refusal of government contracts, restitution, disgorgement, civil penalties and criminal penalties. The FDA generally requires the following before a drug can be marketed in the United States:

- Completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices regulations;
- Submission of an IND, which must become effective before the commencement of human clinical studies;
- Approval by an independent IRB, at each clinical site before the initiation of each trial;
- Performance of adequate and well-controlled human clinical studies according to Good Clinical Practice ("GCP") regulations, to establish the safety and efficacy of the proposed drug for its intended use;
- Preparation and submission of a New Drug Application ("NDA");

- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product, or its components, are produced to ensure compliance with current Good Manufacturing Practice ("CGMP") regulations and to ensure that the facilities, methods, and controls are adequate to preserve the drug's identity, strength, quality, and purity; and

- FDA review and approval of the NDA.

Given that the testing and approval process requires a substantial commitment of time, effort and financial resources, we cannot ensure that our product will be granted approval on a timely basis.

As part of the IND, an IND sponsor must submit the preclinical test results, along with manufacturing information, analytical data and any available clinical data or literature, to the FDA. The sponsor must also include a protocol detailing the objectives of the initial clinical study, the parameters for monitoring safety, and the effectiveness criteria to be assessed (among other things) if the initial clinical study lends itself to an efficacy evaluation. Some preclinical testing may continue after submission of the IND. The IND becomes automatically effective 30 days after receipt by the FDA, unless the FDA raises questions or concerns in response to a proposed clinical study and places the study on a clinical hold within the 30-day timeframe. In such a case, the IND sponsor and the FDA must resolve any outstanding issues before commencing the clinical study. The FDA may impose clinical holds due to safety concerns or non-compliance on all product candidates within a certain pharmaceutical class at any time before or during clinical studies. In addition, the FDA can impose partial clinical holds prohibiting the initiation of clinical studies for a certain dose or of a certain duration.

In accordance with GCP regulations, all clinical studies must be conducted under the supervision of one or more qualified investigators. These regulations require informed consent in writing from all research subjects before their participation in any clinical study. An IRB must review and approve the plan for any clinical study before it commences at any institution, and the IRB must continuously review and re-approve the study at least annually. Among other things, the IRB considers whether the risks to individual participants in the clinical study are minimal and reasonable in relation to the anticipated benefits. The IRB also approves the information regarding the clinical study and the consent form that must be given to each clinical study subject or his or her legal representative. The IRB must also monitor the clinical study until completed. Each new clinical protocol and any amendments thereto must be submitted to the FDA for review, and to the IRB for approval. The protocols detail the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety (among other things). Study sites are subject to inspection for compliance with GCP.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, for public dissemination on the ClinicalTrials.gov website.

Human clinical studies are typically conducted in three sequential phases that may overlap or be combined:

- **Phase 1.** In Phase 1, the product is initially introduced to a limited number of healthy human subjects or patients and may be tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain early evidence on effectiveness. In the case of certain products intended to treat severe or life-threatening diseases, particularly when the product is suspected or known to be unavoidably toxic, initial human testing may be conducted in patients.

- **Phase 2.** Phase 2 involves clinical studies in a limited patient population to identify potential adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific diseases and to determine dosage tolerance, optimal dosage and schedule.

- **Phase 3.** In Phase 3, clinical studies are often conducted on a larger number of subjects or in a patient population located in geographically dispersed clinical sites to further evaluate the dosage, clinical efficacy and safety of the product. Phase 3 clinical studies are intended to determine the overall risks and benefits of the product and provide an adequate basis for product labeling.

Progress reports explaining the results of the clinical studies must be submitted to the FDA at least annually. Safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events. There is no guarantee that Phase 1, Phase 2 and Phase 3 testing will be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical study at any time for various reasons, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Likewise, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

U.S. Review and Approval Processes

Upon the successful completion of the required clinical testing, an NDA is submitted to the FDA requesting approval to market the product. The NDA reports the results of product development, preclinical and clinical studies, descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information.

In connection with the submission of an NDA, the payment of a substantial application user fee is required (although a waiver is available under limited circumstances, including, for the first human drug application submitted by a small business or its affiliate). The sponsor of an approved NDA is also required to pay annual program user fees.

The FDA may also require a Risk Evaluation and Mitigation Strategy ("REMS") to mitigate any identified or suspected serious risks. The REMS typically includes risk minimization tools, medication guides, assessment plans, physician communication plans, and elements to ensure safe use, including restricted distribution methods, and patient registries.

The FDA reviews all NDAs submitted to ensure they are sufficiently complete for substantive review before it accepts them for filing. Rather than accept an application for filing, the FDA may request additional information. In such a case, an applicant must re-submit the application along with the additional information, which remains subject to further FDA review. Once an application is accepted for filing, the FDA performs an in-depth substantive review to determine whether the product is safe and effective for its intended use.

The FDA may refer the NDA to an advisory committee consisting of experts for review, evaluation and recommendation regarding its approval and any conditions that may apply thereto. The FDA, while not bound by the recommendation of an advisory committee, considers such recommendations when making decisions. Before approving an NDA, the FDA will also inspect one or more clinical sites to ensure clinical data supporting the submission comply with GCP.

The FDA may refuse to approve an NDA if regulatory requirements are not satisfied or additional clinical data and information is required. Even after such data and information is furnished, the FDA may refuse to approve an NDA for failure to satisfy regulatory requirements. Data from clinical studies may not always be conclusive. Moreover, the FDA may disagree with the applicant's interpretation of the data.

After evaluating an application, the FDA may issue an approval letter or a complete response letter indicating completion of the review cycle. A complete response letter typically sets forth specific conditions that must be satisfied to secure final approval of the application and may require additional clinical or preclinical testing for the FDA to reconsider the application. The FDA may identify minor deficiencies, such as requiring labeling changes, or major deficiencies, such as requiring additional clinical studies. The complete response letter may also recommend actions to ready the application for approval. An applicant can respond to a complete response letter by correcting all deficiencies and re-submitting the application, withdrawing the application or requesting a hearing.

Even after additional information is submitted, the FDA may determine that an application does not satisfy regulatory requirements and reject it. Once all conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter authorizing commercial marketing of the drug with specific prescribing information for specific indications.

Even after regulatory approval is obtained, approval may be restricted to specific diseases and dosages or limited indications for use. Such limitations could affect the commercial value of the product. On the product labeling, the FDA may require certain contraindications, warnings or precautions. In addition, the FDA may require post-approval studies, including Phase 4 clinical studies, to further evaluate safety and effectiveness. The FDA may also require testing and surveillance programs to monitor the safety of approved commercialized products. After approval, certain changes to the approved product remain subject to additional testing requirements, FDA review and approval. Such changes to the approved product include adding new indications, manufacturing changes, and additional labeling claims.

Approved products manufactured or distributed in accordance with the FDA regulatory process remain subject to continuing FDA oversight post-approval. Continuing regulatory requirements include periodic reporting, record-keeping, product sampling, product distribution, and advertising and reporting on adverse experiences, deviations, and other issues with the product. In addition, most post-approval changes to the approved product, including adding new indications or other labeling claims, remain subject to prior FDA review and approval. There are also continuing obligations to pay annual user fees for marketed products, as well as new application fees for supplemental applications with clinical data.

The FDA strictly regulates the information presented on products on the market, including information on labeling, advertising, and promotion of products. Products may only be promoted for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the rules prohibiting the promotion of off-label use. A company that improperly promotes off-label use may be subject to significant liability. Manufacturers must also continue to comply with extensive CGMP regulations, which requires a commitment of time and financial resources. FDA review and approval is generally required for post-approval changes to the manufacturing process and other changes to the approved product, including the addition of new indications and additional labeling claims.

Manufacturers and others involved in the manufacturing and distribution of approved products must register their establishments with the FDA and certain state agencies. The FDA and state agencies may periodically inspect these establishments, sometimes without prior notice, to ensure compliance with CGMP regulations and other obligations. CGMP requirements apply to all stages of the product manufacturing process, including processing, production, sterilization, packaging, labeling, storage and shipment.

Prior FDA approval is often required for changes to the manufacturing process to be implemented. FDA regulations require investigation and correction of departures from CGMP requirements. The FDA may also impose reporting and documentation obligations upon the sponsor and any third-party manufacturers used by the sponsor. As a result, to remain compliant with CGMP regulations, manufacturers must continue to commit time, effort and financial resources to production and quality control.

The FDA may impose other post-approval requirements as a condition to approving an application, such as post-marketing testing (including Phase 4 clinical trials) and surveillance to monitor and assess the product's safety and effectiveness upon commercialization.

The FDA may withdraw approval of a product if an applicant fails to maintain compliance with regulatory requirements or if certain issues arise after the product is introduced to the market. For instance, a subsequent discovery of previously unknown issues, including adverse events of unexpected frequency or severity, problems with the manufacturing process, or failure to comply with regulatory requirements, could result in restrictions on the product or a complete withdrawal from the market.

In such cases, potential consequences include revisions to the approved labeling to include new safety information; post-market studies or clinical trials to evaluate new safety risks; and imposition of restrictions under a REMS program. Other potential consequences include:

- 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 NDAs or supplements to approved NDAs;
- 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.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States, commercial sales of pharmaceutical 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. 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.

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

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, including HCPs, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. 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 our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we 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 our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources.

Healthcare Reform

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 creating a new manufacturer discount program. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges 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. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions will take effect progressively starting in fiscal year 2023, although the Medicare drug pricing negotiation program is currently 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, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures 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.

Protection of Intellectual Property

We strive to protect our intellectual property in a variety of ways to promote the development of our product candidate and business. Our strategy to safeguard this intellectual property includes the following:

● **Patents and patent applications.** We are in the process of obtaining method of use, formulation, and polymorph patents intended to cover our ANEB-001 product candidate, which are important to the development of our business. We have filed or intend to file patent applications related to aspects of ANEB-001, our product candidate. We have obtained one issued patent, U.S. Patent No. 11,141,404, titled "Formulations And Methods For Treating Acute Cannabinoid Overdose." We have filed and will continue to file in foreign jurisdictions for our patent applications at the relevant time. Issued patents and patents arising from our pending applications are expected to expire at the earliest in 2040.

● **Regulatory exclusivity**. Upon approval of a new chemical entity ("NCE"), which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which the FDA may not approve a generic version of the drug. In addition, in seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an ANDA and then later challenged pursuant to a paragraph IV certification. As part of the Paragraph IV certification process, an NDA holder may initiate a patent infringement lawsuit against the ANDA applicant. The filing of a patent infringement lawsuit by an NDA holder automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the Orange Book-listed patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant. Finally, we could receive an orphan drug designation, which would grant a total of seven years of marketing exclusivity in the United States under the US Orphan Drug Act of 1983, or pediatric drug designation, which provides NDA holders (under the Best Pharmaceuticals for Children Act (the "BPCA")) a six-month extension of any exclusivity (patent or non-patent) for a drug.

● **Trade secrets**. We rely on trade secret laws of general applicability for aspects of our business that are not readily amenable to or appropriate for patent protection.

● **Confidentiality agreements**. We rely upon confidentiality agreements signed by our employees, consultants and third parties.

● **License agreement**. We have entered into an exclusive worldwide licensing agreement with Vernalis to develop, strengthen and commercialize our ANEB-001 compound. This exclusive in-licensing opportunity allows us to maintain and enhance our proprietary position in ANEB-001.

● **Trademarks**. We use "Anebulo" as our trademark. As we develop our drug candidate and business, we intend to add trademarks to our portfolio of intellectual property.

We believe these methods provide us material defensibility around our core intellectual property.

Employees and Human Capital Resources

As of June 30, 2023, we had two full-time employees, none of whom were covered by collective bargaining agreements. In addition, we have a number of outside consultants who are not on our payroll, who are involved directly in scientific research and development activities. We believe that we maintain strong relations with our employees. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

Corporate Information

We were incorporated in Delaware in April 2020. Our principal executive offices are located at 1017 Ranch Road 620 South, Suite 107 Lakeway, Texas 78734, and our telephone number is 512-598-0931.

Available Information

Our website address is www.anebulo.com, which includes a section for investor relations. Information on our website is not incorporated by reference herein. We will make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains an Internet site (http://www.sec.gov) containing reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Item 1A. Risk Factors

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

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 June 30, 2023, we have an accumulated deficit of $57,202,041, which includes a fair value adjustment of $26,626,710 for warrants converted into Series A preferred stock on a cashless basis in connection with our IPO. The likelihood of our future success must be considered in light of the expenses, difficulties, complications and delays often encountered by companies in clinical development, including in connection with ongoing and future clinical trials and the emergence of competing products or therapies. These potential challenges include unanticipated clinical trial delays, poor data, changes in the regulatory and competitive landscape and additional costs and expenses that may exceed current budget estimates. In order to complete certain clinical trials and otherwise operate pursuant to our current business strategy, we anticipate that we will incur increased operating expenses. In addition, we expect to incur significant losses and experience negative cash flow in the future as we fund our operating losses and capital expenditures. We recognize that if we are unable to generate sufficient revenues or source funding, we will not be able to continue operations as currently contemplated, complete planned clinical trials and/or achieve profitability. Our failure to achieve or maintain profitability will also negatively impact the value of our shares. If we are unsuccessful in addressing these risks, then we may need to curtail our business activities.

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

- having inadequate financial or other resources to complete the development of our product candidate;
- the inability to manufacture our product in commercial quantities, at an adequate quality, at an acceptable cost or in collaboration with third parties;
- experiencing delays or unplanned expenditures in product development, clinical testing or manufacturing;
- the inability to establish adequate sales, marketing and distribution channels;
- healthcare professionals may not adopt and patients may not accept our drug, if approved for marketing;
- we may not be aware of possible complications or other side effects from the use of our product since we have limited clinical experience with respect to the actual effects from use of our product;
- technological breakthroughs in reversing 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 the License Agreement with Vernalis, pursuant to which Vernalis granted 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 June 30, 2023, will enable us to fund our current and planned operating expenses and capital expenditures into the fourth 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, seek collaborations, or amend existing collaborations, for research and development programs at an earlier stage than otherwise would be desirable or for the development of programs that we otherwise would have sought to develop independently, or on terms that are less favorable than might otherwise be available, dispose of technology assets, or relinquish or license on unfavorable terms, our rights to technologies or any future product candidates that we otherwise would seek to develop or commercialize ourselves, pursue the sale of our company to a third party at a price that may result in a loss on investment for our stockholders, file for bankruptcy or cease operations altogether. This may materially adversely affect our operations and financial condition as well as our ability to achieve business objectives and maintain competitiveness.

If we raise additional capital by issuing equity securities and/or equity-linked securities, the percentage ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. 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. See also "Risks Related to Our Reliance on Third Parties—We currently outsource, and from time to time in the future may outsource, a portion of our internal business functions to third-party providers. Outsourcing these functions has significant risks, and our failure to manage these risks successfully could materially adversely affect our business."

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. In addition, on May 1, 2023, the FDIC seized First Republic Bank and sold its assets to JPMorgan Chase & Co. While the U.S. Department of Treasury, FDIC and Federal Reserve Board have implemented a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediate liquidity may exceed the capacity of such program, there is no guarantee that such programs will be sufficient. Additionally, it is uncertain whether the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

While we have not experienced any adverse impact to our liquidity or to our current and projected business operations, financial condition or results of operations as a result of the matters relating to SVB, Signature Bank, Silvergate Capital Corp and First Republic Bank, uncertainty remains over liquidity concerns in the broader financial services industry, and our business, our business partners or industry as a whole may be adversely impacted in ways that we cannot predict at this time.

Although we assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

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 2040. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to aspects of our product candidate that are important to our business and maintaining and protecting our existing patents. 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 become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding, or litigation could reduce the scope of, or invalidate or render unenforceable, such patent rights, allow third parties to commercialize our product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as post-grant review at the USPTO or oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates and other technologies. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

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

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

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

We cannot be certain that our 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 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 is not as strong as that in the United States. These products may compete with ANEB-001, and our patent or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

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

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

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

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

Patent protection is important in the development and eventual commercialization of our product candidate. Patents covering our product candidate normally provide market exclusivity, which is important in order for our product candidate to become profitable. 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 described in "Business—Our Clinical Trials and Milestones," 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 Indivior PLC, 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.

We currently outsource, and from time to time in the future may outsource, a portion of our internal business functions to third-party providers. Outsourcing these functions has significant risks, and our failure to manage these risks successfully could materially adversely affect our business.

We currently, and from time to time in the future, may outsource portions of our internal business functions to third-party providers. For example, on March 2, 2023, we entered into a master services agreement with Potrero Hill Advisors, LLC ("Potrero"), pursuant to which, among other things, Potrero agreed to serve as an independent consultant for purposes of providing us with certain strategic and financial advice and support services, including the services of Sandra A. Gardiner as our Acting Chief Financial Officer. On August 29, 2023, Potrero provided written notice to terminate the master services agreement and Ms. Gardiner concurrently notified us of her resignation, each effective September 28, 2023. There can be no assurance that we will able to identify a successor for Ms. Gardiner prior to the effective date of her resignation. If we are unable to retain individuals or organizations to lead and/or support our finance and accounting functions, we may experience significant disruptions in our operations, including our ability to timely comply with our reporting obligations. We may also experience significant disruptions in our operations, including our ability to timely comply with our reporting obligations, if these third-party providers do not perform as expected or if other third-party providers choose to discontinue providing services to us.

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 creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. If the ACA is repealed or modified, or if implementation of certain aspects of the Health Care Reform Law are delayed, such repeal, modification or delay may materially adversely impact our business, strategies, prospects, operating results or financial condition. We are unable to predict the full impact of any repeal or modification in the implementation of the ACA on us at this time.

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. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions will take effect progressively starting in fiscal year 2023, although the Medicare drug pricing negotiation program is currently 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, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures 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.

In the coming years, additional changes could be made to governmental healthcare programs such as allowing the Medicare program to negotiate prices for certain drugs that could significantly impact the development and success of our future product candidates, and we could be adversely affected by current and future healthcare reforms.

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

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, which requires an 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, for so long as we are an emerging growth company or a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation. 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 Securities Exchange Act of 1934, as amended (the "Exchange Act"), the accounting and internal controls provisions of the Foreign Corrupt Practices Act of 1977, as amended, the applicable requirements of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), and the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the "Dodd-Frank Act"), as well as other rules and regulations 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 must 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 if we are also at that time not a "non-accelerated filer" under appliable SEC rules. 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 $1.235 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 pay-versus-performance 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" and a "non-accelerated filer" under SEC rules. For instance, non-accelerated filers are not required to obtain an auditor attestation and report regarding management's assessment of internal control over financial reporting, are smaller reporting companies are not required to provide a compensation discussion and analysis, are not required to provide pay-versus-performance 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 $1.235 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 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. As a further example, effective January 1, 2022, the Tax Cuts and Jobs Act eliminated the option to deduct research and development expenses for tax purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. Although there have been legislative proposals to repeal or defer the capitalization requirement to later years, there can be no assurance that the provision will be repealed or otherwise modified. 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 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 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 a 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, bank failures, 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.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, as further discussed above, the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information. In addition, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 ("CPRA"), (collectively, "CCPA") applies to personal information of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for administrative fines of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, the CPRA expanded the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR") and the United Kingdom's GDPR ("UK GDPR") impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

Additionally, under various privacy laws and other obligations, we may be required to obtain certain consents to process personal data. Our inability or failure to do so could result in adverse consequences, including class action litigation and mass arbitration demands.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (the "EEA") and the United Kingdom (the "UK") have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. For example, in May 2023, the Irish Data Protection Commission determined that a major social media company's use of the standard contractual clauses to transfer personal data from Europe to the United States was insufficient and levied a 1.2 billion Euro fine against the company and prohibited the company from transferring personal data to the United States.

In addition we are bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statement regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change our business model.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials.

In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

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 and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. These threats are prevalent and continue to increase, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal 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 deep fakes, which may be increasingly more difficult to identify as fake, and 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. information technology assets, 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, remote work has become more common and poses increased risks to our information technology systems and data, as more of our employees work from home, 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. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

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. Additionally, our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with our employee's, personnel's, or vendor's use of generative AI technologies, resulting in adverse consequences. In each case, 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 and negatively impact our ability to grow and operate our business. 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 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We manage our business operations from our principal executive office in Lakeway, Texas, in leased space under a sublease with JFL Capital Management LLC, a company controlled by Joseph F. Lawler, the founder and a director of our company. During the fiscal year ended June 30, 2023 we paid rent of approximately $1,300 per month. Subsequent to year end, our rent was reduced to approximately $400 per month. We believe our present office space is adequate for our current operations and for near-term planned expansion.

Item 3. Legal Proceedings.

From time to time, we may be a party to litigation or subject to claims incident to the ordinary course of business. 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. However, the results of litigation and claims cannot be predicted with certainty, and 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.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock has been publicly traded on the Nasdaq Capital Market under the symbol "ANEB" since May 7, 2021. Prior to that time, there was no public market for our common stock.

Holder of Record

As of September 14, 2023, there was approximately 1 holder of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividends

We have not declared or paid any cash dividends on our capital stock since our inception. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends to holders of common stock in the near-term future. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to applicable laws, will depend on a number of factors, including our financial condition, results of operations, capital requirements, contractual restrictions, general business conditions, and other factors that our board of directors may deem relevant.

Unregistered Sales of Equity Securities

None.

Use of Proceeds From 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 June 30, 2023, we have used approximately $14,900,000 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.

Issuer Purchases of Equity Securities

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and related notes and other financial information appearing elsewhere in this Annual Report. Some of the information contained in this discussion and analysis includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk factors" section of this Annual Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biotechnology company developing novel solutions for people suffering from acute cannabinoid intoxication ("ACI") and substance addiction. Our lead product candidate, ANEB-001, is intended to rapidly reverse the negative effects of ACI and reduce time to recovery. The more severe 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, and we are not aware of any competing products that are further along in the development process than ANEB-001 in reversing the effects of delta-9-tetrahydrocannabinol, better known as THC, the principal psychoactive constituent of cannabis. Previous clinical trials completed by a third party have shown that ANEB-001 is rapidly absorbed, well tolerated and, when repeatedly administered to obese subjects, leads to weight loss, an effect that is consistent with central CB1 antagonism. In March 2021, our European clinical trial application ("CTA"), which is equivalent to an investigational new drug application in the United States, was accepted in the Netherlands to allow us to utilize ANEB-001 in a Phase 2 human proof-of-concept clinical trial in the Netherlands for potential use as a treatment for ACI. The study was designed to evaluate the safety, tolerability, pharmacokinetics, and effectiveness of a single dose of ANEB-001 in treating healthy subjects challenged with THC. We announced on January 3, 2022, that the first patient had been dosed in the Netherlands Trial. On May 11, 2022, we announced the dosing of all 60 subjects in Part A of the Netherlands Trial. On March 28, 2023, we announced complete results from Part A and Part B of the Netherlands Trial, in a total of 134 subjects. Dosing of an additional 20 subjects in an open-label extension of the study (Part C) was initiated in July 2023 and completed in August 2023. We met with the FDA in July 2023 for a Type B meeting to discuss the Part A and B Phase 2 data and the potential path forward for Phase 3 development of ANEB-001 and received the minutes of the meeting in August 2023. The FDA indicated that a single well-controlled study of ANEB-001 in ACI patients presenting to the emergency department combined with a larger THC challenge study in volunteers could potentially provide substantial evidence to support a new drug application. In addition, an observational study in patients presenting to emergency departments with ACI is currently ongoing. The study will determine concentrations of cannabinoids and metabolites in plasma and gather information on signs and symptoms, patients' disposition and selected assessments, where possible. We believe the data generated from the Netherlands Trial provide support for our development pathway.

ACI has 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. 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 emergency department visits grew to 1.7 million patients in 2019 and was growing at an approximately 15% compounded annual growth rate between 2011 and 2019. We believe the number of cannabis-related emergency department visits 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 two patent applications covering various methods of use of the compound and delivery systems.

We were incorporated in Delaware on April 23, 2020, and commenced operations in May 2020. Our operations to date have consisted of organizing and acquiring the license rights to Vernalis' licensed products, assembling an executive team, starting preparations for 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 December 31, 2021, Daniel Schneeberger, M.D. advised us of his resignation as Chief Executive Officer ("CEO") of the Company and from the Board of Directors, effective on February 1, 2022. On January 3, 2022, Simon Allen was appointed to be the CEO and elected a member of the Board of Directors, both of which became effective on February 1, 2022.

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 $6.3 million in net proceeds from the Private Placement after deducting offering costs of approximately $317,000. 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 fiscal years ended June 30, 2023 and 2022 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 fiscal years ended June 30, 2023 and 2022 consisted primarily of professional fees, stock-based compensation, insurance, personnel costs and rent.

Results of Operations

Comparison of the Years Ended June 30, 2023 and 2022

The following table summarizes our results of operations:

	For the Years ended June 30,		Period to Period
	2023	2022	Change
Research and development	$ 5,600,197	$ 2,961,538	$ 2,638,659
General and administrative	6,183,402	3,869,636	2,313,766
Total operating expenses	11,783,599	6,831,174	4,952,425
Loss from operations	(11,783,599)	(6,831,174)	(4,952,425)
Other (income) expenses:			
Interest income	(92,407)	(7,332)	(85,075)
Other	41,146	1,777	39,369
Total other income, net	(51,261)	(5,555)	(45,706)
Net loss	$ (11,732,338)	$ (6,825,619)	$ (4,906,719)

Research and Development Expenses

	For the Years ended June 30,		Period to Period
	2023	2022	Change
Pre-clinical and clinical studies	$ 2,501,396	$ 1,535,930	$ 965,466
Contract manufacturing	1,435,705	772,011	663,694
Compensation and related benefits	44,681	89,576	(44,895)
Stock-based compensation expense	-	26,604	(26,604)
Consultants and other research and development	1,618,415	537,417	1,080,998
Total research and development expenses	$ 5,600,197	$ 2,961,538	$ 2,638,659

The overall increases in research and development expenses for the fiscal year ended June 30, 2023 compared with the fiscal year ended June 30, 2022 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 and CMOs 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 and this was fully ramped by the beginning of fiscal year 2023, thus increasing our contract manufacturing expense for the fiscal year ended June 30, 2023.

General and Administrative Expenses

General and administrative expenses consisted of the following:

	For the Years ended June 30,		Period to Period
	2023	2022	Change
Compensation and related benefits	$ 1,839,585	$ 715,394	$ 1,124,191
Professional and consultant fees	2,232,383	1,089,880	1,142,503
Stock-based compensation expense	884,723	454,057	430,666
Directors' and officers' insurance	868,559	1,269,918	(401,359)
Facilities, fees and other costs	358,152	340,387	17,765
Total general and administrative expenses	$ 6,183,402	$ 3,869,636	$ 2,313,766

The overall increases in general and administrative expenses for the fiscal year ended June 30, 2023 compared with the fiscal year ended June 30, 2022 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.

Interest Income

Interest income increased for the fiscal year ended June 30, 2023 as compared to the fiscal year ended June 30, 2022 due to an increase in market interest rates earned on the Company's savings and money market accounts.

Liquidity and Capital Resources

Overview

Since our inception in April 2020, we have incurred significant operating losses. We expect to incur significant expenses and operating losses in the future as we advance the clinical development of our programs. In May 2021, we completed our IPO in which we received net proceeds of approximately $19.8 million. As noted above, on September 28, 2022, we closed the "Private Placement", in which we received net proceeds of approximately $6.3 million. As of June 30, 2023, we had cash of approximately $11.2 million. We anticipate that additional capital will be needed to commence and complete a Phase 3 study of our drug candidate ANEB-001. As and if necessary, we will seek to raise these additional funds through various potential sources, such as equity and debt financings or through 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:

	For the Years ended June 30,	
	2023	2022
Net cash used in operating activities	$ (9,683,133)	$ (5,437,174)
Net cash provided by financing activities	6,382,065	-
Net decrease in cash	$ (3,301,068)	$ (5,437,174)

During the fiscal year ended June 30, 2023, we used cash in operating activities of $9.7 million primarily resulting from our net loss of $11.7 million, partially offset by the non-cash related stock-based compensation of approximately $885,000, and a change in operating assets and liabilities of $1.2 million. We also received cash from financing activities of approximately $6.4 million primarily resulting from the issuance of common stock and warrants of approximately $6.6 million, net of offering costs of approximately $317,000. During the fiscal year ended June 30, 2022, we used cash in operating activities of approximately $5.4 million primarily resulting from our net loss of approximately $6.8 million, partially offset by the non-cash related stock-based compensation of approximately $481,000, and a change in operating assets and liabilities of approximately $908,000.

Funding and Material Cash Requirements

We expect that our cash at June 30, 2023 will enable us to fund our current and planned operating expenses and capital expenditures into the fourth quarter of calendar year 2024. We have based these estimates on assumptions that may prove to be imprecise, 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 candidates.

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

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

Until such time, if ever, as we can generate substantial product revenue from sales of any of our current or future product candidates, to support our material cash requirements in the near-term (within one year) and long-term (beyond one year), we will need to seek additional equity or debt financing or potential collaboration, license or development agreements to provide the capital required to maintain or expand our operations, continue the development of our product candidate, build our sales and marketing capabilities, promote brand identity, develop or acquire complementary technologies, products or businesses, or provide for our working capital requirements and other operating and general corporate purposes. If we raise additional capital by issuing equity securities and/or equity-linked securities, the percentage ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. We may also issue equity securities and/or equity-linked securities that provide rights, preferences and privileges senior to those of our common stock. 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 leased space under a sublease with a related party. During the fiscal year ended June 30, 2023 we paid rent of approximately $1,300 per month. Subsequent to year end, our rent was reduced to approximately $400 per month.

In March 2022, we entered into a manufacturing agreement with a third-party CMO, which was nearly completed as of June 30, 2023. In June 2023, we entered into a new manufacturing agreement with the same third-party CMO. The total cost for the new manufacturing contract is approximately $900,000, which is expected to be fully incurred by the end of the fourth 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. The total cost for the CRO agreement is approximately €2.9 million which is expected to be fully incurred by the end of the fourth 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 financial statements are prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The preparation of our 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 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 described in more detail in Note 2, *Summary of Significant Accounting Policies*, to our financial statements in this Annual Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our 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 financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees payable to:

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

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

Stock-Based Compensation Expense

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

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

There were no significant changes to assumptions used to value options using the Black Scholes option pricing model during the fiscal year ended June 30, 2023, with the exception of the stock and exercise prices.

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 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required for small reporting companies.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report under Item 15, Exhibits and Financial Statement Schedules and incorporated by reference herein.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Based on that evaluation of our disclosure controls and procedures as of June 30, 2023, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f) and 15d-15(f). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control—Integrated Framework, our management concluded that our internal control over financial reporting was effective as of June 30, 2023.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission for emerging growth companies that permit us to provide only management's report in this Annual Report.

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 June 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 will be included under the "PROPOSAL 1. ELECTION OF DIRECTORS," "INFORMATION REGARDING OUR BOARD OF DIRECTORS AND CORPORATE GOVERNANCE," "INFORMATION ABOUT OUR EXECUTIVE OFFICERS" and "SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT—DELINQUENT SECTION 16(A) REPORTS" headings in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

We have adopted a written code of business conduct and ethics (the "Code"), that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the Code is available on the investor section of our website at www.anebulo.com. We intend to disclose on our website any amendments to, or waivers from, our Code that are required to be disclosed pursuant to SEC rules.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 will be included under the "EXECUTIVE AND DIRECTOR COMPENSATION" heading in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 will be included under the "SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT" and "EXECUTIVE AND DIRECTOR COMPENSATION—SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS" headings in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item 13 will be included under the "TRANSACTIONS WITH RELATED PERSONS AND INDEMNIFICATION," "INFORMATION REGARDING OUR BOARD OF DIRECTORS AND CORPORATE GOVERNANCE—INDEPENDENCE OF THE BOARD OF DIRECTORS" and "INFORMATION REGARDING OUR BOARD OF DIRECTORS AND CORPORATE GOVERNANCE—INFORMATION REGARDING COMMITTEES OF THE BOARD OF DIRECTORS" headings in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 will be included under the "PROPOSAL 2. RATIFICATION OF SELECTION OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM—PRINCIPAL ACCOUNTANT FEES AND SERVICES" heading in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

1. Financial Statements. For a list of the financial statements included herein, see "Index to the Financial Statements" on page F-1 of this Annual Report, incorporated into this Item by reference.
2. Financial Statement Schedules. Financial statement schedules have been omitted because they are not required, not applicable or the required information is included in the financial statements or the notes thereto as required to be filed by Item 8 of this Annual Report.
3. Exhibits. An index of the Exhibits is set forth below under the heading "Exhibits Required by Item 601 of Regulation S-K."

Exhibits Required by Item 601 of Regulation S-K

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation of Anebulo Pharmaceuticals, Inc. (filed as Exhibit 3.1 to the Company's Annual Report on Form 10-K filed with the SEC on September 9, 2022 and incorporated herein by reference).
3.2	Certificate of Correction to Second Amended and Restated Certificate of Incorporation of Anebulo Pharmaceuticals, Inc. (filed as Exhibit 3.2 to the Company's Annual Report on Form 10-K filed with the SEC on September 9, 2022 and incorporated herein by reference).
3.3	Amended and Restated By-laws of Anebulo Pharmaceuticals, Inc (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on October 13, 2022 and incorporated herein by reference).
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	Description of Securities (filed as Exhibit 4.4 to the Company's Annual Report on Form 10-K filed with the SEC on September 9, 2022 and incorporated herein by reference).
4.5	Form of Common Stock Purchase Warrant, issued September 28, 2022 (filed as Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on September 29, 2022).
10.1#	License Agreement, dated May 26, 2020, between Vernalis (R&D) Limited and Anebulo Pharmaceuticals, Inc. (filed as Exhibit 10.4 to the Company's Registration Statement on Form S-1 filed with the SEC on April 1, 2021 and incorporated herein by reference).
10.2†	Anebulo Pharmaceuticals, Inc. 2020 Stock Incentive Plan, as amended, and Form of Award Agreement thereunder (filed as Exhibit 10.2 to the Company's Annual Report on Form 10-K filed with the SEC on September 9, 2022 and incorporated herein by reference).
10.3†	Form of Indemnification Agreement between Anebulo Pharmaceuticals, Inc. and each of its directors (filed as Exhibit 10.8 to the Company's Registration Statement on Form S-1 filed with the SEC on April 1, 2021 and incorporated herein by reference).
10.4†	Employment Agreement, dated February 1, 2022, between Simon Allen and Anebulo Pharmaceuticals, Inc. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on January 5, 2022 and incorporated herein by reference)
10.5†	Employment Agreement, effective as of May 20, 2022, between Anebulo Pharmaceuticals, Inc. and Kenneth Cundy (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 24, 2022 and incorporated herein by reference).
10.6	Master Services Agreement, dated March 2, 2023, between the Company and Potrero Hill Advisors, LLC (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on March 8, 2023 and incorporated herein by reference).
10.7†	Non-Employee Director Compensation Policy (filed as Exhibit 10.9 to the Company's Annual Report on Form 10-K filed with the SEC on September 9, 2022).
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on signature page of this Form 10-K)

Exhibit Number	Description
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.
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File – the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

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

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: September 22, 2023

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

Date: September 22, 2023

By: */s/ Sandra Gardiner*
Sandra Gardiner
Acting Chief Financial Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose individual signature appears below hereby authorizes and appoints Simon Allen and Sandra Gardiner, and each of them, with full power of substitution and re-substitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934 this report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Simon Allen Simon Allen	Chief Executive Officer and Director *(Principal Executive Officer)*	September 22, 2023
/s/ Joseph F. Lawler Joseph F. Lawler	Director and Chairman of the Board of Directors	September 22, 2023
/s/ Sandra Gardiner Sandra Gardiner	Acting Chief Financial Officer *(Principal Financial and Accounting Officer)*	September 22, 2023
/s/ Aron R. English Aron R. English	Director	September 22, 2023
/s/ Jason Aryeh Jason Aryeh	Director	September 22, 2023
/s/ Kenneth Lin Kenneth Lin	Director	September 22, 2023
/s/ Areta Kupchyk Areta Kupchyk	Director	September 22, 2023
/s/ Karah Parschauer Karah Parschauer	Director	September 22, 2023
/s/ Nat Calloway Nat Calloway	Director	September 22, 2023

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Anebulo Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Anebulo Pharmaceuticals, Inc. (the "Company") as of June 30, 2023 and 2022, and the related statements of operations, stockholders' equity , and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2023 and 2022, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2020.

EISNERAMPER LLP
Iselin, New Jersey
September 22, 2023

Anebulo Pharmaceuticals, Inc.
Balance Sheets

	June 30, 2023	June 30, 2022
Assets		
Current assets:		
Cash	$ 11,247,403	$ 14,548,471
Prepaid expenses	422,748	1,030,960
Total assets	$ 11,670,151	$ 15,579,431
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 534,545	$ 380,828
Accrued expenses	534,256	131,703
Total liabilities	1,068,801	512,531
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 2,000,000 and no shares authorized, and no shares issued or outstanding at June 30, 2023 and 2022	-	-
Common stock, $0.001 par value; 40,000,000 shares authorized; 25,633,217 and 23,344,567 shares issued and outstanding at June 30, 2023 and 2022, respectively	25,634	23,345
Additional paid-in capital	67,777,757	60,513,258
Accumulated deficit	(57,202,041)	(45,469,703)
Total stockholders' equity	10,601,350	15,066,900
Total liabilities and stockholders' equity	$ 11,670,151	$ 15,579,431

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

Anebulo Pharmaceuticals, Inc.
Statements of Operations

	For the Years Ended June 30,	
	2023	**2022**
Research and development	$ 5,600,197	$ 2,961,538
General and administrative	6,183,402	3,869,636
Total operating expenses	11,783,599	6,831,174
Loss from operations	(11,783,599)	(6,831,174)
Other (income) expenses:		
Interest income	(92,407)	(7,332)
Other	41,146	1,777
Total other income, net	(51,261)	(5,555)
Net loss	$ (11,732,338)	$ (6,825,619)
Weighted average common shares outstanding, basic and diluted	25,074,481	23,344,567
Net loss per share, basic and diluted	$ (0.47)	$ (0.29)

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

Anebulo Pharmaceuticals, Inc.
Statements of Stockholders' Equity
For the Years Ended June 30, 2023 and 2022

	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	-	-	480,661	-	480,661
Net loss	-	-	-	(6,825,619)	(6,825,619)
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 $317,083	2,264,650	2,265	6,327,400	-	6,329,665
Common stock issued upon exercise of options	24,000	24	52,376	-	52,400
Stock-based compensation expense	-	-	884,723	-	884,723
Net loss	-	-	-	(11,732,338)	(11,732,338)
Balance at June 30, 2023	25,633,217	$ 25,634	$67,777,757	$ (57,202,041)	$ 10,601,350

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

Anebulo Pharmaceuticals, Inc.
Statements of Cash Flows

	For the Years Ended June 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (11,732,338)	$ (6,825,619)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	884,723	480,661
Changes in operating assets and liabilities:		
Prepaid expenses	608,212	636,886
Accounts payable	153,717	270,780
Accrued expenses	402,553	118
Net cash used in operating activities	(9,683,133)	(5,437,174)
Cash flows from financing activities:		
Proceeds from issuance of common stock to the public, net of underwriter discount	6,646,748	-
Payment of initial public offering costs	(317,083)	-
Proceeds from issuance of common stock upon exercise of options	52,400	-
Net cash provided by financing activities	6,382,065	-
Net decrease in cash	(3,301,068)	(5,437,174)
Cash, beginning of period	14,548,471	19,985,645
Cash, end of the period	$ 11,247,403	$ 14,548,471

The accompanying notes are an integral part of these 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 substance 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 $11,732,338 for the fiscal year ended June 30, 2023. As of June 30, 2023, the Company had an accumulated deficit of $57,202,041. 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 financial statements have been prepared in conformity with U.S. Generally Accepted Accounting Principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Note 2. Summary of Significant Accounting Policies

Use of estimates

The preparation of the audited financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

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

Fair Value of Financial Instruments

Fair value is applied for all financial assets and liabilities. The carrying amount of the Company's financial instruments, including accounts payable and accrued expenses, approximate fair value due to the short-term duration of those instruments.

Equity Issuance Costs

The Company capitalizes incremental legal, professional, accounting and other third-party fees that are directly associated with its stock offerings as other non-current assets until the offerings are consummated. Upon consummation, these costs are recorded in stockholders' equity as a reduction of additional paid-in-capital generated as a result of the offerings. Should a planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statement of operations. After consummation of an equity offering, which closed on September 28, 2022, total offering costs of approximately $317,000 were recorded in stockholders' equity as a reduction of additional paid-in capital generated as a result of the offering. As of June 30, 2023 and 2022, there were no deferred offering costs.

Research and Development Costs

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

Stock-Based Compensation

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

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

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

Common stock price – Due to the absence of an active market for the Company's common stock prior to the initial public offering ("IPO") in May 2021, the Company utilized methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation,* to estimate the fair value of its common stock. In determining the exercise prices for options granted, the Company considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock has been determined at each grant date based upon a variety of factors, including the illiquid nature of the common stock, arm's-length sales of the Company's capital stock (including redeemable convertible preferred stock), the effect of the rights and preferences of the preferred stockholders, and the prospects of a liquidity event. Among other factors are the Company's financial position and historical financial performance, the status of technological developments within the Company's research, the composition and ability of the current research and management team, an evaluation or benchmark of the Company's competition, and the current business climate in the marketplace. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date. Subsequent to the IPO, the Company has used the quoted market price of its common stock on the measurement date.

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

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

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

The Company has made an entity-wide accounting policy election to account for pre-vesting award forfeitures when they occur.

Leases

The Company determines if an arrangement is or contains a lease at inception. Right-of-use ("ROU") assets and lease liabilities are recognized at commencement based on the present value of the lease consideration in the contracts over the expected lease term. The Company does not record leases with an initial term of 12 months or less on the Company's balance sheet but continue to record rent expense on a straight-line basis over the lease term. To the extent that any lease agreements include options to extend or renew the lease terms, such options are excluded from the ROU assets and lease liabilities unless they are reasonably certain to be exercised. The Company accounts for the lease and non-lease components as a single lease component. Operating lease expense is recognized on a straight-line basis over the lease term.

In August 2020, the Company entered into a month-to-month sub-lease for office space in Lakeway, Texas, from a related party and recorded rent expense of approximately $15,100 and $14,400 for the fiscal years ended June 30, 2023 and 2022, respectively. As of June 30, 2023 and 2022, the Company had no ROU assets or lease liabilities recorded on the balance sheet.

Loss Per Share

Basic and diluted net income (loss) per share are calculated using the weighted average number of shares of common stock outstanding for the year.

Basic and diluted net loss per share are the same because the impact of assuming the exercise of common stock options outstanding would be anti-dilutive and excludes such common stock options from the computation of diluted weighted-average shares outstanding.

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the Company's financial statements and tax returns. Deferred tax assets and liabilities are determined based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards, using enacted tax rates expected to be in effect in the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that these assets may not be realized. The Company determines whether it is more likely than not that a tax position will be sustained upon examination. If it is not more likely than not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the contingency. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes. The Company does not have any material uncertain tax positions for which reserves would be required.

Segment and geographic information

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker ("CODM") or decision-making group, in deciding how to allocate resources and in assessing performance. The CODM is the Company's Chief Executive Officer. The Company views its operations as and manages its business in one operating segment operating exclusively in the United States. The Company has one lead product candidate, ANEB-001, under development, which was licensed from Vernalis Development Ltd in May 2020 ("License Agreement"), as described in Note 4.

Note 2. Prepaid Expenses

Prepaid expenses consisted of the following:

	June 30,	
	2023	**2022**
Prepaid insurance	$ 391,750	$ 790,343
Prepaid research and development	-	210,865
Prepaid other	30,998	29,752
Total prepaid expenses	$ 422,748	$ 1,030,960

Note 3. Accrued Expenses

Accrued expenses consisted of the following:

	June 30,	
	2023	**2022**
Accrued research and development	$ 344,135	$ 105,980
Accrued payroll related expenses	190,121	25,723
Total accrued expenses	$ 534,256	$ 131,703

Note 4. License Agreement

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

As part of the IPO in May 2021, the Company issued 192,857 shares of common stock to Vernalis in lieu of future milestone payments by the Company of $1,350,000, whether or not the Company achieves those milestones. The Company has determined that no further milestone payments are considered probable as of June 30, 2023, and therefore no liability has been recorded.

Note 5. Stockholders' Equity

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 $6,330,000 in net proceeds after deducting offering costs of approximately $317,000. 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.

The Company's amended and restated certificate of incorporation (the "Restated Certificate") with the Secretary of the State of Delaware authorizes the company to issue up to 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.

Note 6. Income Taxes

The reconciliation of the U.S. federal statutory rate (21%) to the Company's effective tax rate for the fiscal years ended June 30, 2023 and 2022 is as follows:

	2023	2022
U.S. statutory federal income tax rate	21.0%	21.0%
Change in valuation allowance	-21.0%	-21.0%
Effective tax rate	0.0%	0.0%

The significant components of the Company's deferred tax assets consist of the following at June 30, 2023 and 2022:

	June 30,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 2,866,860	$ 1,843,175
Other assets and liabilities	272,162	265,741
Stock- based compensation	298,135	120,576
Capitalized research and development expenditures	1,248,760	-
Gross deferred tax assets	4,685,917	2,229,492
Valuation allowance	$ (4,685,917)	$ (2,229,492)
Total deferred tax assets, net of valuation allowance	-	-

The Company did not record a benefit for income taxes. ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Based upon the level of historical U.S. losses and future projections over the period in which the net deferred tax assets are deductible, at this time, management believes it is more likely than not that the Company will not realize the benefits of these deductible differences, and as a result the Company continues to maintain a valuation allowance for the full amount of the deferred tax assets until there is sufficient evidence to support the reversal of some portion of the allowance. The valuation allowance increased by approximately $2.5 million for the fiscal year ended June 30, 2023. The increase in the 2023 valuation allowance is primarily attributable to the current year loss and capitalized research and development expenditures under Section 174.

As of June 30, 2023, the Company had federal net operating losses ("NOLs") of approximately $13.7 million, which are available to offset future taxable income. These net operating loss carryforwards will carryforward indefinitely but are subject to annual taxable income limitations in the year of utilization.

Under Internal Revenue Code Section 382, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. Generally, an ownership change occurs when certain shareholders increase their aggregated ownership by more than 50 percentage points over their lowest ownership percentage in a testing period (typically three years). The Company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since becoming a "loss corporation" as defined in Section 382. Future changes in stock ownership, which may be outside of the Company's control, may trigger an ownership change. In addition, future equity offerings or acquisitions that have an equity component of the purchase price could result in an ownership change. If an ownership change has occurred or does occur in the future, utilization of the NOL carryforwards or other tax attributes may be limited, which could potentially result in the expiration of a portion of the federal and state net operating losses and tax credit carryforwards before utilization, the reduction of the Company's gross deferred tax assets and corresponding valuation allowance, and increased future tax liability to the Company.

The Company has no unrecognized tax benefits. Interest and penalty charges, if any, related to uncertain tax positions would be classified as income tax expenses in the accompanying statements of operations. At June 30, 2023 and 2022, the Company had no accrued interest or penalties related to uncertain tax positions.

Since the Company is in a loss carryforward position, the Company is generally subject to examination by the U.S. federal tax authorities for all tax years in which a loss carryforward was generated or used. The statute of limitations for assessment by federal and state tax jurisdictions in which the Company has business operations is open until three years from the year the net operating losses are used.

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. As of June 30, 2023 and 2022, the Company had 594,187 and 756,041, respectively, shares available for future issuance under the 2020 Stock Incentive Plan.

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

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 the Company's common stock, the expected term of the stock options, the risk-free interest rate for a period that approximates the expected term, and the Company's expected dividend yield. Each of these inputs is subjective and generally requires significant judgement to determine. Stock-based compensation is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period, which is generally the vesting period of the respective award.

The following table provides the assumptions used in determining the fair value of option awards for the fiscal years ended June 30, 2023 and 2022:

	June 30, 2023	June 30, 2022
Expected volatility	50.0% - 60.0%	50%
Risk-free interest rate	2.87% - 4.32%	0.79% - 2.97%
Expected dividend yield	–	–
Expected term (in years)	4.5-6.25	3.0 – 4.5

The following table summarizes stock option activity for the fiscal year ended June 30, 2023:

	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	(10,800)	$ 6.00		
Outstanding at June 30, 2023	2,049,313	$ 4.54	3.7	$ 96,734
Options exercisable at June 30, 2023	829,112	$ 4.29	3.3	$ 63,458

The weighted-average grant date fair value of options awarded during the fiscal years ended June 30, 2023 and 2022 was approximately $1.86 and $2.32, respectively, per share. As of June 30, 2023, unrecognized stock-based compensation expense related to unvested stock options totaled approximately $2.4 million, which is expected to be recognized over a weighted average period of 2.6 years.

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

	June 30,	
	2023	2022
Research and development	$ -	$ 26,604
General and administrative	884,723	454,057
Total	$ 884,723	$ 480,661

Note 8. Net Loss Per Share Attributable to Common Stockholders

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

	June 30,	
	2023	2022
Stock options outstanding	2,049,313	1,911,459
Warrants outstanding	2,264,650	-
Total	4,313,963	1,911,459